Alan Jones & Associates
Salary and Benefit Survey Specialists

Contract Research Organisations

Salary Survey

Job Descriptions &
Guide to Completing Survey Questionnaire

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Contents

Contract Research Organisations Salary Survey

Notes on Survey Schedule & Output

The UK CRO survey is run continuously. This means that, once they have joined, the survey participant will receive a questionnaire when they are known to have had a major salary review and they will be expected to update their information by the deadline specified.

The survey results are posted on the Alan Jones website (www.alan-jones.co.uk) and accessible using your Alan Jones user name and password. Using 'Instant Analysis' you can drill down into the information, see your own position vs the survey group (statistically and in chart form) and you can drop results into Excel or export them to pdf (using the Instant Analysis link).

From Instant Analysis, you can also download the survey in full in Excel and pdf versions including your personalised copies of the survey results. A different view of the results is shown in the 'Click & View' tool which gives a job by job view of the results including the relevant job description.

Other services are available using links in your client home page. In addition, there is a link to a tutorial on how to use our services.

Guide to Completing Survey Questionnaire

Please remember always to complete the Company Information tab in your questionnaire.

1. Give your company name and the details of the contact for the survey. The name given here is the person to whom the survey results will be sent. If the person who completes the input is not the main contact, but should be contacted over queries, etc., please also give their details making it clear that they are a secondary contact.

2. Please give any additional company data requested, e.g. company turnover (annual £m), number of employees, location of the employees.

3. Give the date of your last major salary review, the average percentage increase given, and the date of your next salary review.

JOB MATCHING

For each job title assess whether there is a job within your organisation covering the typical responsibilities. Each company has small differences it is the broad fit of the description and organisation which is important. We do not expect companies to match every job.

DATA INPUT *Use these notes to help you fill in the salary section of the questionnaire.*

1. **Job Match Identifier (Optional)**

   Where you have a code which identifies the job holder you have matched to the survey job role, and you would like to have this information for future reference, give it here and we will add it to the database. This information will not be used by us except to help you identify your matches.

2. **Job Match (+,=,-)**

In this column of the questionnaire please indicate your assessment of the job match, i.e. as compared with the job specification does your job match have more responsibility (+), is the job a good match for the generic job description (=) or does your job have less responsibility (-) than described.

3. **Number of Job Holders**

Show the number of job holders against each salary. If there are job holders with the same salary, bonus, car, etc., these may be grouped.

4. **Basic Salary**

Give annual basic salary, i.e. monthly contractual pay x 12. Exclude any shift and overtime pay. Include any fixed elements of salary paid as part of monthly pay, e.g. London weighting. Give full-time equivalent for any part-timers.

5. **Actual Bonus Paid**

Please give additional cash paid to the job. This may include company bonus, Christmas bonus, profit share, performance bonus, etc. Bonus may be variable or fixed but do not include car allowance, shift or overtime pay or other cash paid to an individual for activity which is not part of the job, e.g. first aid payments. Express as an annual amount. Give the most recent 12 month figures available to you. Give full-time equivalent for any part-timers.

6. **On Target Bonus %**

Where you have on target bonus payments, please give here the percentage of basic salary paid to the job holder when targets are achieved. Bonus targets may be based on individual, team or company performance (or a combination of these). Give the most recent on-target figures available to you.

7. **Weekly Hours**

Please give the contractual weekly hours worked by the job holder/s.

8. **Car List Price**

Give the list price of the typical/representative company car for which the job holder is eligible. Give the current list price of the car which is offered (even if the job holder takes a cash allowance instead of a car or trades up/down). Exclude delivery, road fund licence and number plates. If in doubt quote the make and model.

9. **Car Allowance**

Give the annual amount offered/paid as an alternative to a company car. Give this figure even if the car option is taken. Please quote as an annual amount.

10. **Number of Staff Reporting**

Please give number of staff reporting to each jobholder on Job 24.05 Senior Clinical Research Manager - Line Responsibility, 24.06 Clinical Research Manager - Line Responsibility and 24.07 Clinical Research Manager - Technical Responsibility.

11. **Location of Job Holder**

Where the location of the job holder is different to that shown in the Company Information section of this questionnaire, please indicate here which location is appropriate for your job match:

1 = Inner London
2 = Inside M25
3 = South East
4 = East of England
5 = South West
6 = Wales
7 = West Midlands
8 = East Midlands
9 = Yorkshire & the Humber
10 = North West
11 = North East
12 = Scotland
13 = Northern Ireland

Level Structure & Definitions *There is a level structure for this survey and all jobs will have been assigned a level (with a read across to WTW grades and Hay Points). This information is useful for job matching, and we also provide salary analysis by level in the survey output. The level analysis will include jobs with too few matches to include individually giving an additional dimension to the feedback. The Levels are:*

Level	Level Definition	Definition/Reporting Relationships	Qualifications	Experience	Other Skills	Hay Point Range	Willis Towers Watson Level
Level 1	**International/Corporate Level**						
Level 2	**Managing Director**					1218-1648	
Level 3	**Director**	Member of the legally constituted Board of Directors of the UK company or a member of the executive decision-making committee of a UK company who has status and remuneration equivalent to a Director. Reporting to Managing Director.				913-1235	
Level 4	**Head of Function**	To match this level job holders must have responsibility for a large function/department and with Level 5 jobs reporting. Reporting to Director Level. This level may only be present in larger organisations. May be called Director of Function or Associate Director in some companies				800-1100	16
Level 5	**Senior Management**	Senior role with functional responsibilities. Job holder will make significant policy decisions for the function. Managers at this level will be responsible for a significant department with direct and indirect reports and including professionally qualified staff. Reporting to Director or Head of Function level. In all but the largest organisations, this level will be the most senior in the function below Director		Experienced managerial position; job holder would normally have had considerable appropriate experience		691-935	14/15

Level Structure & Definitions cont'd

Level	Level Definition	Definition/Reporting Relationships	Qualifications	Experience	Other Skills	Hay Point Range	Willis Towers Watson Level
Level 6	**Management/ Senior Professional**	Normally reporting to a level 5 or higher. Managers at this level will be responsible for a number of direct and indirect reports including professionally qualified staff. If Senior Professional may report to a manager who does not have the same level of expertise. Senior Professionals at this level may have some subordinate staff but not necessarily.	Graduate or equivalent often with an appropriate post-graduate qualification. Professional staff will have appropriate professional qualification. At this level, scientific staff will normally be PhD level	Well-experienced. Will be a recognised expert in their field. Likely to have had 5 years' relevant experience		537-727	13
Level 7	**Junior Management/ Established Professional**	Normally reporting to a level 6 or a level 5 role. In Management this level will normally be directly responsible for a team of staff (possibly including team leaders if large numbers within the team). At this level Professional staff would not require close supervision and may oversee the work of/give advice to more junior colleagues/supervise a small number of subordinate staff.	Graduate or equivalent often with an appropriate post-graduate qualification. Professional staff will have appropriate professional qualification. At this level, scientific staff will normally be PhD level	In professional positions, this is the Established level where, as a rough guide, we would expect job matches to have at least 4 years' experience in the same or similar job role		435-588	11/12
Level 8	**Senior Supervisor/ Development Professional/ Non-professional Established**	Normally reporting to a level 7 or a level 6 position, this level will have responsibility for a small group of staff or may be a supervisor in a large department. The job holder at this level receives greater supervision than the Established level and is expected to make further progress in the job.	Graduate or equivalent often with an appropriate post-graduate qualification (or may still be working toward professional qualification). Professional staff will have appropriate professional qualification. At this level, scientific staff will often be PhD level	In professional positions this is the Development level and, as a guide, we would expect job matches here to have between 2 and 4 years' experience in the same or similar job role		368-498	10

Level Structure & Definitions cont'd

Level	Level Definition	Definition/Reporting Relationships	Qualifications	Experience	Other Skills	Hay Point Range	Willis Towers Watson Level
Level 9	**Supervisory/ Entry Level Professional**	Normally reporting to a level 7 or higher, this is a first step in Management and Team Leaders typically would be matched here. In the professional structure, Entry levels are matched here. These job matches are not new graduates.	Graduate or equivalent, expected to make progress toward an appropriate post-graduate qualification	To be a match must have had up to 12 months' experience as new graduates before moving to this role. To be a match at Entry level job holder would normally have less than 2 years' experience and be expected to make significant progress in the role		321-434	9
Level 10	**Graduate Entry/Skilled Supervisory/ Senior Support Staff**	Normally reporting to a level 8 or level 7 position, at this level Graduate Entry staff will be closely supervised and expected to make significant progress in work. Skilled supervisory job holders will have day to day control of the work of group supervised ensuring that given targets are met.	Graduate or equivalent/senior support staff level	Skilled supervisory levels		277-375	7/8
Level 11	**Administration**	Expected to work with minimal supervision and be able to oversee work of less experienced/more junior staff	A level/City & Guilds/NVQ level 3	Likely to have had a minimum of 5+ years' relevant working experience.	Excellent keyboard and IT skills using range of standard software		6/7
	Craft	Expected to work with minimal supervision and be able to oversee work of less experienced/more junior staff.	Minimum HNC level	Experienced	Technically-able craftspersons		
	Production/ Warehouse	In production, packaging and warehouse, roles at level 11 would have supervisory responsibility.	Numerate and literate with GCSE and/or equivalent NVQ qualifications	Likely to have had 5+ years' experience			

Level Structure & Definitions cont'd

Level	Level Definition	Definition/Reporting Relationships	Qualifications	Experience	Other Skills	Hay Point Range	Willis Towers Watson Level
Level 12	**Administration**	Likely to have some routine data entry/paperwork/calls but is expected to work without close supervision and to deal with routine problems.	A level standard education or NVQ level 3 in Administration Skills	Likely to have had a minimum of 4 years' work experience	Keyboard and IT skills using standard software		5/6
	Craft	Non-supervisory position with no others reporting.	City & Guilds apprenticeship or equivalent				
Level 13	**Administration**	Expected to be able to work without very close supervision.	GCSE standard education or NVQ level 2 in Administration Skills	Likely to have had a minimum of 2 years' work experience	Keyboard and IT skills using standard software. Likely to be dealing with a significant volume of routine data entry/paperwork/ calls		4/5
	Shop Floor	Non-supervisory position with no others reporting. May provide guidance to less-experienced job holders. Normally would report to a level 11	Must be numerate and literate with basic GCSE and/or equivalent NVQ qualifications	The roles at level 13 would normally require at least 3 months' working experience for the job holder to become competent			
Level 14	**Administration**	Closely supervised in work.	GCSE standard education or NVQ level 1 in Administration Skills	Limited work experience	Keyboard and basic IT skills using standard software. Likely to be dealing with large volume of routine data entry/paperwork/calls		3/4
	Shop Floor	Non-supervisory position with no others reporting. Normally would report to a level 11	Must be numerate and literate with basic GCSE and/or equivalent NVQ qualifications	The roles at level 14 would normally require less than 3 months' working experience for the job holder to become competent			

Summary of the Levels for each of the jobs in the survey:

	1	4	5	6	7	8
Medical Affairs **Function 10**		Senior Medical Director **Medical Director** Head of Medical Affairs	Senior Medical Monitor/Physician	Medical Monitor/Physician		
Regulatory Affairs **Function 11**	VP Regulatory Affairs	Head of Regulatory Affairs	Senior Regulatory Affairs Manager	Regulatory Affairs Manager **Senior Technical Specialist**	Regulatory Affairs Consultant – Established	Regulatory Affairs Consultant – Development
Data Management **Function 12**	VP Data Management	Head of Data Management	Senior Clinical Data Manager	Clinical Data Manager **Database Programming Manager**	Clinical Data Team Leader **Clinical Data Associate – Established** Database Programmer - Established	Clinical Data Associate – Development **Database Programmer – Development**
Statistics **Function 14**		Head of Statistics	Senior Statistics Manager	Statistics Manager **Principal Statistician**	Statistician – Established	Statistician – Development
Statistical Programming **Function 15**		Head of Statistical Programming	Senior Manager Statistical Programming	Manager Statistical Programming	Statistical Programmer – Established	Statistical Programmer – Development
Medical Writing **Function 16**		Head of Medical Writing	Senior Manager Medical Writing	Manager Medical Writing	Medical Writer – Established	Medical Writer – Development
Quality Assurance **Function 17**	VP Quality Assurance	Head of Quality Assurance	Senior Quality Assurance Manager	Quality Assurance Manager	Quality Assurance Auditor – Established	Quality Assurance Auditor – Development **Document Controller**
Drug Safety **Function 18**		Head of Drug Safety	Senior Drug Safety Manager	Drug Safety Manager	Drug Safety Team Leader **Drug Safety Associate – Established**	Drug Safety Associate – Development

	9	10	11	12	13	14
Medical Affairs **Function 10**						
Regulatory Affairs **Function 11**	Regulatory Affairs Consultant – Entry					
Data Management **Function 12**	Clinical Data Associate – Entry **Database Programmer – Entry**	Clinical Data Associate – New Graduate				
Statistics **Function 14**	Statistician – Entry					
Statistical Programming **Function 15**	Statistical Programmer – Entry					
Medical Writing **Function 16**	Medical Writer – Entry					
Quality Assurance **Function 17**	Quality Assurance Auditor – Entry					
Drug Safety **Function 18**	Drug Safety Associate – Entry					

	1	4	5	6	7	8
Projects **Function 19**	VP Projects	Head of Projects **Senior Project Director** Project Director	Assoc Project Director **Project Manager – Established**	Project Manager – Development **Project Manager – Entry**	Project Associate – Established	Project Associate – Development
Business Development **Function 20**	VP Business Development	Head of Business Development	Associate Director of Business Development	Business Development Manager	Business Development Executive **Key Accounts Manager**	
Contracts & Proposals **Function 21**	VP Contracts & Proposals	Head of Contracts **Head of Proposals**	Senior Contracts Manager **Senior Proposal Manager**	Contracts Manager **Proposal Manager**	Contracts Associate – Established **Proposal Associate – Established**	Contracts Associate – Development **Proposal Associate – Development**
Technical Training **Function 23**			Head of Technical Training	Technical Training Manager		Technical Training Officer/Consultant
Clinical Research **Function 24**	VP Clinical Operations	Head of Clinical Operations **Director Clinical Research**	Associate Director Clinical Research **Senior Clinical Research Manager – Line Responsibility**	Clinical Research Manager – Line Responsibility **Clinical Research Manager – Technical Responsibility** Clinical Team Leader – Established	Clinical Team Leader – Development **Clinical Team Leader– Entry** CRA – Established **CRA In-house – Established**	CRA – Development **CRA In-house – Development**
Feasibility **Function 25**			Senior Feasibility Project Manager	Feasibility Project Manager	Senior Feasibility Co-ordinator	Feasibility Co-ordinator
Start Up Services **Function 26**			Senior Site Services Manager	Site Services Manager	Site Services Specialist – Established **Senior Contract Specialist**	Site Services Specialist – Development **Contract Specialist**

	1	4	5	6	7	8
Medical Laboratory **Function 27**		Director Medical Laboratory		Medical Laboratory Manager		Senior Medical Technologist
Patient Recruitment **Function 28**		Head of Patient Recruitment	Senior Patient Recruitment Manager	Patient Recruitment Manager	Patient Recruitment Associate – Established	Patient Recruitment Associate – Development
Records Management **Function 30**		Director Records Management		Records Management Manager		
Clinical Pharmacology (Phase 1) **Function 50**		Unit Director/Manager **Unit Medical Head**	Scientific Director **Senior Clinical Research Physician**	Clinical Research Manager **Clinical Manager** Physician **Nurse Manager** Business Development Manager	Project Manager – Clinical Pharmacology **Senior Clinical Research Scientist/Manager** **Technicians** Senior Clinical Research Nurse **Lab Manager – Clinical Pathology** Quality Manager	Senior Contracts Associate **Clinical Training Officer – Qualified** Clinical Research Nurse (Recruitment & Screening) **Clinical Research Nurse** Senior Clinical Research Monitor

	9	10	11	12	13	14
Projects **Function 19**	Project Associate – Entry					
Business Development **Function 20**	Key Accounts Executive					
Contracts & Proposals **Function 21**	Contracts Associate – Entry **Proposal Associate – Entry**					
Technical Training **Function 23**						
Clinical Research **Function 24**	CRA – Entry **CRA In-house – Entry**	CRA – New Graduate **CRA In-house – New Graduate** Clinical Trials Administrator – Established	Clinical Trials Administrator – Development	Clinical Trials Administrator – Entry		
Feasibility **Function 25**						
Start Up Services **Function 26**	Site Services Specialist – Entry **Site Services Associate**			Site Services Assistant		
Medical Laboratory **Function 27**		Medical Technologist				
Patient Recruitment **Function 28**	Patient Recruitment Associate – Entry	Patient Recruitment Coordinator				

	9	10	11	12	13	14
Records Management **Function 30**	Senior Archivist	Archivist	Senior Records Administrator	Records Administrator	Records Administrator Assistant	
Clinical Pharmacology (Phase 1) **Function 50**	Resource Supervisor **Pharmacist** Clinical Training Officer – Non-Qualified **Clinical Research Monitor** Clinical Technical Officer	Pharmacy Supervisor **Volunteer Coordinator and/or Screening Coordinator** Quality Officer	Senior Clinical Research Technician	Volunteer Telephone Recruiter **Volunteer Recreation Officer**	Unit Receptionist/ Administrator **Clinical Support Assistant/Technician (Development/ Established)**	Clinical Support Assistant/Technician (Entry)

Medical

In each job, the survey code for each job is shown followed by the survey job title.

CROS 10.01	**Senior Medical Director**
Survey Level	4
Alternative Title/s	VP Medical
Experience	Likely to have had 15 years' experience in medical field and clinical research
Qualifications	MD Degree, post-graduate training in relevant therapeutic area/s

Responsibilities

- To lead and manage a therapeutic area
- To provide professional services related to medical and safety management of clinical
- projects
- To provide expertise in therapeutic area issues and to assist with the development and implementation of plans for global business growth
- To be responsible for business development activity, feasibility studies, design of clinical development programs and study protocols, management of medical information for therapy area
- Liaise with other functions in order to ensure client satisfaction through successful execution of clinical projects
- To pursue novel business opportunities to add to revenue
- Maintain a high level of expertise with client projects and marketplace developments
- Contribute to design, writing and review of study-related documents and professional manuscripts
- Responsible for development and management of direct and indirect reports

Level Responsibility

- Line Management - High - 6+
- Project - High - 3+ Countries
- Financial – High - Primary Responsibility
- Technical - High - Expert

CROS 10.02	**Medical Director**
Survey Level	4
Experience	Likely to have had 12 years' experience in medical field and clinical research
Qualifications	MD Degree, post-graduate training in relevant therapeutic area/s

Responsibilities

- To lead and manage a therapeutic area
- To provide professional services related to medical and safety management of clinical projects
- To provide expertise in therapeutic area issues and to assist with the development and implementation of plans for global business growth
- To be responsible for business development activity, feasibility studies, design of clinical development programs and study protocols, management of medical information for therapy area
- Liaise with other functions in order to ensure client satisfaction through successful execution of clinical projects
- To pursue novel business opportunities to add to revenue
- Maintain a high level of expertise with client projects and marketplace developments
- Contribute to design, writing and review of study-related documents and professional manuscripts
- Responsible for development and management of direct and indirect reports

Level Responsibility

- Line Management - High - 6+
- Project - High - 3+ Countries
- Financial - High - Primary Responsibility
- Technical - Expert

CROS 10.03	**Head of Medical Affairs**
Survey Level	4
Alternative Title/s	Director of Medical Affairs
Experience	Likely to have had at least 10 years' experience in medical field and clinical research
Qualifications	MD Degree

Responsibilities

- The Director of Medical Affairs is responsible for the management of the department providing medical information for investigators and/or Clinical Research Associates
- To ensure that department responds to protocol-specific questions on patient eligibility and medical procedures
- Responsible for ensuring that activities and processes performed by medical affairs staff are conducted according to company and sponsor requirements
- To develop excellent client relationships (both internal and external)
- To provide support for Business Development

Level Responsibility

- Line Management - High - 6+
- Project - High - 3+ Countries
- Financial - Medium
- Technical - High - Expert

CROS 10.04	**Senior Medical Monitor/Physician**
Survey Level	5
Experience	3-5 years' experience in medical field or clinical research
Qualifications	MD Degree

Responsibilities

- The Senior Medical Monitor is responsible for responding to protocol-specific questions of patient eligibility and medical procedures posed by investigators or Clinical Research Associates.
- Must ensure that activities and processes performed by medical affairs staff are conducted according to company and sponsor requirements.

Level Responsibility

- Line Management - Medium - 1-5
- Project - High - 3 Countries
- Financial - Low
- Technical - High - Expert

CROS 10.05	**Medical Monitor/Physician**
Survey Level	6
Experience	2 years' experience in medical field or clinical research
Qualifications	MD Degree

Responsibilities

- The Medical Monitor is responsible for responding to protocol-specific questions of patient eligibility and medical procedures posed by investigators or Clinical Research Associates
- Must ensure that activities and processes performed by medical affairs staff are conducted according to company and sponsor requirements

Level Responsibility

- Line Management - Medium - 1-5
- Project - High - 3+ Countries
- Financial - Low
- Technical - High - Expert

Regulatory Affairs

In each job, the survey code for each job is shown followed by the survey job title.

CROS 11.01	**VP Regulatory Affairs**
Survey Level	**-**
Experience	Likely to have had 15 years' experience in regulatory affairs and clinical research
Qualifications	Life Science, Pharmacy or Medical degree

Responsibilities

- To lead and manage the Regulatory Affairs function of the company
- To ensure the provision of regulatory expertise to business development activities
- To provide regulatory expertise to assist with the development and implementation of plans for global business growth
- To be responsible for the provision of scientific, technical and consultancy services to clients regarding development, regulatory approval and commercialisation of medicinal products and devices
- To ensure the Regulatory Affairs function fulfils projects on time and within budget
- Maintain a high level of expertise with in Regulatory Affairs in the UK and internationally
- Responsible for development and management of direct and indirect reports

Level Responsibility

- Line Management - High - 6+
- Project - High - 3+ Countries
- Financial - High
- Technical - High - Expert

CROS 11.02	**Head of Regulatory Affairs**
Survey Level	4
Alternative Title/s	**Director of Regulatory Affairs**
Experience	Likely to have had 10 years' experience in regulatory affairs in the pharmaceutical industry or a CRO. Some time spent with a regulatory body such as the MCA or EMEA an advantage
Qualifications	Life science, pharmacy or medical degree

Responsibilities

- Manage a team of regulatory affairs professionals and support staff
- Provide regulatory input to business development activities
- Provide scientific, technical and consultancy services to clients regarding development, regulatory approval and commercialisation of medicinal products and devices
- Train and mentor inexperienced regulatory affairs staff
- Gives leadership and direction to project teams in regulatory matters and manage projects within deadlines and budgets
- Monitor and review the technical and commercial progress of regulatory projects

Level Responsibility

- Line Management - High - 6+
- Project - Medium - 2 Countries
- Financial - High - Primary Responsibility
- Technical - High - Expert

CROS 11.03	**Senior Regulatory Affairs Manager**
Survey Level	5
Alternative Title/s	Associate Director Regulatory Affairs
Experience	Likely to have had 8 years' experience in regulatory affairs in the pharmaceutical industry or a CRO. Some time spent with a regulatory body such as the MCA or EMEA an advantage
Qualifications	Life science, pharmacy or medical degree

Responsibilities

- Manage regulatory affairs professionals and support staff working on regulatory projects and/or providing regulatory consultancy for in-house clinical projects
- Provide regulatory input to business development activities
- Provide scientific, technical and consultancy services to clients regarding development, regulatory approval and commercialisation of medicinal products and devices
- Train and mentor inexperienced regulatory affairs staff
- Monitor and review the technical and commercial progress of regulatory projects
- Deputise for Head of Regulatory Affairs as needed

Level Responsibility

- Line Management - High - 6+
- Project - Medium - 2 Countries
- Financial - Medium
- Technical - High - Expert

CROS 11.04 **Regulatory Affairs Manager**

Survey Level 6

Experience Minimum of 6 years' experience in regulatory affairs in the pharmaceutical industry or a CRO

Qualifications Life science, pharmacy or medical degree

Responsibilities

- Provide regulatory consultation for in-house clinical projects or stand-alone regulatory projects
- Review regulatory documentation to approve initiation of clinical trials and/or shipment of clinical trial supplies
- Prepare and submit regulatory documents in support of clinical trials
- Assist in the preparation of regulatory submissions
- Assist in client development activities
- Prepare and/or review scientific technical documents for regulatory adequacy and compliance with appropriate regulatory guidelines/regulations
- Co-ordinate company's documentation practices in order to promote efficient compliance with regulatory requirements
- Maintain proficiency in current knowledge of all applicable regulatory guidelines and regulations
- Manage junior Regulatory Affairs staff

Level Responsibility

- Line Management - Medium - 1-5
- Project - Medium - 2 Countries
- Financial - Medium
- Technical - High - Expert

CROS 11.05 **Senior Technical Specialist**

Survey Level 6

Experience Minimum of 8 years' experience in regulatory affairs in the pharmaceutical industry or a CRO. Some time spent with a regulatory body, e.g. MCA, EMEA, an advantage

Qualifications Life science, pharmacy or medical degree

Responsibilities

- Provide regulatory input to business development activities
- Provide scientific, technical and consultancy services to clients regarding development, regulatory approval and commercialisation of medicinal products and devices
- Train and mentor inexperienced regulatory affairs staff
- Gives leadership and direction to project teams in regulatory matters and manage projects within deadlines and budgets
- Monitor and review the technical and commercial progress of regulatory projects

Level Responsibility

- Line Management - Low - 0
- Project - Medium - 2 Countries
- Financial - Low
- Technical - High - Expert

CROS 11.06 **Regulatory Affairs Consultant - Established Level**

Survey Level 7

Experience Likely to have had at least 4 years' experience in regulatory affairs in the pharmaceutical industry, a CRO or a regulatory body, e.g. MCA, EMEA

Qualifications Life science, pharmacy or medical degree

Responsibilities

- Provide scientific, technical, advisory and support services to clients regarding the development and regulatory approval of medicinal products and devices
- Develop and maintain knowledge of current industry practices in regulatory affairs and update knowledge of regulatory requirements
- Give leadership and direction to project teams in regulatory matters and manage projects within deadlines and budgets
- Compile reports and regulatory submissions in compliance with statutory rules, regulations and guidelines
- May supervise less experienced staff

Level Responsibility

- Line Management - Medium - 1-5
- Project - Medium - 2 Countries
- Financial - Low
- Technical - Medium

CROS 11.07 **Regulatory Affairs Consultant - Development**

Survey Level 8

Experience Likely to have had 2-4 years' experience in regulatory affairs in the pharmaceutical industry, a CRO or a regulatory body, e.g. MCA, EMEA

Qualifications Life science, pharmacy or medical degree

Responsibilities

- Provide scientific, technical, advisory and support services to clients regarding the development and regulatory approval of medicinal products and devices
- Develop and maintain knowledge of current industry practices in regulatory affairs and update knowledge of regulatory requirements
- Give leadership and direction to project teams in regulatory matters and manage projects within deadlines and budgets
- Compile reports and regulatory submissions in compliance with statutory rules, regulations and guidelines

Level Responsibility

- Line Management - Low - 0
- Project - Medium - 2 Countries
- Financial - Low
- Technical - Medium

CROS 11.08	**Regulatory Affairs Consultant - Entry Level**
Survey Level	9
Experience	Likely to have had 0-2 years' experience in regulatory affairs in the pharmaceutical industry, a CRO or a regulatory body, e.g. MCA, EMEA
Qualifications	Life science, pharmacy or medical degree

Responsibilities

- Provide scientific, technical, advisory and support services to clients regarding the development and regulatory approval of medicinal products and devices
- Develop and maintain knowledge of current industry practices in regulatory affairs and update knowledge of regulatory requirements
- Compile reports and regulatory submissions in compliance with statutory rules, regulations and guidelines

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - Low
- Technical - Low

Data Management

In each job, the survey code for each job is shown followed by the survey job title.

CROS 12.01	**VP Data Management**
Survey Level	-
Experience	Likely to have had 15 years' experience in data management and clinical research
Qualifications	Life Science degree or similar

Responsibilities

- To lead and manage the Data Management function of the company. This is likely to include responsibility for Statistics
- To ensure the provision of data management and statistical support to business development activities
- To be responsible for ensuring that the data management and statistical functions meet their global and local project targets
- To be responsible for ensuring projects are adequately resourced
- To be responsible for development and maintenance of client relationships
- To monitor expenditure against budgets and ensure that any necessary adjustments are implemented
- To be responsible for future planning for function
- Responsible for development and management of direct and indirect reports

Level Responsibility

- Line Management - High - 6+
- Project - High - 3+ Countries
- Financial - High
- Technical - High - Expert

CROS 12.02	**Head of Data Management**
Survey Level	4
Alternative Title/s	Director of Data Management
Experience	Likely to have had at least 10 years' CRO/Data Management industry experience
Qualifications	Degree level - life sciences or similar

Responsibilities

- To manage internal financial budgets and processing metrics to ensure successful adherence to global and local targets
- To ensure all projects are adequately resourced to meet client deliverables whilst ensuring integrity and quality of the data
- To ensure departmental and individual compliance with regulated processes and to ensure the continued improvement of these processes
- To develop excellent client relationships (both internal and external)
- To resource department to ensure that project deadlines and pre-defined targets are met
- To manage expenditure to remain within budgetary constraints
- To work to develop future plans and goals for Data Management

Level Responsibility

- Line Management - High - 6+
- Project - High - 3+ Countries
- Financial - High - Primary Responsibility
- Technical - High - Expert

CROS 12.03	**Senior Clinical Data Manager**
Survey Level	5
Alternative Title/s	Associate Director Data Management
Experience	Likely to have had 6-8 years' CRO/Data Management industry experience
Qualifications	Degree level - life sciences or similar

Responsibilities

- To manage internal financial budgets and processing metrics to ensure successful adherence to global and local targets
- To ensure all projects are adequately resourced to meet client deliverables whilst ensuring integrity and quality of the data
- To ensure departmental and individual compliance to regulated processes and to ensure the continued improvement of these processes
- To develop excellent client relationships (both internal and external)
- To review monthly financial reports with Director of Data Management
- To be aware of the Company's structure, strategy, goals and performance
- To assist with the hiring and training of new staff
- Deputise for the Head of Clinical Data Management as needed

Level Responsibility

- Line Management - High - 6+
- Project - High - 3+ Countries
- Financial - Medium
- Technical - High - Expert

CROS 12.04	**Clinical Data Manager**
Survey Level	6
Alternative Title/s	Clinical Data Group Leader
Experience	Likely to have had a minimum of 5 years' experience in data management
Qualifications	Degree level - life sciences or similar

Responsibilities

- To manage a group of CDMs and their projects
- To ensure that each project is planned, resourced and is running within budget
- To assist with bids as required
- To act as the senior data management contact for projects

Level Responsibility

- Line Management - High - 6+
- Project - High - 3+ Countries
- Financial - Medium
- Technical - High - Expert

CROS 12.05 **Clinical Data Team Leader**

Survey Level 7

Experience Likely to have had a minimum of 3 years' experience in data management

Qualifications Degree level - life sciences or similar

Responsibilities

- To ensure the data management manual is created correctly, to QC and update it on an ongoing basis
- To liaise with trial monitors and statisticians to design computer database
- To assist in liaising with clients as required
- To put in place an appropriate tracking system
- To supervise data entry and CDA staff
- To monitor data handling to enable data entry and validation while trials are proceeding
- To be responsible for study progress including data checking, the integrity of the database and tracking information
- To advise on case report design
- To supervise and allocate tasks to the members of the team on a day to day basis
- To train new staff on study specifics
- To assist the Group Leader in preparing budgets and forecasts
- To provide regular status reports to the Group Leader and project management group
- To highlight resource needs and assist the Group Leader in the preparation of all plans

Level Responsibility

- Line Management - Medium - 1-5
- Project - High - 3+ Countries
- Financial - Medium
- Technical - High - Expert

CROS 12.06 **Clinical Data Associate - Established Level**

Survey Level 7

Experience Likely to have had a minimum of 4 years' experience in a CRO

Qualifications Degree level - life sciences or similar

Responsibilities

- As for CDA - Development Level
- Carry out specialist tasks e.g. co-ordinating end points
- To check competencies of CDAs and DPTs and feedback results to them
- To liaise with clients on behalf of the CD Manager
- To be responsible for providing regular updates to the CD Manager
- To assist at client meetings
- To co-ordinate small studies

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - N/A
- Technical - Medium

CROS 12.07 **Clinical Data Associate - Development Level**

Survey Level 8

Experience Likely to have had 2-4 years' experience in a CRO

Qualifications Degree level - life sciences or similar

Responsibilities

- To pre-review case report forms
- To identify patients for progression in the data management process
- To review validation errors
- To ensure working knowledge of query systems
- To be able to do a complete check of manual validation printouts
- To clearly highlight errors to ensure effective database editing
- To review manual queries
- To undertake standard coding of data
- To have full knowledge of query database including running reports and understanding tracking
- To run validation programs
- To allocate tasks to other CDAs and data processing technicians
- To calculate error rates and generate error reports
- To train and mentor more junior CDAs and DPTs
- Attend project review meetings
- Carry out specialist tasks e.g. co-ordinating end points

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - N/A
- Technical - Medium

CROS 12.08 **Clinical Data Associate - Entry Level**

Survey Level 9

Experience Likely to have had 0-2 years' experience in a CRO

Qualifications Degree level - life sciences or similar

Responsibilities

- To pre-review case report forms
- To identify patients for progression in the data management process
- To review validation errors
- To ensure working knowledge of query systems
- To be able to do a complete check of manual validation printouts
- To clearly highlight errors to ensure effective database editing
- To review manual queries
- To undertake standard coding of data
- To have full knowledge of query database including running reports and understanding tracking
- To run validation programs

Level Responsibility

- Line Management - N/A
- Project - N/A
- Financial - N/A
- Technical - Medium

CROS 12.09 **Clinical Data Associate - New Graduate**

Survey Level 10

Experience 0-6 months' experience in a CRO

Qualifications Degree level - life sciences or similar

Responsibilities

- To pre-review case report forms
- To identify patients for progression in the data management process
- To review validation errors
- To ensure working knowledge of query systems
- To be able to do a complete check of manual validation printouts
- To clearly highlight errors to ensure effective database editing

Level Responsibility

- Line Management - N/A
- Project - N/A
- Financial - N/A
- Technical - Low

CROS 12.10 **Database Programming Manager**

Survey Level 6

Experience 5 years' relevant database programming or system validation experience, including at least 2 years in a clinical/data management environment

Qualifications Bachelor's Degree, preferably in Computer Science or Oracle database certified with 8 years' relevant experience

Responsibilities

- Supervise and train Database Programming staff
- Interface with IT staff to ensure proper maintenance of Clinical Data Management Systems (CDMS), including requests for new instances, database links, etc.
- Ensure CDMS support specialists perform to minimise downtime and to resolve problems quickly
- May act as CDMS Database Administrator providing new user accounts/groups, updating user groups, etc.
- Ensure that all project-related programming tasks are completed in accordance with company standards
- Track milestones and issue status reports, e.g. the status of database release or completion of edit checks
- Participate in strategic planning for and the management of Data Management related system development projects conducted by IT or external consultants
- Assist in the creation and documentation of new or revised departmental procedures
- Design and implement project-related reports
- May represent Data Management at Business Development or other sponsor related meetings and at professional meetings
- May co-ordinate the validation of a CDMS or related supporting software

Level Responsibility

- Line Management - High - 6+
- Project - High - 3+ Countries
- Financial - High - Primary Responsibility
- Technical - High - Expert

CROS 12.11	**Database Programmer - Established Level**
Survey Level	7
Experience	Likely to have had a minimum of 4 years' relevant experience
Qualifications	Degree, preferably in Computer Science or Oracle database certified with 6 years' relevant experience

Responsibilities

- Provide Clinical Data Management System (CDMS) database support to minimise downtime and resolve problems quickly
- Implement or ensure implementation of "fixes" to CDMS
- Instruct staff on use of CDMS and train new employees on Data Management procedures and systems

Other Responsibilities

- Act as CDMS database administrator providing new user accounts/groups, updating user groups, etc.
- Train programming staff
- Create annotated CRF using company standards or sponsor's naming conventions
- Create and test the CDMS set up for new studies/projects and data entry screens
- Program and test automated edit checks
- Create and test files for electronic data upload
- Upload electronic data received
- Communicate the database set-up status and the achievement of milestones to project team members
- Update company standard data dictionaries and edit check libraries
- Program and generate data listings and project tracking reports
- Ensure archiving of electronic data and required documentation is effected on study completion
- Program CDMS enhancements
- Co-ordinate and participate in the validation of a CDMS or related supporting software

Level Responsibility

- Line Management - Medium - 1-5
- Project - Medium - 2 Countries
- Financial - Low
- Technical - Medium

CROS 12.12	**Database Programmer - Development Level**
Survey Level	8
Experience	Likely to have had 2-4 years' relevant experience
Qualifications	Degree, preferably in Computer Science or Oracle database certified with 4 years' relevant experience

Responsibilities

- Provide Clinical Data Management System (CDMS) database support to minimise downtime and resolve problems quickly
- Implement or ensure implementation of "fixes" to CDMS
- Instruct staff on use of CDMS and train new employees on Data Management procedures and systems

Other Responsibilities

- Create annotated Case Report Form (CRF) using company standards or sponsor's naming conventions
- Create and test the CDMS set up for new studies/projects and data entry screens
- Program and test automated edit checks
- Create and test files for electronic data upload
- Upload electronic data received
- Communicate the database set-up status and the achievement of milestones to project team members
- Program and generate data listings and project tracking reports
- Archive electronic data and required documentation on study completion
- Co-ordinate and take part in validation of CDMS or related supporting software

Level Responsibility

- Line Management - Low - 0
- Project - Medium - 2 Countries
- Financial - Low
- Technical - Medium

CROS 12.13 **Database Programmer - Entry Level**

Survey Level 9

Experience Likely to have had 0-2 years' relevant experience

Qualifications Degree, preferably in Computer Science or 3 years' relevant experience

Responsibilities

- Provide Clinical Data Management System (CDMS) database support to minimise downtime and resolve problems quickly
- Implement or ensure implementation of "fixes" to CDMS
- Instruct staff on use of CDMS and train new employees on Data Management procedures and systems
- May train new employees on data management procedures and systems

Other Responsibilities

- Create an annotated Case Report Form (CRF) using company standards or sponsor's naming conventions
- Create and test the CDMS set up for new studies/projects
- Assist with programming and testing of automated edit checks for new studies
- Create and test files for electronic data upload
- Upload electronic data received through external sources
- Program and generate data listings for ongoing studies
- May program and generate project tracking reports
- Assist in archiving of electronic data and required documentation on study completion
- Assist with validation of CDMS or related software

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - Low
- Technical - Low

Statistics

In each job, the survey code for each job is shown followed by the survey job title.

CROS 14.01	**Head of Statistics**
Survey Level	4
Alternative Title/s	Director of Statistics
Experience	Likely to have had at least 10 years' experience
Qualifications	MSc in a Statistics subject; broad range of statistical and computing skills; Chartered Statistician - Royal Statistical Society

Responsibilities

- To be responsible for management of the statistics group
- To ensure all projects are adequately resourced
- To manage Statistics function personnel. To oversee all recruitment activity
- To ensure appropriate development and training for all staff
- To manage expenditure to remain within budgetary constraints
- To work to develop future plans and goals for Statistics function
- To develop excellent client relationships (both internal and external)

Level Responsibility

- Line Management - High - 6+
- Project - High - 3+ Countries
- Financial - High - Primary Responsibility
- Technical - High - Expert

CROS 14.02 **Senior Statistics Manager**

Survey Level 5

Alternative Title/s Associate Director of Statistics

Experience Likely to have had at least 8 years' experience

Qualifications MSc in a Statistics subject; broad range of statistical and computing skills; Chartered Statistician - Royal Statistical Society

Responsibilities

- To be responsible for management of designated section and/or activities of the statistics group
- To act as project manager for nominated projects
- To ensure appropriate development and training for all staff
- To assist with management of expenditure
- To work to develop future plans and goals for Statistics function
- To develop excellent client relationships (both internal and external)
- Deputise for the Head of Statistics as needed
- To evaluate new processes for statistics function and make recommendations
- To structure and co-ordinate work of designated section of statistics function

Level Responsibility

- Line Management - High - 6+
- Project - High - 3+ Countries
- Financial - Medium
- Technical - High - Expert

CROS 14.03 **Statistics Manager**

Survey Level 6

Experience Likely to have had at least 6 years' experience

Qualifications MSc in a Statistics subject; broad range of statistical and computing skills; Chartered Statistician - Royal Statistical Society

Responsibilities

- To structure and co-ordinate the work of the designated section of the statistics group including line management, resource planning and recruitment
- Act as project manager for nominated projects
- To ensure appropriate development and training for all staff
- To evaluate new processes for statistical activities, make recommendations, plan implementation and co-ordinate changes
- To represent statistics both internally and externally as required

Level Responsibility

- Line Management - High - 6+
- Project - High - 3+ Countries
- Financial - Medium
- Technical - High - Expert

CROS 14.04 **Principal Statistician**

Survey Level 6

Alternative Title/s Consultant Statistician

Experience Likely to have had at least 5 years' experience

Qualifications MSc in a Statistics subject; broad range of statistical and computing skills; Chartered Statistician - Royal Statistical Society

Responsibilities

- To advise clients and staff on statistical and associated regulatory considerations during the planning of individual studies and drug development programmes
- To further statistical competency and technical development of statisticians by application of appropriate review and training
- To identify developments in statistical practices, particularly in the areas of drug development and review with regard to their appropriateness for business needs
- To devise and implement technical development plans for the statistics function

Level Responsibility

- Line Management - Low - 0
- Project - High - 3+ Countries
- Financial - Medium
- Technical - High - Expert

CROS 14.05 **Statistician - Established Level**

Survey Level 7

Experience Likely to have had a minimum of 4 years' relevant experience

Qualifications MSc in a Statistics subject; broad range of statistical and computing skills; Graduate/Chartered Statistician - Royal Statistical Society

Responsibilities

- To prepare and review Statistical Analysis Plans
- To advise other staff and clients on statistical methodology and statistical principles
- To write and review the statistical methodology and results sections of reports, to include review of tables, figures and listings
- To give statistical input to the design and review of Protocols and Case Report forms
- To act as project manager for nominated projects
- To provide advice and support for time and cost estimates and presentations to potential clients

Level Responsibility

- Line Management - Medium - 1-5
- Project - Medium - 2 Countries
- Financial - Medium
- Technical - Medium

CROS 14.06	**Statistician - Development Level**
Survey Level	8
Experience	Likely to have had 2-4 years' relevant experience
Qualifications	MSc in a Statistics subject; broad range of statistical and computing skills; Graduate Statistician - Royal Statistical Society

Responsibilities

- Statistical analysis of clinical trials
- Be aware of quality requirements and perform checks to achieve them
- To prepare and review the Statistical Analysis Plans under supervision
- Write and review the statistical methodology and results sections of reports, to include review of tables, figures and listings under supervision
- To give statistical input to the design and review of Protocols and Case Report forms under supervision
- Contribute to team working

Level Responsibility

- Line Management - Low - 0
- Project - Medium - 2 Countries
- Financial - Low
- Technical - Medium

CROS 14.07	**Statistician - Entry Level**
Survey Level	9
Experience	Likely to have had 0-2 years' relevant experience
Qualifications	MSc in a Statistics subject; broad range of statistical and computing skills; Graduate Statistician - Royal Statistical Society

Responsibilities

- Statistical analysis of clinical trials under supervision
- Be aware of quality requirements and perform checks to achieve them
- To prepare and review the Statistical Analysis Plans under supervision
- Write and review the statistical methodology and results sections of reports, to include review of tables, figures and listings under supervision
- Contribute to team working

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - Low
- Technical - Low

In each job, the survey code for each job is shown followed by the survey job title.

CROS 15.01	**Head of Statistical Programming**
Survey Level	4
Alternative Title/s	Director of Statistical Programming
Experience	Likely to have had a least 10 years' experience in statistical programming
Qualifications	BSc in computing, life sciences, mathematical or statistical subjects. Line management experience

Responsibilities

- Co-ordinate and oversee activities of statistical programming teams
- Develop programming standards
- Develop utility SAS macros for use in project programs
- Develop programming technologies to increase efficiencies in clinical study reporting
- Generate summary data tables and analyses as part of clinical study reports and ISS/ISE documents for FDA submission
- Key programmer for the production of interim analysis tables needed by data monitoring boards
- Collaborate with IT department to enhance Biostatistics technologies; serve as key contact for SAS issues
- Program and validate data transfers and data conversions between SAS and other software for clients and regulatory agencies
- Develop, test, and validate SAS interfaces to non-SAS data sources
- Supervise, instruct, and mentor junior staff
- Participate in business development activities

Level Responsibility

- Line Management - High - 6+
- Project - High - 3+ Countries
- Financial - Medium
- Technical - High - Expert

CROS 15.02	**Senior Manager Statistical Programming**
Survey Level	5
Alternative Title/s	Associate Director Statistical Programming
Experience	Likely to have had at least 8 years' experience
Qualifications	BSc in computing, life sciences, mathematical or statistical subjects. Demonstrated skills in the use of SAS. Line management experience

Responsibilities

- To be responsible for management of designated section and/or activities of the statistical programming group
- Act as project programmer or manager for nominated projects - as Senior Manager will deal with larger projects
- Develop and validate SAS programs as required for reporting of clinical trial data
- To prepare and review programming plans
- Ensure all activities are carried out according to quality procedures
- Deputise for the Head of Statistical Programming as needed

Level Responsibility

- Line Management - High - 6+
- Project - High - 3+ Countries
- Financial - Medium
- Technical - High - Expert

CROS 15.03	**Manager Statistical Programming**
Survey Level	6
Experience	Likely to have had at least 6 years' experience
Qualifications	BSc in computing, life sciences, mathematical or statistical subjects. Demonstrated skills in the use of SAS. Line management experience

Responsibilities

- To structure and co-ordinate the work of the Statistical Programming group, including line management, resource planning and recruitment
- Act as project programmer or manager for nominated projects
- To develop and validate SAS programs as required for reporting of clinical trial data
- To prepare and review programming plans
- Ensure all activities are carried out according to quality procedures

Level Responsibility

- Line Management - High - 6+
- Project - High - 3+ Countries
- Financial - Medium
- Technical - High - Expert

CROS 15.04 **Statistical Programmer - Established Level**

Survey Level 7

Experience Likely to have had a minimum of 4 years' relevant experience

Qualifications BSc in computing, life sciences, mathematical or statistical subjects. Demonstrated skills in the use of SAS

Responsibilities

- To develop and validate SAS programs as required for management of clinical trial data
- To develop and validate SAS programs for the tabulation of data, preparation of patient data listings, graphical output and statistical analysis of data
- To prepare and review programming plans
- To act as Project Programmer for nominated projects
- To carry out electronic data transfer
- To carry out all activities according to quality procedures
- To advise staff and external clients on programming techniques
- To assist with training of programmers

Level Responsibility

- Line Management - Medium - 1-5
- Project - Medium - 2 Countries
- Financial - Medium
- Technical - Medium

CROS 15.05 **Statistical Programmer - Development Level**

Survey Level 8

Experience Likely to have had 2-4 years' relevant experience

Qualifications BSc in computing, life sciences, mathematical or statistical subjects. Demonstrated skills in the use of SAS

Responsibilities

- To develop and validate SAS programs as required for management of clinical trial data
- To develop and validate SAS programs for the tabulation of data, preparation of patient data listings, graphical output and statistical analysis of data
- To prepare and review programming plans
- To acquire knowledge of other aspects of the work of a senior Statistical Programmer under the supervision of senior statistical programming staff
- To carry out electronic data transfer
- To carry out all activities according to quality procedures

Level Responsibility

- Line Management - Low - 0
- Project - Medium - 2 Countries
- Financial - Low
- Technical - Medium

CROS 15.06	**Statistical Programmer - Entry Level**
Survey Level	9
Experience	Likely to have had 0-2 years' relevant experience
Qualifications	BSc in computing, life sciences, mathematical or statistical subjects. Demonstrated skills in the use of SAS

Responsibilities

- To develop and validate SAS programs as required for management of clinical trial data
- To develop and validate SAS programs for the tabulation of data, preparation of patient data listings, graphical output and statistical analysis of data
- To prepare and review programming plans under the supervision of senior statistical programming staff
- To acquire knowledge of other aspects of the work of a Statistical Programmer - Development Level under the supervision of senior statistical programming staff

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - Low
- Technical - Low

Medical Writing

In each job, the survey code for each job is shown followed by the survey job title.

CROS 16.01 **Head of Medical Writing**

Survey Level 4

Experience Likely to have had at least 10 years' CRO/Pharmaceutical experience with a minimum of 6 years in medical writing

Qualifications Life Sciences degree or equivalent

Responsibilities

- To be responsible for the management of the Medical Writing function
- To provide professional leadership for medical writing projects
- To monitor and review medical writing projects
- To ensure that the department provides an efficient and effective medical writing service to the company within agreed budget
- To provide input from a medical writing perspective into business proposals
- To ensure that staff receive appropriate training and development

Level Responsibility

- Line Management - High - 6+
- Project - High - 3+ Countries
- Financial - High - Primary Responsibility
- Technical - High - Expert

CROS 16.02 **Senior Manager Medical Writing**

Survey Level 5

Experience Likely to have had at least 10 years' CRO/Pharmaceutical experience with a minimum of 4 years in medical writing

Qualifications Minimum BSc in life sciences

Responsibilities

- To manage all aspects of the medical writing function, including line management
- To provide professional input into medical writing projects
- To establish and manage the departmental budget
- To provide input into business proposals as appropriate

Level Responsibility

- Line Management - High - 6+
- Project - High - 3+ Countries
- Financial - High - Primary Responsibility
- Technical - High - Expert

CROS 16.03 **Manager Medical Writing**

Survey Level 6

Experience Likely to have had at least 8 years' CRO/Pharmaceutical experience with a minimum of 2 years in medical writing

Qualifications Minimum BSc in life sciences

Responsibilities

- To manage all aspects of the medical writing function, including line management
- To provide professional input into medical writing projects
- To establish and manage the departmental budget
- To provide input into business proposals as appropriate

Level Responsibility

- Line Management - Medium - 1-5
- Project - High - 3+ Countries
- Financial - High - Medium
- Technical - High - Expert

CROS 16.04 **Medical Writer - Established Level**

Survey Level 7

Experience Likely to have had 4+ years' experience of preparing clinical documents

Qualifications Minimum BSc in life sciences

Responsibilities

- To produce clinical documents, including integrated statistical/clinical reports, manuscripts for publication, protocols, investigator brochures, patient information documentation, regulatory submissions and other documents as required.
- To review the documents of other medical writers.
- To participate in client meetings.
- Giving guidance to less experienced writers.

Level Responsibility

- Line Management - Low - 0
- Project - Medium - 2 Countries
- Financial - Low
- Technical - High - Expert

CROS 16.05 **Medical Writer - Development Level**

Survey Level 8

Experience Likely to have had 2-4 years' experience of preparing clinical documents

Qualifications Minimum BSc in life sciences

Responsibilities

- To produce clinical documents, including integrated statistical/clinical reports, manuscripts for publication, protocols, investigator brochures, patient information documentation, regulatory submissions and other documents as required
- To review the documents of other medical writers
- To participate in client meetings

Level Responsibility

- Line Management - Low - 0
- Project - Medium - 2 Countries
- Financial - Low
- Technical - Medium

CROS 16.06 **Medical Writer - Entry Level**

Survey Level 9

Experience Likely to have had 0-2 years' experience of preparing clinical documents

Qualifications Minimum BSc in life sciences

Responsibilities

- To assist in producing clinical documents, including integrated statistical/clinical reports, manuscripts for publication, protocols, investigator brochures, patient information documentation, regulatory submissions and other documents as required.

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - Low
- Technical - Low

In each job, the survey code for each job is shown followed by the survey job title.

CROS 17.01	**VP Quality Assurance**
Survey Level	**-**
Alternative Title/s	**Director of Quality Assurance**
Experience	Likely to have had at least 15 years' experience in the pharmaceutical industry, or a CRO
Qualifications	Degree in medicine, science or other relevant discipline

Responsibilities

- To lead and manage the Quality Assurance (QA) function of the company
- Likely to be responsible for QA for a designated region
- To be responsible for ensuring that company procedures are effectively implemented in all offices and updated as necessary.
- To liaise with clients and Project Managers on quality issues and represent QA at senior level meetings
- To ensure that QA is recognised in the company and that quality aspects of studies are fulfilled
- To be responsible for the provision of quality consultancy services to clients regarding development, regulatory approval and commercialisation of medicinal products and devices
- To ensure the QA function contributes positively to projects on time and within budget
- Maintain a high level of expertise within QA in the UK and internationally
- Responsible for development and management of direct and indirect reports

Level Responsibility

- Line Management - High - 6+
- Project - High - 3+ Countries
- Financial - High - Primary Responsibility
- Technical - High - Expert

CROS 17.02	**Head of Quality Assurance**
Survey Level	4
Alternative Title/s	Director of Quality Assurance
Experience	Likely to have had at least 10 years' experience in the pharmaceutical industry, or a CRO
Qualifications	Degree in medicine, science or other relevant discipline

Responsibilities

- Manage the QA departments in a region.
- Ensure that company procedures are effectively implemented in all offices and updated as necessary
- Liaise with clients and project managers on quality issues and represent QA at executive meetings

Level Responsibility

- Line Management - High - 6+
- Project - High - 3+ Countries
- Financial - High - Primary Responsibility
- Technical - High - Expert

CROS 17.03	**Senior Quality Assurance Manager**
Survey Level	5
Alternative Title/s	Associate Director Quality Assurance
Experience	Likely to have had at least 8 years' experience in the pharmaceutical industry, or a CRO
Qualifications	Degree in Bioscience

Responsibilities

- Full range of auditing activities, plus manage activities and staff of the QA department
- Liaise with clients as necessary, and with project managers on the quality aspects of studies
- Ensure that quality remains a high priority in the office
- Have either line management responsibility or significant project responsibility for larger projects
- Deputise for the Head of Quality as needed

Level Responsibility

- Line Management - High - 6+
- Project - High - 3+ Countries
- Financial - Medium
- Technical - High - Expert

CROS 17.04 **Quality Assurance Manager**

Survey Level 6

Experience Likely to have had at least 6 years' experience in the pharmaceutical industry, or a CRO

Qualifications Degree in Bioscience

Responsibilities

- Full range of auditing activities, plus manage activities and staff of the QA department
- Liaise with clients as necessary, and with project managers on the quality aspects of studies
- Ensure that quality remains a high priority in the office
- Have either line management responsibility or significant project responsibility

Level Responsibility

- Line Management - Medium - 1-5
- Project - High - 3+ Countries
- Financial - Medium
- Technical - High - Expert

CROS 17.05 **Quality Assurance Auditor - Established Level**

Survey Level 7

Experience Likely to have had a minimum of 4 years' experience in the pharmaceutical industry, or a CRO

Qualifications Degree in Bioscience

Responsibilities

- Fully familiar with SOPs from all departments, with GCP, and appropriate regulations.
- Plan, conduct and report audits of the quality system both internal and external.
- Follow up on effectiveness of corrective/preventive actions.
- Fully competent to audit alone.
- Assist as necessary in training new auditors and in training employees in other departments regarding GCP and ISO standards.

Level Responsibility

- Line Management - Low - 0
- Project - Medium - 2 Countries
- Financial - Low
- Technical - High - Expert

CROS 17.06 **Quality Assurance Auditor - Development Level**

Survey Level 8

Experience Likely to have had 2-4 years' experience in the pharmaceutical industry, or a CRO

Qualifications Degree in Bioscience

Responsibilities

- Become familiar with SOPs from all departments, with GCP, and appropriate regulations.
- Plan, conduct and report audits of the quality system both internal and external.
- Follow up on effectiveness of corrective/preventive actions.
- Fully competent to audit alone.
- Assist as necessary in training new auditors and in training employees in other departments regarding GCP and ISO standards.

Level Responsibility

- Line Management - Low - 0
- Project - Medium - 2 Countries
- Financial - Low
- Technical - Medium

CROS 17.07 **Quality Assurance Auditor - Entry Level**

Survey Level 9

Experience Likely to have had 0-2 years' experience in the pharmaceutical industry, or a CRO

Qualifications Degree in Bioscience

Responsibilities

- Become familiar with SOPs from all departments, with GCP, and appropriate regulations.
- Plan, conduct and report audits of the quality system both internal and external. Follow up on effectiveness of corrective/preventive actions.

Level Responsibility

- Line Management - Low - 0
- Project - Medium - 2 Countries
- Financial - Low
- Technical - Low

CROS 17.08 **Document Controller**

Survey Level 8

Experience Likely to have had 3-5 years' relevant experience

Qualifications Life sciences graduate

Responsibilities

- Responsible for maintaining the document and SOP system, and assisting staff in writing SOPs conforming to clinical trials standard
- Responsibility for archiving all documentation
- Prepare documents and data for review by clients at audits
- Maintain the SOP and controlled document monitoring system
- May be responsible for sending out documents, e.g. accreditation packages, CVs, reference ranges, to clients

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - Low
- Technical - Medium

Drug Safety (Pharmacovigilance)

In each job, the survey code for each job is shown followed by the survey job title.

CROS 18.01	**Head of Drug Safety**
Survey Level	4
Alternative Title/s	Director of Drug Safety
Experience	Likely to have had at least 10 years' experience within drug safety or relevant area. Significant previous line management experience
Qualifications	Life science degree or medical qualification

Responsibilities

- To be responsible for the management of the Drug Safety group
- Keep abreast of external developments in current/future safety system initiatives and act as business advisor on short, medium and long-term safety system enhancements
- Ensure adequacy of procedures used in drug safety from legislative and project points of view
- To manage the Drug Safety personnel and to oversee all recruitment activity
- To ensure that Drug Safety projects are all adequately resourced
- Leadership and co-ordination of business development activities relating to drug safety management

Level Responsibility

- Line Management - High - 6+
- Project - High - 3+ Countries
- Financial - High - Primary Responsibility
- Technical - High - Expert

CROS 18.02 **Senior Drug Safety Manager**

Survey Level 5

Alternative Title/s Associate Director of Drug Safety

Experience Likely to have had 8-10 years' experience within drug safety or relevant area. Previous line management experience

Qualifications Life science degree or medical qualification

Responsibilities

- Management of resources for designated area of responsibility within the group
- Keep abreast of external developments in current/future safety system initiatives and act as business advisor on short, medium and long-term safety system enhancements
- Ensure adequacy of procedures used in drug safety from legislative and project points of view
- Managerial and leadership responsibility for designated area of drug safety
- Leadership and co-ordination of business development activities relating to designated area of responsibility
- Deputise for the Head of Drug Safety as needed

Level Responsibility

- Line Management - High - 6+
- Project - High - 3+ Countries
- Financial - Medium
- Technical - High - Expert

CROS 18.03 **Drug Safety Manager**

Survey Level 6

Experience Likely to have had 7 years' experience within drug safety or relevant area. Previous line management experience

Qualifications Life science degree or medical qualification

Responsibilities

- Management of resources for designated area of responsibility within the group
- Keep abreast of external developments in current/future safety system initiatives and act as business advisor on short, medium and long-term safety system enhancements
- Ensure adequacy of procedures used in drug safety from legislative and project points of view
- Managerial and leadership responsibility for designated area of drug safety
- Leadership and co-ordination of business development activities relating to designated area of responsibility

Level Responsibility

- Line Management - High - 6+
- Project - High - 3+ Countries
- Financial - Medium
- Technical - High - Expert

CROS 18.04 **Drug Safety Team Leader**

Survey Level 7

Experience Likely to have had 5-7 years' experience within drug safety or relevant area

Qualifications Life science degree or medical qualification

Responsibilities

- Overall project responsibility
- Project development - design project set up, kick off meetings and resources for the project
- Operations - monitor billing against budget, co-ordinate production of submission metrics and analyse metrics
- Provide training inside and outside the department
- Contribute to the running of department meetings
- Supervise and mentor less experienced staff

Level Responsibility

- Line Management - High - 6+
- Project - High - 3+ Countries
- Financial - Medium
- Technical - High - Expert

CROS 18.05 **Drug Safety Associate - Established Level**

Survey Level 7

Alternative Title/s Safety Surveillance Officer - Established Level

Experience Likely to have had a minimum of 4 years' relevant experience

Qualifications Life science degree or medical qualification

Responsibilities

- To work with clients on project set up to ensure clients needs are met and oversee project to ensure delivery meets expectations
- To co-ordinate the investigation, reporting and follow up of all notifications of adverse event reports related to pre-marketed and marketed drugs
- To develop a database of AE reports. To decide on communications to regulatory authorities outside normal guidelines
- May supervise less experienced staff

Level Responsibility

- Line Management - Medium - 1-5
- Project - Medium - 2 Countries
- Financial - Low
- Technical - Medium

CROS 18.06	**Drug Safety Associate - Development Level**
Survey Level	8
Alternative Title/s	Safety Surveillance Officer - Development Level
Experience	Likely to have had 2-4 years' relevant experience
Qualifications	Life science degree or medical qualification

Responsibilities

- Understanding of the business (both safety evaluation and case management) and sound working knowledge of the relevant world-wide regulations and guidelines
- To enter and process case information consistent with relevant documentation
- Identify follow-up questions to obtain missing data from cases
- Become an "expert" in the assigned therapeutic area/products
- Participate in the development processes to improve quality of clinical safety data
- Assist in training new employees concerning adverse event reporting

Level Responsibility

- Line Management - Low - 0
- Project - Medium - 2 Countries
- Financial - Low
- Technical - Medium

CROS 18.07	**Drug Safety Associate - Entry Level**
Survey Level	9
Alternative Title/s	Safety Surveillance Officer - Entry Level
Experience	Likely to have had 0-2 years' relevant experience
Qualifications	Life science degree or medical qualification

Responsibilities

- Learning to understand the business (both safety evaluation and case management) and sound working knowledge of the relevant world-wide regulations and guidelines
- To enter and process case information consistent with relevant documentation
- Identify follow-up questions to obtain missing data from cases
- Participate in the development processes to improve quality of clinical safety data

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - Low
- Technical - Low

Projects

In each job, the survey code for each job is shown followed by the survey job title.

CROS 19.01	**VP Projects**
Survey Level	**-**
Alternative Title/s	Executive Director Projects/VP Projects
Experience	Likely to have had at least 15 years' project management and clinical trial management experience
Qualifications	MD or Life science degree plus advanced degree and/or post-graduate qualification

Responsibilities

- To lead and manage the Projects function of the company
- Likely to be responsible for projects in a designated region
- To be responsible for ensuring that projects are delivered within contractual terms and that project teams adhere at all time to regulations
- To be responsible for development and management of direct and indirect reports
- To be responsible for medium and long term strategic planning activities for project management
- To be proactive in the creation and implementation of systems to enhance quality and efficiency of clinical operations
- To be responsible for ensuring projects are adequately resourced
- To be responsible for development and maintenance of client relationships
- To monitor expenditure against budgets and ensure that any necessary adjustments are implemented

Level Responsibility

- Line Management - High - 6+
- Project - High - 3+ Countries
- Financial - High - Primary Responsibility
- Technical - High - Expert

CROS 19.02	**Head of Projects**
Survey Level	4
Alternative Title/s	Executive Director Projects
Experience	Likely to have had at least 10 years' project management and clinical trial management experience
Qualifications	MD or Life science degree plus advanced degree and/or post-graduate qualification

Responsibilities

- To be responsible for projects within their designated therapeutic area
- To ensure delivery of projects within contractual terms
- To ensure compliance with regulations
- To oversee staff recruitment, development and training
- To manage project staff
- To undertake strategic planning activities for project management
- To assist in the creation and implementation of systems to enhance quality and efficiency of clinical operations

Level Responsibility

- Line Management - High - 6+
- Project - High - 3+ Countries
- Financial - High - Primary Responsibility
- Technical - High - Expert

CROS 19.03	**Senior Project Director**
Survey Level	4
Alternative Title/s	Manager Project Directors
Experience	Likely to have had at least 8 years' project management and clinical trial management
Qualifications	MD or Life science degree

Responsibilities

- To be responsible for the delivery of projects and customer satisfaction for a designated region/ therapeutic area/clinical operating unit
- To be responsible for all projects in area including quality of service delivered, meeting/exceeding of customer expectations, positive cash flow, maximum revenue and project profitability
- To develop and maintain excellent relationships with internal and external clients
- To supervise senior management team in area/unit
- To have overall responsibility for unit staff recruitment, development and training
- To review budgets and proposals
- To lead/participate in the negotiation process on key contracts and as needed
- To contribute to overall project management goals and objectives

Level Responsibility

- Line Management - High - 6+
- Project - High - 3+ Countries
- Financial - High - Primary Responsibility
- Technical - High - Expert

CROS 19.04	**Project Director**
Survey Level	4
Experience	Likely to have had at least 6 years' project management and clinical trial management
Qualifications	MD or Life science degree

Responsibilities

- To direct, develop and supervise designated Project Managers
- To ensure that customers are satisfied and to develop business
- To assist Group Project Director with responsibility for the commercial and technical success of all projects allocated to the group

Level Responsibility

- Line Management - Medium - 1-5
- Project - High - 3+ Countries
- Financial - High - Primary Responsibility
- Technical - High - Expert

CROS 19.05 **Associate Project Director**

Survey Level 5

Experience 5+ years' project management and clinical trial management

Qualifications MD or Life science degree

Responsibilities

- To direct, develop and supervise Project Managers
- To ensure that customers are satisfied and to develop business
- To take responsibility for the commercial and technical success of all projects allocated to the group

Level Responsibility

- Line Management - Medium - 1-5
- Project - High - 3+ Countries
- Financial - High - Primary Responsibility
- Technical - High - Expert

CROS 19.06 **Project Manager - Established Level**

Survey Level 5

Experience 4+ years' project management and clinical trial management

Qualifications Life science degree

Responsibilities

- To manage a range of European or one Global project with very limited supervision, ensuring client satisfaction and delivery of the project on time and within budget

Level Responsibility

- Line Management - Low - 0
- Project - High - 3+ Countries
- Financial - Medium
- Technical - High - Expert

CROS 19.07 **Project Manager - Development Level**

Survey Level 6

Experience 2-4 years' project management and clinical trial management

Qualifications Life science degree

Responsibilities

- To manage one or more European projects with some limited supervision, ensuring client satisfaction and delivery of the project on time and within budget

Level Responsibility

- Line Management - Low - 0
- Project - High - 3+ Countries
- Financial - Medium
- Technical - Medium

CROS 19.08 **Project Manager - Entry Level**

Survey Level 6

Experience Clinical trial management experience, 0-2 years' project management experience

Qualifications Life science degree

Responsibilities

- To manage local projects or one European project with some supervision, ensuring client satisfaction and delivery of the project on time and within budget

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - Low
- Technical - Medium

CROS 19.09 **Project Associate – Established Level**

Survey Level 7

Experience Likely to have had a minimum of 4 years' project administration experience

Qualifications Graduate or equivalent

Responsibilities

- To support and assist the project management group and team in the co-ordination of activities relevant to the project - meetings minutes, filing, preparing overheads, project status report preparation and distribution
- May oversee work of more junior colleagues
- Job holder works without close supervision

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - Low
- Technical - Medium

CROS 19.10 **Project Associate – Development Level**

Survey Level 8

Experience Likely to have had a minimum of 2-4 years' project administration experience

Qualifications Graduate or equivalent

Responsibilities

- To support and assist the project management group and team in the co-ordination of activities relevant to the project - meetings minutes, filing, preparing overheads, project status report preparation and distribution
- Job holder works with some supervision

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - Low
- Technical - Low

CROS 19.11 **Project Associate – Entry Level**

Survey Level 9

Experience Likely to have had a minimum of 0-2 years' project administration experience

Qualifications Graduate or equivalent

Responsibilities

- To support and assist the project management group and team in the co-ordination of activities relevant to the project - meetings minutes, filing, preparing overheads, project status report preparation and distribution
- Job holder works with close supervision and is expected to make significant progress at this level

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - Low
- Technical - Low

Business Development

In each job, the survey code for each job is shown followed by the survey job title.

CROS 20.01	**VP Business Development**
Survey Level	**-**
Experience	Likely to have had at least 15 years' experience of business development with a CRO or pharmaceutical company in an international service environment
Qualifications	Life sciences degree, MBA, further language

Responsibilities

- To be responsible for management of the Business Development function for a designated Region
- To be responsible for strategic planning for Business Development and ensure that the resources are available for achieving business goals
- To be responsible for ensuring that opportunities for revenue generation are identified and developed through the maintenance and improvement of existing client relationships to increase market share
- To ensure Business Development function identifies and develops new business opportunities to increase market penetration
- Liaise and work with cross-functional colleagues at senior levels to define client strategy
- To be responsible for monitoring and controlling Business Development budget
- Maintain a high level of expertise with in Business Development in the UK and internationally
- Responsible for development and management of direct and indirect reports

Level Responsibility

- Line Management -High - 6+
- Project - High - 3+ Countries
- Financial - High - Primary Responsibility
- Technical - High - Expert

CROS 20.02	**Head of Business Development**
Survey Level	4
Experience	Likely to have had at least 10 years' experience of business development with a CRO or pharmaceutical company in an international service environment
Qualifications	Life sciences degree, MBA, further language

Responsibilities

- Responsible for management of the Business Development function
- Define strategy for Business Development and ensure that the resources are available for achieving business goals
- Responsible for ensuring that opportunities for revenue generation are identified and developed through the maintenance and improvement of existing client relationships to increase market share
- Responsible for ensuring that new business opportunities to increase market penetration are identified and developed
- Liaise and work with cross-functional colleagues to define client strategy
- Responsible for staff development and recruitment

Level Responsibility

- Line Management - High - 6+
- Project - High - 3+ Countries
- Financial - High - Primary Responsibility
- Technical - High - Expert

CROS 20.03	**Associate Director of Business Development**
Survey Level	5
Alternative Title/s	Senior Client Relations Director/Account Director
Experience	5-8 years' experience of business development with a CRO or pharmaceutical company in an international service environment
Qualifications	Life sciences degree, MBA, further language

Responsibilities

- Identify and develop opportunities for revenue generation by maintaining and improving existing client relationships to increase market share
- Identify and develop new business opportunities to increase market penetration
- Liaise and work with cross-functional colleagues to develop client strategy
- Responsible for key client accounts

Level Responsibility

- Line Management - Medium - 1-5
- Project - High - 3+ Countries
- Financial - Medium
- Technical - High - Expert

CROS 20.04	**Business Development Manager**
Survey Level	6
Alternative Title/s	Client Relations Director/Account Manager
Experience	At least 5 years' experience of business development with a CRO or pharmaceutical company in an international service environment
Qualifications	Life sciences degree, MBA, further language useful

Responsibilities

- Identify and develop opportunities for revenue generation by maintaining and improving existing client relationships to increase market share
- Identify and develop new business opportunities to increase market penetration
- Liaise and work with cross-functional colleagues to develop client strategy
- Responsible for client accounts

Level Responsibility

- Line Management - Low - 0
- Project - High - 3+ Countries
- Financial - High - Primary Responsibility
- Technical - High - Expert

CROS 20.05	**Business Development Executive**
Survey Level	7
Alternative Title/s	Client Relations Manager
Experience	At least 1 year's experience in an international service environment
Qualifications	Life sciences degree

Responsibilities

- Identify and develop opportunities for revenue generation by maintaining and improving existing client relationships to increase market share
- Identify and develop new business opportunities to increase market penetration
- Liaise and work with cross-functional colleagues to develop client strategy
- Responsible for smaller client accounts

Level Responsibility

- Line Management - Low - 0
- Project - Medium - 2 Countries
- Financial - Medium
- Technical - Medium

CROS 20.06 **Key Accounts Manager**

Survey Level 7

Experience 3-5 years' appropriate CRO/Pharmaceutical experience

Qualifications Life sciences degree

Responsibilities

- Identify and develop opportunities for revenue generation by maintaining and improving relationships with key accounts
- Identify and develop new business opportunities with existing clients
- Liaise and work with cross-functional colleagues to develop strategies for designated accounts
- Directly responsible for selected key accounts
- May be responsible for overseeing work of Key Account Executive/s

Level Responsibility

- Line Management - Medium - 1-6
- Project - Medium - 2 Countries
- Financial - Medium
- Technical - Medium

CROS 20.07 **Key Accounts Executive**

Survey Level 9

Experience 1-3 years' appropriate CRO/Pharmaceutical experience

Qualifications Life sciences degree

Responsibilities

- Identify and develop opportunities for revenue generation by maintaining and improving relationships with designated key accounts
- Identify and develop new business opportunities with existing clients
- Liaise and work with cross-functional colleagues to develop strategies for own accounts

Level Responsibility

- Line Management - Low - 0
- Project - Medium - 2 Countries
- Financial - Medium
- Technical - Medium

In each job, the survey code for each job is shown followed by the survey job title.

Note: There are two contracts jobs in the Start-Up Section of the survey – if you have not already done so please match your Start-Up Contract Specialists in Section 26 - 26.08 Senior Contract Specialist, 26.09 Contract Specialist.

CROS 21.01	**VP Contracts & Proposals**
Survey Level	**-**
Experience	Likely to have had at least 15 years' experience in contract and proposal administration
Qualifications	Degree in a commercial subject with post-graduate business qualification, e.g. MBA

Responsibilities

- To be responsible for the management of the Contracts & Proposals function/s ensuring that client contracts are developed and project managed
- To be responsible for ensuring that proposals are produced and delivered to required quality and on time
- To be responsible for management of complex strategic accounts and difficult negotiations
- To be responsibility for contracts and proposals involving global accounts and specialist accounts
- Responsible for staff development and recruitment; ensures resources are available for optimum functioning of departments
- To be responsible for monitoring budgets for functions
- Maintain a high level of expertise within Contracts and Proposals in the UK and internationally
- Responsible for development and management of direct and indirect reports

Level Responsibility

- Line Management - High - 6+
- Project - High - 3+ Countries
- Financial - High - Primary Responsibility
- Technical - High - Expert

CROS 21.02 **Head of Contracts**

Survey Level 4

Experience Likely to have had at least 10 years' experience in contract administration

Qualifications Degree in a commercial subject, MBA preferred

Responsibilities

- Responsible for the Contracts function ensuring that client contracts are developed and project managed
- May take some direct responsibility for complex strategic accounts and difficult negotiations
- Overall responsibility for contracts with global accounts and specialist accounts
- Responsible for Contract staff development and recruitment; ensures resources are available for optimum functioning of department
- Responsible for reviewing invoices and for maintaining cash flow and revenues
- Present at conferences and meetings

Level Responsibility

- Line Management - High - 6+
- Project - High - 3+ Countries
- Financial - High - Primary Responsibility
- Technical - High - Expert

CROS 21.03 **Senior Contracts Manager**

Survey Level 5

Experience Likely to have had at least 7 years' experience in contract administration

Qualifications Degree in a commercial subject, MBA preferred

Responsibilities

- Develop, negotiate and project manage client contracts
- Responsible for complex strategic accounts and difficult negotiations
- Global account responsibilities or responsibilities in a specialist area
- Co-ordinate contract team
- Review invoices, cash flow and revenues
- Conduct client meetings and teleconferences
- Present at conferences and meetings

Level Responsibility

- Line Management - High - 6+
- Project - High - 3+ Countries
- Financial - Medium
- Technical - High - Expert

CROS 21.04 **Contracts Manager**

Survey Level 6

Experience Likely to have had at least 5 years' experience in contract administration or a related role

Qualifications Degree in a commercial subject

Responsibilities

- Overall project management responsibility of the contract process for specific accounts
- Co-ordinate relevant parties to review and negotiate final contracts
- Develop and negotiate client account specific standards
- Co-ordinate finalisation of account sub contracts
- Ongoing review of contractual status and identification of out of scopes
- Review invoices, cash flow and payment terms - renegotiating where necessary
- Ongoing interface with clients regarding contractual issues

Level Responsibility

- Line Management - Low - 0
- Project - Medium - 2 Countries
- Financial - Medium
- Technical - Medium

CROS 21.05 **Contracts Associate - Established Level**

Survey Level 7

Experience Likely to have had a minimum of 4 years' Contracts experience

Qualifications Degree in a health related field

Responsibilities

- Develop and prepare contracts for assigned customers
- Act as Team Leader on assigned projects and manage contract development process for large, complex contracts
- Primary customer contact with customers on large projects; develop and maintain customer relationships
- Revise and develop contracts, budgets and scope of work as needed; ensure changes are integrated into study contract
- Attend customer meetings
- Create budgets, scopes and contracts as required
- Provide advice, support and guidance to less experienced colleagues as needed
- Mentor and train team members

Level Responsibility

- Line Management - Low - 0
- Project -Medium - 2 Countries
- Financial - Low
- Technical - High - Expert

CROS 21.06 **Contracts Associate - Development Level**

Survey Level 8

Experience 2-4 years' Contracts experience

Qualifications Degree in a health related field

Responsibilities

- Develop and prepare contracts for assigned customers
- Work closely with project teams to determine appropriate terms and conditions of contracts
- Develop and prepare contracts
- Liaise with customers on large projects; develop and maintain customer relationships
- Revise and develop contracts, budgets and scope of work as needed; ensure changes are integrated into study contract
- Attend customer meetings
- Create budgets, scopes and contracts as required
- Work with some supervision
- May provide guidance to less experienced colleagues as needed

Level Responsibility

- Line Management - Low - 0
- Project -Medium - 2 Countries
- Financial - Low
- Technical - Medium

CROS 21.07 **Contracts Associate - Entry Level**

Survey Level 9

Experience 0-2 years’ experience in CRO, pharmaceutical or health related organisation

Qualifications Degree in a health related field

Responsibilities

- Under general supervision to develop and prepare contracts for assigned customers
- Work closely with project teams to determine appropriate terms and conditions of contracts
- Develop and prepare contracts
- Liaise with customers on smaller projects and provide support for colleagues dealing with larger customers/projects
- Revise and develop contracts, budgets and scope of work as needed; ensure changes are integrated into study contract
- Update and maintain contract databases and files

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - Low
- Technical - Low

CROS 21.08	**Head of Proposals**
Survey Level	4
Experience	Likely to have had at least 10 years' management experience and extensive proposal development experience
Qualifications	Degree in a health related field

Responsibilities

- Responsible for the Proposals function ensuring the quality and timeliness of proposals produced
- Develop strategies to improve design and delivery of effective proposals
- Interface with all service group directors to ensure effective proposal strategy
- Responsible for Proposals staff development and recruitment; ensure resources are available for optimum functioning of department
- May directly lead client discussions and presentations
- Responsible for establishment of effective client negotiation after delivery of proposal

Level Responsibility

- Line Management - High - 6+
- Project - High - 3+ Countries
- Financial - High - Primary Responsibility
- Technical - High - Expert

CROS 21.09	**Senior Proposal Manager**
Survey Level	5
Experience	5-8 years' management experience and extensive proposal development experience
Qualifications	Degree in a health related field

Responsibilities

- Manage designated section to ensure quality and timeliness of proposals
- Work with business development and technical groups to design effective proposals
- Interface with all service group directors to gather appropriate information for proposals
- Review documents before they are sent to clients to ensure quality, accuracy and timeliness
- Leading client discussions, preparing for and delivering client presentations
- Participate in client negotiation after delivery of proposal

Level Responsibility

- Line Management - High - 6+
- Project - High - 3+ Countries
- Financial - Medium
- Technical - High - Expert

CROS 21.10 **Proposal Manager**

Survey Level 6

Experience 1 year's management experience and 3-5 years' proposal development experience, CRO or Pharma experience

Qualifications Degree in a health related field

Responsibilities

- Lead proposal development team to prepare quality, timely proposals, rebids and exhibits
- Review Request for Proposals, identify issues, negotiate deadlines with clients
- Conduct scoping calls, participate in pre-RFP client meetings
- Present and justify budgets to internal teams and clients
- Conduct CRC meetings

Level Responsibility

- Line Management - Low - 0
- Project - Medium - 2 Countries
- Financial - Medium
- Technical - Medium

CROS 21.11 **Proposal Associate - Established Level**

Survey Level 7

Experience Likely to have had a minimum of 3 years' Proposals experience

Qualifications Degree in a health related field

Responsibilities

- Assist the Proposal Manager in the development of client proposals
- Participate in client teleconferences to ascertain scope of work requested
- Arrange and participate in Proposal Development Team meetings
- Gather internal and external information required for the final proposal
- Prepare final documents for delivery to clients
- Assist in the development, modification and testing of proposal tools and systems

Level Responsibility

- Line Management - Low - 0
- Project -Medium - 2 Countries
- Financial - Low
- Technical - High - Expert

CROS 21.12 **Proposal Associate - Development Level**

Survey Level 8

Experience Likely to have had 2-4 years' Proposals experience

Qualifications Degree in a health related field

Responsibilities

- Assist more senior Proposal staff in the development of client proposals
- Participate in client teleconferences to ascertain scope of work requested
- Participate in Proposal Development Team meetings
- Gather internal and external information required for the final proposal
- Prepare final documents for delivery to clients
- Assist in the development, modification and testing of proposal tools and systems

Level Responsibility

- Line Management - Low - 0
- Project -Medium - 2 Countries
- Financial - Low
- Technical - Medium

CROS 21.13 **Proposal Associate - Entry Level**

Survey Level 9

Experience Likely to have had 0-2 years' experience in CRO, pharmaceutical or health related organisation

Qualifications Degree in a health related field

Responsibilities

- Assist with the development of client proposals as directed
- Participate in Proposal Development Team meetings
- Gather internal and external information as directed
- Assist with preparation of final documents for delivery to clients
- Assist in the development, modification and testing of proposal tools and systems

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - Low
- Technical - Low

In each job, the survey code for each job is shown followed by the survey job title.

CROS 23.01	**Head of Technical Training**
Survey Level	5
Experience	Extensive training experience
Qualifications	Degree level education or equivalent; may have a training qualification

Responsibilities

- To create/design technical training modules for third line and senior management
- Responsible for defining budget, revenue and costs and ensuing budget achieved
- Management of the technical training team
- Defining strategy for the organisation for technical/operational training
- Responsibility across organisations/sites/Executive Development Centres
- Ensure ongoing success and growth of the training business.

Level Responsibility

- Line Management - High - 6+
- Project - High - 3+ Countries
- Financial - High - Primary Responsibility
- Technical - High - Expert

Job Matching Note

Where your job match does not spend all of their time in this role, the job holder will be a match where 50% of their time matches the job specification.

CROS 23.02 **Technical Training Manager**

Survey Level 6

Experience 3 years' clinical/data management experience in Pharmaceutical/CRO environment. Training experience desirable

Qualifications Degree level

Responsibilities

- To create/design modules for technical training of CRAs/Data Management Associates.
- Responsible for the management of the training team
- To define department policy and procedures.
- Management, motivation, coaching, mentoring of CRAs/Data Management Associates.
- Work with the Head of Training to develop budget revenue and cost forecasts.
- Controlling, overseeing above, once approved.
- Ensure quality of training delivery and content.
- To deliver courses.
- To carry out presentations to customers.
- Support Head of Training in implementing business initiatives.
  Quality Control - maintain high quality monitoring methods; review audit reports

Level Responsibility

- Line Management - Medium - 1-5
- Project - Medium - 2 Countries
- Financial - Medium
- Technical - Medium

Job Matching Note
Where your job match does not spend all of their time in this role, the job holder will be a match where 50% of their time matches the job specification.

CROS 23.03 **Technical Training Officer/Consultant**

Survey Level 8

Experience Minimum 2 years' clinical/data management experience in Pharmaceutical/CRO environment. Training experience

Qualifications Degree level

Responsibilities

- Involved in defining course content and development of certain training materials (up to first line manager level).
- Training needs analysis.
- Develop new modules where required.
- Review existing courses and continuously improve.
- Maintain quality materials, facilitator notes, etc.
- Marketing/running of open learning centre.
- Deliver quality training/workshops.

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - Low
- Technical – Medium

Job Matching Note
Where your job match does not spend all of their time in this role, the job holder will be a match where 50% of their time matches the job specification.

In each job, the survey code for each job is shown followed by the survey job title.

CROS 24.01	**VP Clinical Operations**
Survey Level	**-**
Experience	Minimum of 15 years' clinical research experience within a Pharmaceutical company and/or CRO. Minimum of 6 years' managerial/supervisory experience to include both project and people management
Qualifications	Degree (life sciences preferred) or Registered Nurse or equivalent

Responsibilities

- To be responsible for the Clinical Operations function for a designated Region
- To be responsible for financial management of Clinical Operations ensuring that the function operates within budget and achieves targeted profit margins
- To be responsible for management of Clinical Operations resources
- To maintain and develop relations with senior management in Clinical Operations on a global basis in order to ensure Operations conforms to and reinforces company's standards globally
- To ensure that the function is committed to process improvement
- To contribute to strategic planning for Clinical Operations and ensure that the resources are available for achieving business goals
- Liaise and work with cross-functional colleagues at senior levels to define client strategy
- Maintain a high level of expertise within Clinical Operations in the UK and internationally
- Responsible for development and management of direct and indirect reports

Level Responsibility

- Line Management - High - 6+
- Project - High - 3+ Countries
- Financial - High - Primary Responsibility
- Technical - High - Expert

CROS 24.02	**Head of Clinical Operations**
Survey Level	4
Experience	Minimum of 10 years' clinical research experience within a Pharmaceutical company and/or CRO. Minimum of 4 years' managerial/supervisory experience to include both project and people management
Qualifications	Degree (life sciences preferred) or Registered Nurse or equivalent

Responsibilities

- Overall management of Clinical Operations department including Clinical Operations Management and CRAs
- Financial responsibility for Clinical Operations including pricing, budgets, profit margins
- Oversee CRA utilisation
- Liaise with Clinical Operations colleagues globally to ensure continuity throughout Operations
- Overall responsibility for process improvement and development and implementation of Standard Operating Procedures
- Oversee recruitment, retention and ongoing professional development of Operations staff
- Liaise with other Clinical Research departments to ensure success of projects

Level Responsibility

- Line Management - High - 6+
- Project - High - 3+ Countries
- Financial - High - Primary Responsibility
- Technical - High - Expert

CROS 24.03 **Director Clinical Research**

Survey Level 4

Experience Likely to have had 8-10 years' experience in clinical research

Qualifications Degree (life sciences preferred) or Registered Nurse or equivalent

Responsibilities

- Responsible for management of designated Clinical Operations area
- Financial responsibility for designated area
- Serve as a source of scientific and therapeutic expertise
- Liaise globally with Clinical Operations colleagues in relevant therapeutic areas
- Responsibility for process improvement and development and implementation of Standard Operating Procedures for own area
- Responsible for recruitment, retention and ongoing professional development of Operations staff in designated area
- Coach and motivate direct reports
- Deputise for Head of Clinical Operations as needed

Level Responsibility

- Line Management - High - 6+
- Project - High - 3+ Countries
- Financial - High - Primary Responsibility
- Technical - High - Expert

CROS 24.04 **Associate Director Clinical Research**

Survey Level 5

Experience Likely to have had 7-8 years' experience in clinical research

Qualifications Degree (life sciences preferred) or Registered Nurse or equivalent

Responsibilities

- Responsible for management of designated Clinical Operations area
- Financial responsibility for designated area
- Serve as a source of scientific and therapeutic expertise
- Liaise globally with Clinical Operations colleagues in relevant therapeutic areas
- Responsibility for process improvement and development and implementation of Standard Operating Procedures for own area
- Responsible for recruitment, retention and ongoing professional development of Operations staff in designated area
- Coach and motivate direct reports
- To be a match here the jobholder must manage Clinical Research Managers

Level Responsibility

- Line Management - High - 6+
- Project - High - 3+ Countries
- Financial - High - Primary Responsibility
- Technical - High - Expert

CROS 24.05	**Senior Clinical Research Manager - Line Responsibility**
Survey Level	5
Experience	Likely to have had 7-8 years' experience in clinical research, with significant line management experience
Qualifications	Degree in a health related field

Responsibilities

- To line manage clinical research staff
- Provide training and consultation related to clinical study initiation and ongoing operating activities in the conduct of clinical trials
- To be responsible for ensuring that the CRAs achieve their performance and productivity targets. To assess their performance on site and to monitor their relationships with site staff
- Collate feedback from Project Managers and Clinical Team Leaders, plan career progression and assess training requirements
- To be responsible for establishing good communications with CRAs ensuring that company requirements and goals are understood and adhered to
- To communicate any problems or issues within the company
- Coach, mentor, motivate and develop direct reports

Level Responsibility

- Line Management - High - 6+
- Project - Medium
- Financial - Medium
- Technical - High - Expert

CROS 24.06 **Clinical Research Manager - Line Responsibility**

Survey Level 6

Experience Likely to have had 5-6 years' experience in clinical research, with at least 2 years in a clinical team co-ordinating capacity and with 18 months' line management experience

Qualifications Degree in a health related field

Responsibilities

- To line manage clinical research staff
- Provide training and consultation related to clinical study initiation and ongoing operating activities in the conduct of clinical trials
- To be responsible for ensuring that the CRAs achieve their performance and productivity targets. To assess their performance on site and to monitor their relationships with site staff
- Collate feedback from Project Managers and Clinical Team Leaders, plan career progression and assess training requirements
- To be responsible for establishing good communications with CRAs ensuring that company requirements and goals are understood and adhered to
- To communicate any problems or issues within the company
- Coach, mentor, motivate and develop direct reports

Level Responsibility

- Line Management - High - 6+
- Project - Medium
- Financial - Medium
- Technical - High - Expert

CROS 24.07 **Clinical Research Manager - Technical Responsibility**

Survey Level 6

Experience Likely to have had 5-6 years' experience in clinical research, with at least 2 years in a clinical team co-ordinating capacity

Qualifications Degree in a health related field

Responsibilities

- To provide scientific and therapeutic expertise to the Clinical Research staff
- To be responsible for providing and/or co-ordinating technical expertise to project teams
- Monitor project hours and overall workloads
- Collate feedback from Project Managers and Clinical Team Leaders
- Organise and chair team meetings
- Matches here will be technical experts providing advice and support for Clinical Research staff but not line managing

Level Responsibility

- Line Management - Low - 0
- Project - High - 3+ Countries
- Financial – Medium
- Technical - High - Expert

CROS 24.08 **Clinical Team Leader - Established Level**

Survey Level 6

Experience 3-5 years' experience as Clinical Team Leader

Qualifications Degree in a health related field

Responsibilities

- To lead the clinical part of a project
- To contribute to scope of work with Project Management, Business Development and customer
- To meet deadlines for clinical components of projects in accordance with contracted scope of work, budgeted hours and timelines ensuring maximum efficiency and profitability
- To prepare, manage and refine clinical plan
- To form the clinical team. To plan and monitor tasks for the team. To be responsible for team training
- To communicate project progress
- To assist Project Manager with management of clinical budget throughout the project
- To contribute to maintenance of high quality deliverables
- May act as a CRA within the project
- May supervise work of less experienced Clinical Team Leaders

Level Responsibility

- Line Management - High - 6+
- Project - Medium - 2 Countries
- Financial - Medium
- Technical - High - Expert

CROS 24.09 **Clinical Team Leader - Development Level**

Survey Level 7

Experience 1-3 years' experience as Clinical Team Leader

Qualifications Degree in a health related field

Responsibilities

- To lead the clinical part of a project within a region
- To contribute to scope of work with Project Management, Business Development and customer
- To meet deadlines for clinical components of projects in accordance with contracted scope of work, budgeted hours and timelines ensuring maximum efficiency and profitability
- To prepare, manage and refine clinical plan
- To form the clinical team. To plan and monitor tasks for the team. To be responsible for team training
- To communicate project progress
- To track and manage clinical budget
- May act as a CRA within the project

Level Responsibility

- Line Management - High - 6+
- Project - Medium - 2 Countries
- Financial - Low
- Technical - Medium

CROS 24.10 **Clinical Team Leader - Entry Level**

Survey Level 7

Experience At least 4 years' experience as a Clinical Research Associate

Qualifications Degree in a health related field

Responsibilities

- To lead the clinical part of a project within a region
- To contribute to scope of work with Project Management, Business Development and customer
- To meet deadlines for clinical components of projects in accordance with contracted scope of work, budgeted hours and timelines ensuring maximum efficiency and profitability
- To prepare, manage and refine clinical plan
- To form the clinical team. To plan and monitor tasks for the team. To be responsible for team training
- To communicate project progress
- To track and manage clinical budget
- May act as a CRA within the project

Level Responsibility

- Line Management - High - 6+
- Project - Low - 1 Country
- Financial - Low
- Technical - Medium

CROS 24.11 **Clinical Research Associate - Established Level**

Survey Level 7

Experience Likely to have had at least 4 years' CRA experience

Qualifications Relevant degree/nursing qualification

Responsibilities

- Co-ordinate one or more clinical projects as a local project co-ordinator and acts as local client contact
- May manage small projects with supervision
- Select and recruit potential investigators
- Full study site administration including pre-study visits, site initiations, routine monitoring and close down visits
- Organise investigator meetings
- Participate in writing clinical trial reports
- Conduct investigator grant payments
- May be involved in monitoring trainees/junior staff
- Assist with preparation of LREC submissions and notifications to regulatory authorities

Level Responsibility

- Line Management - Medium - 1-5
- Project - Medium - 2 Countries
- Financial - Low
- Technical - High - Expert

CROS 24.12 **Clinical Research Associate - Development Level**

Survey Level 8

Experience Likely to have had 2-4 years’ CRA experience

Qualifications Relevant degree/nursing qualification

Responsibilities

- May co-ordinate designated clinical projects with supervision
- Select and recruit potential investigators
- Full study site administration, including routine monitoring and close-down of clinical sites, maintenance of study files, conducts pre-study and initiated visits
- Prepare trip reports
- May contribute to design of clinical trial protocols
- May mentor a CRA Trainee (New Graduate Level)
- Assist with the recruitment of potential investigators, preparation of LREC submissions and notifications to regulatory authorities

Level Responsibility

- Line Management - Low - 0
- Project - Medium - 2 Countries
- Financial - Low
- Technical - Medium

CROS 24.13 **Clinical Research Associate - Entry Level**

Survey Level 9

Experience Up to 2 years' trainee CRA experience

Qualifications Relevant degree/nursing qualification

Responsibilities

- Responsible for all aspects of study site management - routine monitoring, close down of clinical sites, maintenance of study files, pre-study and initiation visits with guidance
- Prepare accurate and timely trip reports
- Assist with the recruitment of potential investigators, preparation of LREC submissions and notifications to regulatory authorities
- In-house review of CRFs and query resolution

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - Low
- Technical - Low

CROS 24.14 **Clinical Research Associate - New Graduate**

Survey Level 10

Experience No specific experience required

Qualifications Relevant degree/nursing qualification

Responsibilities

- Responsible for all aspects of study site management with close supervision - routine monitoring, close down of clinical sites, maintenance of study files, pre-study and initiation visits
- Under supervision prepare accurate and timely trip reports
- Assist with the recruitment of potential investigators, preparation of LREC submissions and notifications to regulatory authorities under close supervision
- In-house review of CRFs and query resolution under supervision

NOTE *Give only one salary here - the actual or notional salary which is your CRA graduate recruitment rate*

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - Low
- Technical - Low

CROS 24.15 **In-House Clinical Research Associate - Established Level**

Survey Level 7

Experience Likely to have had at least 4 years' relevant experience

Qualifications Relevant degree/nursing qualification

Responsibilities

- Responsible for remote monitoring designated clinical trials
- Co-ordinate one or more clinical projects as a project co-ordinator and acts as client contact
- May manage small projects with supervision
- Select and recruit potential investigators
- Full study administration
- Organise investigator meetings
- Participate in writing clinical trial reports
- Conduct investigator grant payments
- May be involved in monitoring trainees/junior staff
- Assist with preparation of LREC submissions and notifications to regulatory authorities

Level Responsibility

- Line Management - Medium - 1-5
- Project - Medium - 2 Countries
- Financial - Low
- Technical - High - Expert

CROS 24.16 **In-House Clinical Research Associate - Development Level**

Survey Level 8

Experience Likely to have had 2-4 years' CRA experience

Qualifications Relevant degree/nursing qualification

Responsibilities

- Carry out remote monitoring of clinical trials
- May co-ordinate designated clinical projects with supervision
- Select and recruit potential investigators
- Full study administration
- May contribute to design of clinical trial protocols
- May mentor a CRA Trainee (New Graduate Level)
- Assist with the recruitment of potential investigators, preparation of LREC submissions and notifications to regulatory authorities

Level Responsibility

- Line Management - Low - 0
- Project - Medium - 2 Countries
- Financial - Low
- Technical - Low

CROS 24.17 **In-House Clinical Research Associate - Entry Level**

Survey Level 9

Experience Up to 2 years' trainee CRA experience

Qualifications Relevant degree/nursing qualification

Responsibilities

- Carry out remote monitoring of clinical trials
- Responsible for all aspects of study site management
- Assist with the recruitment of potential investigators, preparation of LREC submissions and notifications to regulatory authorities
- Review of CRFs and query resolution

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - Low
- Technical - Low

CROS 24.18 **In-House Clinical Research Associate - New Graduate**

Survey Level 10

Experience No specific experience required

Qualifications Relevant degree/nursing qualification

Responsibilities

- Carry out remote monitoring of clinical trials
- Responsible for all aspects of study site management with close supervision
- Assist with the recruitment of potential investigators, preparation of LREC submissions and notifications to regulatory authorities under close supervision
- Review of CRFs and query resolution under supervision

NOTE *Give only one salary here - the actual or notional salary which is your CRA graduate recruitment rate*

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - Low
- Technical - Low

CROS 24.19 **Clinical Trials Administrator - Established Level**

Survey Level 10

Experience Likely to have had a minimum of 4 years' relevant experience

Qualifications Good general education

Responsibilities

- Assist CRAs with all aspects of clinical trials administration with the aim of providing a basic understanding of and training for all aspects or study site management.
- Central co-ordination for all communication/ correspondence regarding clinical aspects of project.
- Tracking of regulatory documents.
- Contribute to preparation of MREC/LREC submissions
- May oversee work of more junior colleagues
- Job holder works without close supervision
- Assist with tracking of clinical budgets
- Provide administration support to projects as needed

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - Low
- Technical - Medium

CROS 24.20 **Clinical Trials Administrator - Development Level**

Survey Level 11

Experience Likely to have had 2-4 years' relevant experience

Qualifications Good general education

Responsibilities

- Assist CRAs with all aspects of clinical trials administration with the aim of providing a basic understanding of and training for all aspects or study site management.
- Central co-ordination for all communication/ correspondence regarding clinical aspects of project.
- Tracking of regulatory documents.
- Assist in preparation of MREC/LREC submissions.
- Job holder works without close supervision.

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - Low
- Technical - Low

CROS 24.21	**Clinical Trials Administrator - Entry Level**
Survey Level	12
Experience	Likely to have had 0-2 years' relevant experience
Qualifications	Good general education

Responsibilities

- Assist CRAs with all aspects of clinical trials administration with the aim of providing a basic understanding of and training for all aspects or study site management
- Central co-ordination for all communication/ correspondence regarding clinical aspects of project
- Tracking of regulatory documents
- Assist in preparation of MREC/LREC submissions
- Job holder is closely supervised in work

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - Low
- Technical - Low

In each job, the survey code for each job is shown followed by the survey job title.

CROS 25.01	**Senior Feasibility Project Manager**
Survey Level	5
Alternative Title/s	Associate Director Feasibility Projects
Experience	Minimum of 8 years' clinical research experience with at least 3 years' experience co-ordinating feasibility studies
Qualifications	Degree (life sciences preferred) or Registered Nurse or equivalent

Responsibilities

- To oversee project management of feasibility projects. To ensure that accurate, high quality feasibility data is delivered to internal and external customers on time and within budget
- Determine feasibility strategy/approach/requirements in collaboration with Medical Affairs, Project Management, Business Development, Regulatory
- Line manage feasibility team
- Liaise as needed for global feasibility studies
- Determine appropriate resource for conduct of feasibility studies and analysis of results
- Provide information as needed on status of feasibility studies
- Review feasibility data and present analysis to senior management to assist with decision-making process concerning trail feasibility
- Recommend strategies and tactics to maximise data collection

Level Responsibility

- Line Management - High - 6+
- Project - High - 3+ Countries
- Financial - Medium
- Technical - High - Expert

CROS 25.02	**Feasibility Project Manager**
Survey Level	6
Experience	Minimum of 5 years' clinical research experience with at least 1 year's experience co-ordinating feasibility studies
Qualifications	Degree (life sciences preferred) or Registered Nurse or equivalent

Responsibilities

- Project manage designated feasibility projects to deliver accurate, high quality feasibility data to internal and external customers on time and within budget
- Determine feasibility strategy/approach/requirements in collaboration with Medical Affairs, Project Management, Business Development, Regulatory
- Line manage designated feasibility team
- Liaise as needed for global feasibility studies
- Determine appropriate resource for conduct of feasibility studies and analysis of results
- Provide information as needed on status of feasibility studies
- Review feasibility data and present analysis to senior management to assist with decision-making process concerning trail feasibility
- Recommend strategies and tactics to maximise data collection

Level Responsibility

- Line Management - Medium - 1-5
- Project - High - 3+ Countries
- Financial - Medium
- Technical - High - Expert

CROS 25.03 **Senior Feasibility Co-ordinator**

Survey Level 7

Experience Likely to have had 4 years' experience in clinical research

Qualifications Degree (life sciences preferred) or Registered Nurse or equivalent

Responsibilities

- Assist with co-ordinating global feasibility studies and delivering accurate, high quality feasibility data to internal and external customers on time and within budget.
- Co-ordination of feasibility studies as assigned by Feasibility Project Manager
- Create feasibility questionnaires, cover letters and protocol synopses for review by Manager, and medical and operational teams.
- Co-ordinate generation of feasibility documents including confidentiality agreements if needed
- Collate information and documents needed in initiation of feasibility studies
- To source investigators
- Forward feasibility documentation and timelines to CRAs
- Collate and format all feasibility information and forward as needed
- Organise feasibility training if required

Level Responsibility

- Line Management - Low - 0
- Project - High - 3+ Countries
- Financial - Low
- Technical - Medium

CROS 25.04 **Feasibility Co-ordinator**

Survey Level 8

Experience Likely to have had 2 years' experience in clinical research

Qualifications Degree (life sciences preferred) or Registered Nurse or equivalent

Responsibilities

- Support the Feasibility Project Manager in co-ordinating global feasibility studies and delivering accurate, high quality feasibility data to internal and external customers on time and within budget.
- Co-ordination of feasibility studies as assigned by Feasibility Project Manager
- Create draft feasibility questionnaires, cover letters and protocol synopses for review by Manager, and medical and operational teams.
- Co-ordinate generation of feasibility documents including confidentiality agreements if needed
- Collate information and documents needed in initiation of feasibility studies
- Assist in sourcing of investigators
- Forward feasibility documentation and timelines to CRAs
- Collate and format all feasibility information and forward as needed
- Organise feasibility training if required

Level Responsibility

- Line Management - Low - 0
- Project - High - 3+ Countries
- Financial - Low
- Technical - Medium

In each job, the survey code for each job is shown followed by the survey job title.

CROS 26.01	**Senior Site Services Manager**
Survey Level	5
Experience	Minimum of 7-10 years' relevant clinical research experience in a pharmaceutical company/CRO, including line management and clinical project management experience
Qualifications	Life science degree or certification in a related allied health profession from an appropriately accredited institution (e.g. nursing certification, medical or laboratory technology) or equivalent working experience

Responsibilities

- To be responsible for the management of site start-up activities
- To be responsible for line management of Site Service personnel: hiring, mentoring, performance management, etc.
- To provide local leadership and direct supervision of staff concerned with site start up activities and project feasibility
- To work with other functions, e.g. Business Development, Operations, to provide feasibility data and other relevant data critical to the ability of the organisation to develop evidence-based plans for the successful implementation and conduct of global clinical trials.
- To ensure that pre-study, drug supply and labelling processes comply with applicable guidelines and regulations and fulfil client and Company requirements.
- Where applicable, provide logistical support for clinical trial supply co-ordination
- To provide input into business development activities as appropriate
- Requires good knowledge of regulatory requirements, GCP, ICH.

Level Responsibility

- Line Management - High - 6+
- Project - High - 3+ Countries
- Financial - Medium
- Technical - High - Expert

CROS 26.02	**Site Services Manager**
Survey Level	6
Experience	Minimum of 5 years' relevant clinical research experience in a pharmaceutical company/CRO, including line management and clinical project management experience
Qualifications	Life science degree or certification in a related allied health profession from an appropriately accredited institution (e.g. nursing certification, medical or laboratory technology) or equivalent working experience

Responsibilities

- To be responsible for the management of site start-up activities
- To be responsible for line management of Site Service personnel: hiring, mentoring, performance management, etc.
- To provide local leadership and direct supervision of staff concerned with site start up activities and project feasibility
- To work with other functions, e.g. Business Development, Operations, to provide feasibility data and other relevant data critical to the ability of the organisation to develop evidence-based plans for the successful implementation and conduct of global clinical trials.
- To ensure that pre-study, drug supply and labelling processes comply with applicable guidelines and regulations and fulfil client and Company requirements.
- Where applicable, provide logistical support for clinical trial supply co-ordination
- To provide input into business development activities as appropriate
- Requires good knowledge of regulatory requirements, GCP, ICH.

Level Responsibility

- Line Management - High - 6+
- Project - High - 3+ Countries
- Financial - Medium
- Technical - High - Expert

CROS 26.03 **Site Services Specialist – Established**

Survey Level 7

Experience 4 years or more work experience in clinical research, including a strong working knowledge of the ICH guidelines and FDA, IRB/IEC regulations

Qualifications Life science degree or certification in a related allied health profession from an appropriate accredited institution (e.g. nursing certification, medical or laboratory technology)

Responsibilities

- To co-ordinate the delivery of the Site Services component of assigned studies across a region or globally which includes overall accountability for delivery to time, cost and quality
- To lead the drafting and finalising of Study Plans related to Site Service activities
- To be responsible for directing day to day work flow of assigned staff in the collection and review of investigator and regulatory documents
- To oversee site start-up activities for studies in which Site Services is working with customers: ensure compliance with timelines/milestones for site activation through planning and review of work with individual team members
- To ensure, through training and quality monitoring, that these documents meet the specifications required by local regulations, EU Clinical Trial Directive, ICH-GCP, FDA regulations (for IND studies) and/or the study sponsor
- May be responsible for line management of Site Service personnel: mentoring, performance management, etc.
- To work with other functions, e.g. Business Development, Operations, to provide feasibility data and other relevant data critical to the ability of the organisation to develop evidence-based plans for the successful implementation and conduct of global clinical trials
- To input into Drug Supplies co-ordination as applicable.

Level Responsibility

- Line Management - Medium - 1-5
- Project - Medium - 2 Countries
- Financial - Medium
- Technical - High - Expert

CROS 26.04	**Site Services Specialist – Development**
Survey Level	8
Experience	3 years' work experience in clinical research, including a strong working knowledge of the ICH guidelines and FDA, IRB/IEC regulations
Qualifications	Life science degree or certification in a related allied health profession from an appropriate accredited institution (e.g. nursing certification, medical or laboratory technology)

Responsibilities

- To be responsible for delivery of the Site Services component of assigned studies within a country or globally which includes accountability for delivery to time, cost and quality for assigned activities
- To be the primary contact with investigative sites during site start-up activities
- To be responsible for working with investigative sites to collect the required investigator and regulatory documents for a study and ensuring that the documents meet the specifications required by local regulations, EU Clinical Trial Directive, ICH-GCP, FDA regulations (for IND studies) and/or the study sponsor
- To be responsible for maintenance of site address and personnel information in the study database as well as maintenance of regulatory documents throughout the duration of the clinical trial.
- To work with other functions, e.g. Business Development, Operations, to provide feasibility data and other relevant data critical to the ability of the organization to develop evidence-based plans for the successful implementation and conduct of global clinical trials
- Where applicable, provide logistical support for clinical trial supply coordination

Level Responsibility

- Line Management - Low - 0
- Project - Medium - 2 Countries
- Financial - Low
- Technical - Medium

CROS 26.05	**Site Services Specialist – Entry**
Survey Level	9
Experience	2 years' work experience in clinical research, including a strong working knowledge of the ICH guidelines and FDA, IRB/IEC regulations
Qualifications	Life science degree or certification in a related allied health profession from an appropriate accredited institution (e.g., nursing certification, medical or laboratory technology)

Responsibilities

- To be responsible for delivery of the Site Services component of assigned studies within a country or globally which includes accountability for delivery to time, cost and quality for assigned activities
- To be the primary contact with investigative sites during site start-up activities
- To be responsible for working with investigative sites to collect the required investigator and regulatory documents for a study and ensuring that the documents meet the specifications required by local regulations, EU Clinical Trial Directive, ICH-GCP, FDA regulations (for IND studies) and/or the study sponsor.
- To be responsible for maintenance of site address and personnel information in the study database as well as maintenance of regulatory documents throughout the duration of the clinical trial.
- To work with other functions, e.g. Business Development, Operations, to provide feasibility data and other relevant data critical to the ability of the organisation to develop evidence-based plans for the successful implementation and conduct of global clinical trials
- Where applicable, provide logistical support for clinical trial supply coordination

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - Low
- Technical - Medium

CROS 26.06	**Site Services Associate**
Survey Level	9
Experience	12 months' relevant experience
Qualifications	Life Science degree or certification in a related allied health profession from an appropriate accredited institution (e.g. nursing certification, medical or laboratory technology) or a lower qualification with longer relevant experience

Responsibilities

- To be the primary contact with investigative sites during site start-up activities with responsibility for collecting required investigator and regulatory documents for a study and ensuring that the documents meet the specifications of applicable regulations
- To be responsible for maintenance of allocated site address information in the study database as well as maintenance of regulatory documents throughout the duration of the clinical trial.
- To work with staff in other functions to provide feasibility data and other relevant data critical to the ability of the organisation to develop evidence-based plans for the successful implementation and conduct of global clinical trials.
- To be responsible for final review and approval of regulatory documentation for sites managed by another Site Services professional (final independent review)
- Where applicable, provide logistical support for clinical trial supply coordination
- Working knowledge of ICH, FDA, IRB/IEC and other applicable regulations/ guidelines; familiarity with investigator start up documents

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - Low
- Technical - Medium

CROS 26.07	**Site Services Assistant**
Survey Level	12
Experience	2-3 years' Secretary/Medical Administrative experience and experience of clinical research activities.
Qualifications	A level education or equivalent

Responsibilities

- To collect the required investigator and local contact information to enter into database
- To be responsible for maintenance of site address and personnel information in the study database of allocated country/countries.
- Where applicable distribute study specific information direct to investigative sites or to local monitors
- To provide data entry support to Site Services; enter feasibility information or investigative site information (study supply shipping information/clinical study locations/ site personnel)
- To liaise with investigative sites to facilitate retrieval of site start-up documentation
- To provide administrative support to Site Services activities
- Basic knowledge of ICH, FDA, IRB/IEC and other applicable regulations/guidelines; familiarity with investigator start up documents

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - Low
- Technical - Low

CROS 26.08	**Senior Contract Specialist**
Survey Level	7
Experience	Likely to have had 5 years' relevant industry experience
Qualifications	Graduate in Life Science, Business or equivalent; MBA or Paralegal certification. Good knowledge of contract management principles

Responsibilities

- To prepare and be able to finalise draft contract documents including Start-up Agreements, Work Orders and Change Orders in a client ready format
- To amend, finalise and present project budgets as required
- May negotiate budget changes with client
- To prepare payment schedules
- To liaise with clients working with assigned Contract Manager or Line Manager
- To provide quality client deliverables to strict deadlines
- To facilitate review and approval of contractual documents and budgets in accordance with relevant policies and procedures
- To participate in contract review meetings with clients and internal customers
- To review client contractual templates and edit as appropriate. To highlight areas of concern
- To ensure contractual documents are processed as needed
- May train and mentor other team members

Level Responsibility

- Line Management - Low - 0
- Project - High - 3+ Countries
- Financial - Medium
- Technical - High

CROS 26.09	**Contract Specialist**
Survey Level	8
Experience	Likely to have had 2-3 years' relevant industry experience
Qualifications	**G**raduate in Life Science, Business or equivalent; MBA or Paralegal certification. Knowledge of contract management principles

Responsibilities

- To prepare draft contract documents including Start-up Agreements, Work Orders and Change Orders in a client ready format
- To amend project budgets as required
- May negotiate budget changes with client
- To assist with preparation of payment schedules
- To liaise with clients working with assigned Contract Manager or Line Manager
- To provide quality client deliverables to strict deadlines
- To facilitate review and approval of contractual documents and budgets in accordance with relevant policies and procedures
- To participate in contract review meetings with clients and internal customers
- To review client contractual templates and edit as appropriate. To highlight areas of concern
- To ensure contractual documents are processed as needed
- May train and mentor other team members

Level Responsibility

- Line Management - Low - 0
- Project - High - 3+ Countries
- Financial - Medium
- Technical - High

Medical Laboratory

In each job, the survey code for each job is shown followed by the survey job title.

CROS 27.01	**Director, Medical Laboratory**
Survey Level	4
Experience	12 years' relevant experience including 3 years managing staff
Qualifications	Degree in a health sciences field. Applicable certifications and licenses as required by country, state, and/or other regulatory bodies

Responsibilities

- To oversee the overall operations of the clinical testing function of the laboratory organisation. To ensure that laboratory operations meet or exceed all applicable regulatory requirements.
- To ensure that the highest standards of quality and customer service are maintained.
- To collaborate with Quality Assurance staff on development and implementation of effective programs. To monitor outside proficiency testing program as required; take corrective action promptly when results are unsatisfactory. To establish effective staff selection and training programs.
- To ensure that laboratory staff are trained on and comply with safety procedures. To establish and implement procedures to ensure that the physical laboratory environment meet safety requirements.
- To participate in the development and implementation of the department's operating budget.
- To keep abreast of new technical developments. To implement new tests, equipment, programs and/or procedures in the department as needed. To lead continuous improvement initiatives to increase quality of services and operational efficiency.
- To manage staff in accordance with organisation's policies and applicable regulations.

Level Responsibility

- Line Management - High - 6+
- Project - High - 3+ Countries
- Financial - Medium
- Technical - High - Expert

CROS 27.02	**Medical Laboratory Manager**
Survey Level	6
Experience	7 years' relevant experience including 1 year leading staff
Qualifications	Bachelor's degree in a health sciences field. Applicable certifications and licenses as required by country, state, and/or other regulatory bodies

Responsibilities

- To manage a team of laboratory staff. Assist with administration of laboratory testing in accordance with applicable regulations governing clinical laboratories.
- To manage and direct the daily activities of assigned laboratory work group(s) through appropriate delegation, technical skills training, and work supervision.
- To assist in establishment and revision of laboratory policies and procedures. To maintain appropriate control and quality assurance procedures. To ensure compliance with safety requirements.
- To keep abreast of new technical developments. To assist with implementation of new tests, equipment, programs and/or procedures in the assigned area(s) as needed. To contribute to continuous improvement initiatives to increase quality of services and operational efficiency.
- To manage staff in accordance with organisation's policies and applicable regulations: responsibilities include planning, assigning, and directing work; appraising performance and guiding professional development; rewarding and disciplining employees; addressing employee relations issues and resolving problems. Approve actions on human resources matters.

Level Responsibility

- Line Management - High - 6+
- Project - Medium - 2 Countries
- Financial - Medium
- Technical - High - Expert

CROS 27.03	**Senior Medical Technologist**
Survey Level	8
Experience	4 years' relevant experience
Qualifications	Degree or educational equivalent in Medical/Histo technology. Applicable certifications and licenses as required by country, state, and/or other regulatory bodies

Responsibilities

- To manage instrumentation and Technologists to ensure that laboratory results are reported accurately and in a timely manner. To maintain supply inventory and communicate operational issues to management. To perform routine testing and troubleshoot problems. To assist Laboratory management with the development of new methods, safety and training.
- To initiate training of new staff within the technical group and monitor work performance
- To maintain quality control of laboratory testing to ensure accurate and timely lab reporting. To document corrective and preventative actions taken using good documentation practices.
- To perform moderate/highly complex analysis of patient specimens.
- To assist management with implementing SOPs for laboratory testing and safety procedures. To implement changes in laboratory notifying all employees of changes.
- To collaborate with Project Manager over client requests and concerns.

Level Responsibility

- Line Management - Medium - 1-5
- Project - Low - 1 Country
- Financial - Medium
- Technical - High - Expert

CROS 27.04 **Medical Technologist**

Survey Level 10

Experience 6 months' relevant experience

Qualifications Degree or educational equivalent in Medical/Histo technology. Applicable certifications and licenses as required by country, state, and/or other regulatory bodies

Responsibilities

- To perform a wide variety of routine and complex clinical testing procedures to obtain data for use in clinical/anatomic trials research
- To perform routine and complex analysis of patient specimens according to standard operating procedures. To evaluate specimen acceptability upon receipt and during the review of analysis results. To evaluate validity of specimen results against the algorithms displayed by the lab computer system. To document all corrective actions taken. To perform secondary review of patient results when required to ensure accuracy of primary result entry.
- To provide oversight and guidance to Medical/Histo Laboratory Technicians and/or Assistants.
- To maintain quality control of all laboratory testing to ensure accurate and timely lab reporting.
- To assist in the development and writing of new Medical/Histo laboratory procedures and techniques.

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - Low
- Technical - Medium

Patient Recruitment

In each job, the survey code for each job is shown followed by the survey job title.

CROS 28.01	**Head of Patient Recruitment**
Survey Level	4
Alternative Title/s	Director of Patient Recruitment
Experience	Likely to have had at least 10 years' experience in Patient Recruitment and Clinical Research
Qualifications	Life Science degree or Registered Nurse or equivalent

Responsibilities

- To manage the Patient Recruitment & Retention function
- To be responsible for project activities and for the delivery of projects on time and within budget
- To oversee and contribute to project proposals
- To establish and implement a Patient Recruitment training programme
- Responsible for ensuring that activities and processes performed by Patient Recruitment staff are conducted according to company and sponsor requirements
- To develop excellent client relationships (both internal and external)
- To provide support for Business Development; to work with business units to identify growth opportunities
- Responsible for line management of Patient Recruitment team/s

Level Responsibility

- Line Management - High - 6+
- Project - High - 3+ Countries
- Financial - Medium
- Technical - High - Expert

CROS 28.02	**Senior Patient Recruitment Manager**
Survey Level	5
Experience	Extensive experience in Patient Recruitment, Clinical Research or Health Communications
Qualifications	Life Science degree

Responsibilities

- To manage and oversee Patient Recruitment and Retention projects whilst supporting the daily running of the business unit
- Act as main client contact whilst coordinating project activities for assigned programmes
- Develop and maintain project plans to ensure deliverables within agreed timelines/scope of work
- Manage internal project team
- Compile study status and financial reports
- Responsible for staff training, inductions, recruitment, etc.
- Support and mentor Patient Recruitment Managers
- Responsible for liaison with third party vendors and for effective oversight of vendor activities
- Support company business development; actively seek out new business opportunities
- Responsible for budget management

Level Responsibility

- Line Management - High - 6+
- Project - Medium - 2 Countries
- Financial - Medium
- Technical - High - Medium

CROS 28.03	**Patient Recruitment Manager**
Survey Level	6
Experience	Extensive experience in Patient Recruitment, Clinical Research or Health Communications
Qualifications	Life Science degree

Responsibilities

- To manage Patient Recruitment and Retention programmes for defined projects
- Provide client liaison at frequency required for specific project from point of contract to project completion
- Compilation of status reports for clients
- Brief, coordinate and update team members
- Manage delegation of roles to ensure day-to-day activities are completed
- Identify requirements for third party vendors and provide detailed brief to chosen supplier
- Obtain quotes prior to commencement of work
- Overseeing activities completed by third parties; liaising with clients as needed
- Contribute to the development of project budgets
- Monitor costs and review service fees
- Assist with staff training and mentoring
- Involved in staff recruitment

Level Responsibility

- Line Management - High - 6+
- Project - Medium - 2 Countries
- Financial - Medium
- Technical - High - Medium

CROS 28.04 **Patient Recruitment Associate - Established Level**

Survey Level 7

Experience Likely to have had at least 4 years' Patient Recruitment experience

Qualifications Life Science degree

Responsibilities

- To manage patient recruitment and retention programmes for defined projects
- Work with Project Management to ensure projects are delivered on time and within budget
- Increasingly responsible for client liaison and managing elements of client update meetings
- Provide recommendations as needed for projects
- Create status reports for clients as needed
- Manage third party vendors
- Interview, brief, update and coordinate contractors/vendors
- Overseeing activities completed by third parties; liaising with clients as needed
- Obtain quotes prior to commencement of work
- Support budgeting process and budget management
- Assist with training and supporting new staff
- Brief, coordinate and update team members
- Manage delegation of roles to ensure day-to-day activities are completed

Level Responsibility

- Line Management - Medium - 1-5
- Project - Medium - 2 Countries
- Financial - Low
- Technical - High – Medium

CROS 28.05 **Patient Recruitment Associate - Development Level**

Survey Level 8

Experience Likely to have had 2-4 years' Patient Recruitment experience

Qualifications Life Science degree

Responsibilities

- To manage daily activities relating to patient recruitment and retention programmes
- To manage patient recruitment and retention programmes for defined projects
- Manage patient recruitment and retention files
- Manage third party vendors
- Obtain quotes prior to work and discuss details
- Assist in overseeing activities completed by third parties
- Assist with training of new staff
- Compile status reports for clients
- Brief and update team members
- May mentor less experienced staff

Level Responsibility

- Line Management - Low - 0
- Project - Medium - 2 Countries
- Financial - Low
- Technical - Medium

CROS 28.06 **Patient Recruitment Associate - Entry Level**

Survey Level 9

Experience Likely to have had up to 2 years' trainee Patient Recruitment experience

Qualifications Life Science degree

Responsibilities

- To deal with activities relating to patient recruitment and retention programmes
- To contribute to management of patient recruitment and retention programmes for defined projects
- Manage patient recruitment and retention files
- Manage third party vendors
- Obtain quotes prior to work and discuss details
- Assist in overseeing activities completed by third parties
- Assist with training of new staff
- Compile status reports for clients
- Brief and update team members as needed

Level Responsibility

- Line Management - Low - 0
- Project - Medium - 2 Countries
- Financial - Low
- Technical - Low

CROS 28.07 **Patient Recruitment Coordinator**

Survey Level 10

Experience Likely to have had a minimum of 4 years' relevant experience

Qualifications Good general education

Responsibilities

- Assist with the daily activities relating to patient recruitment and retention programmes
- Assist the management team
- Provide administrative support as designated, e.g. to the patient and site engagement team, site operations team, the office operations team
- Assist with the vendor process
- Communicate any client requests to the team
- Job holder works without close supervision
- Provide administration support to projects as needed

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - Low
- Technical - Medium

Records Management

In each job, the survey code for each job is shown followed by the survey job title.

CROS 30.01	**Director, Records Management**
Survey Level	4
Experience	Clinical research experience including project management. Likely to have had 5 years' Records Management experience including 3 years managing staff. International experience
Qualifications	Degree in a health sciences field or equivalent nursing qualification.

Responsibilities

- To oversee the overall operations of the records management function globally.
- To lead, motivate and develop the Records Management team.
- To develop and maintain global SOPs, guidelines, policies and tools/systems
- To develop global Records Management strategies and objectives
- To input into strategic initiatives.
- To participate in Business Development activities
- To attend meetings, seminars, conferences relevant to Records Management responsibilities
- To manage a local country/regional team.
- To promote standardisation and efficiency across the company
- To support senior management on local Records Management issues
- To ensure company Record Management standards are in line with industry and best practice

Level Responsibility

- Line Management - High - 6+
- Project - High - 3+ Countries
- Financial - Medium
- Technical - High - Expert

CROS 30.02 **Records Management Manager**

Survey Level 6

Experience 5 years' experience in clinical research and project management with up to 2 years' line management experience

Qualifications Degree in a health sciences field or equivalent nursing qualification.

Responsibilities

- To manage country/regional Records Management department
- To lead, motivate and develop the Records Management team
- To prioritise work and monitor quality of work, timelines, training, etc.
- To develop local Records Management procedures and objectives
- To maintain awareness of appropriate regulations
- To support operational departments on Records Management issues
- To oversee and provide advice to Archivists and Records Management team
- To liaise externally as required
- To develop, manage and monitor the implementation of country/regional Records Management process improvements

Level Responsibility

- Line Management - High - 6+
- Project - Medium - 2 Countries
- Financial - Medium
- Technical - High - Expert

CROS 30.03 **Senior Records Administrator**

Survey Level 11

Experience Several years' experience in records management
Good administrative knowledge, computer literacy

Qualifications Good general education

Responsibilities

- To oversee the work carried out within the country/regional Records Management department
- To ensure smooth running of department and to provide advice on Records Management issues and questions
- To carry out Records Administrator duties following relevant SOPs, guidelines, policies and systems of the company or the client and well as relevant regulatory requirements
- To be aware of project specific and general Records Management issues and report to Line Manager as needed
- To collate, file and track documents received from project team members
- To raise queries as necessary regarding documents and to follow through to resolution
- To liaise as appropriate with members of the project team, and externally as needed
- To ensure documents are filed in timely manner

Level Responsibility

- Line Management - Medium - 1-5
- Project - Low - 1 Country
- Financial - Low
- Technical - Medium

CROS 30.04 **Records Administrator**

Survey Level 12

Experience Previous experience in clinical research, e.g. clinical trials administration. Good administrative knowledge, computer literacy

Qualifications Good general education

Responsibilities

- To receive, collate, file and track documents
- To raise queries as necessary regarding documents including queries regarding document coding and other related matters and to ensure query resolution
- To carry out Records Administrator duties following relevant SOPs, guidelines, policies and systems of the company or the client and well as relevant regulatory requirements
- To ensure documents are filed in timely manner
- To liaise as appropriate with members of the project team, and externally as needed
- To provide advice regarding the filing of documents

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - Low
- Technical - Medium

CROS 30.05 **Records Administrator Assistant**

Survey Level 13

Experience Previous experience in clinical research, e.g. clinical trials administration. Good administrative knowledge, computer literacy

Qualifications Good general education

Responsibilities

- To set up files
- To collate documents received from project team members
- To raise queries as necessary regarding documents including queries regarding document coding and other related matters and to ensure query resolution
- To carry out duties following relevant SOPs, guidelines, policies and systems of the company or the client as well as relevant regulatory requirements
- To ensure documents are filed in timely manner
- To liaise as appropriate with members of the project team
- To assist the Records Administrators to perform their duties

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - Low
- Technical – Low

CROS 30.06 **Senior Archivist**

Survey Level 9

Experience Several years' experience in archiving/records management in clinical research. Good administrative knowledge, computer literacy

Qualifications Good general education

Responsibilities

- To develop and maintain archiving related global SOPs, guidelines, policies and tools and systems working in consultation with senior records management
- To promote communicate and provides advice to Archivists in all company offices
- To carry out duties of an Archivist. To manage and control the deposit, retrieval and access to archived records, and to ensure that sufficient information is provided by the depositor (Responsible Person) to allow adequate identification of the archived records
- To carry out duties following relevant SOPs, guidelines, policies and systems of the company or the client and well as relevant regulatory requirements. To contribute to development of guidelines and procedures
- To maintain awareness of general and project specific archiving issues
- To ensure archive facilities meet company standards. To ensure regular checks of facilities to ensure archive is accessible and secure including off-site facilities
- To represent company archiving in audits

Level Responsibility

- Line Management - Medium - 1-5
- Project - Low - 1 Country
- Financial - Low
- Technical - Medium

CROS 30.07 **Archivist**

Survey Level 10

Experience Experience in archiving/records management related to clinical research. Good administrative knowledge, computer literacy

Qualifications Good general education

Responsibilities

- To manage and control the deposit, retrieval and access to archived records, and to ensure that sufficient information is provided by the depositor (Responsible Person) to allow adequate identification of the archived records
- To carry out duties following relevant SOPs, guidelines, policies and systems of the company or the client and well as relevant regulatory requirements
- To manage the relationship between the company and any off-site storage vendor
- To ensure archive facilities meet company standards. To ensure regular checks of facilities to ensure archive is accessible and secure including off-site facilities
- To represent company archiving in audits

Level Responsibility

- Line Management - Medium - 1-5
- Project - Low - 1 Country
- Financial - Low
- Technical – Medium

Clinical Pharmacology (Phase 1)

In each job, the survey code for each job is shown followed by the survey job title.

CROS 50.01	**Unit Director/Manager**
Survey Level	4
Experience	10 years + management experience/CRO Phase I experience
Qualifications	Degree +

Responsibilities

- Manages the Phase 1 Unit, ensuring it is optimally resourced to undertake Phase 1 and II studies
- Ensures the administrative function in the Unit is well organised, providing a high level of support to the medical and nursing staff
- Works closely with the Unit Medical Head, developing the direction of the Unit, forming strategies and building links with hospitals, local GPs, clients and other CROs
- Responsible for the Unit budget, forecasting and revenue recognition

Level Responsibility

- Line Management - High - 6+
- Project - Low - 1 Country
- Financial - High - Primary Responsibility
- Technical - Medium

CROS 50.02	**Unit Medical Head**
Survey Level	4
Experience	10 years + Phase I experience
Qualifications	Full GMC Regulations, MB BS, ideally have Dip Pharm Medicine

Responsibilities

- Manages the Unit and its resources from both a scientific/technical and Business perspective to ensure that it is profitable and compliant with regulations
- Will also play a key role in the business development process, with emphasis on key, strategic accounts
- Establishes and maintains function of the Unit in line with ICH-GCP directives
- Principal Investigator according to UK laws and regulations
- Represent the Unit during national and international meetings, seminars, workshops and congresses by giving lectures and /or supporting marketing and sales activities
- Runs Steering and Management Committees
- Contributes to the International Management of WW Phase I by participating in the Senior Management Team

Level Responsibility

- Line Management - Medium - 1-5
- Project - Low - 1 Country
- Financial - Medium
- Technical - High - Expert

CROS 50.03 **Scientific Director**

Survey Level 5

Experience 5 years + Phase I experience

Qualifications BSc

Responsibilities

- Ensures the organisation and conduct of studies in both volunteers and patients, in a wide range of therapeutic areas, is carried out in a well co-ordinated manner, according to agreed protocols and ICH and GCP standards
- Responsible for managing the laboratory team
- Member of the senior management team, setting policies and contributing to the development of new strategies and the development of the Unit
- Responsible for computer validation issues within the Unit

Level Responsibility

- Line Management - High - 6+
- Project - Low - 1 Country
- Financial - Medium
- Technical - High - Expert

CROS 50.04 **Clinical Research Manager**

Survey Level 6

Experience Previous line and project management experience in the conduct of clinical trials to ICH GCP

Qualifications Degree/higher degree in biological sciences

Responsibilities

- To be line manager for the Project Management Group, Clinical Research Monitors, CRF Designers and Clinical Secretarial Staff
- To be responsible for developing individual roles and improving systems in association with this
- To assist the Medical Director with Client liaison
- To develop and implement improved systems for more effective project management within the company

Level Responsibility

- Line Management - High - 6+
- Project - Low - 1 Country
- Financial - Medium
- Technical - Medium

CROS 50.05 **Clinical Manager**

Survey Level 6

Experience 5 years + Phase I experience

Qualifications BSc, UKCC registered

Responsibilities

- Ensures the organisation and conduct of studies in both volunteers and patients, in a wide range of therapeutic areas, is carried out in a well co-ordinated manner, according to agreed protocols and ICH and GCP standards
- Manages the nursing team
- Manages the catering and housekeeping function
- Member of management team, setting policies and contributing to the development of new strategies

Level Responsibility

- Line Management - High - 6+
- Project - Low - 1 Country
- Financial - Medium
- Technical - Medium

CROS 50.06 **Senior Contracts Associate**

Survey Level 8

Experience Minimum three years Costing & Scheduling

Qualifications Degree, HND or Professional Qualification

Responsibilities

- The Senior Contracts Associate is responsible for analysing protocols to generate price and timeframe estimates for Business Development to use in negotiations with Clients and to manipulate schedules daily or as necessary to meet or exceed the revenue targets
- Identify and contact suppliers and sub-contractors and negotiate quotations for services and goods
- Complete basis for volunteer payments on every new proposal and estimate volunteer travel allowance
- Calculate changes in costs as required
- Prepare clinical revenue and bed utilisation reports and forecasts

Level Responsibility

- Line Management - Medium - 1-5
- Project - Low - 1 Country
- Financial - High - Primary Responsibility
- Technical - High - Expert

CROS 50.07 **Resource Supervisor**

Survey Level 9

Experience Minimum one year as Clinical Research Resource Co-ordinator

Qualifications Degree in Life Science or Nursing qualification

Responsibilities

- Responsible for inputting the “Breakdown of Clinical Operations Hours” onto spreadsheets and submitting monthly reports
- Responsible for completion of all documentation required to produce the Clinical Operations duty rota and flow charts
- Completion of the physicians rota
- Responsible for the completion of the laboratory, urine duty, training meetings and general rotas on a weekly basis and other rotas as required
- Assist with the completion of the bed allocation in accordance with specific study and project team requirements

Level Responsibility

- Line Management - Medium - 1-5
- Project - Low - 1 Country
- Financial - Medium
- Technical - High - Expert

CROS 50.08 **Senior Clinical Research Physician**

Survey Level 5

Experience At least 3 years’ experience of designing and conducting clinical pharmacology studies

Qualifications Registered medical practitioner; intercalated or full science degree

Responsibilities

- To assist with planning of new studies and allocation of new studies to therapeutic area teams
- To assist with allocation of Clinical Unit staff to studies on a weekly basis
- To assist with training sessions in the Clinical Unit requiring physician input
- To be the line manager for selected Clinical Research Physicians
- To recruit and train locum physicians in the conduct of screening and post-study medicals
- Other duties as for Clinical Research Physician

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - Low
- Technical - High - Expert

CROS 50.09 **Physician**

Survey Level 6

Experience Ideally 12 months' Research/Phase I experience

Qualifications MD, Full GMC Registration

Responsibilities

- Responsible for the day-to-day medical cover and supervision of volunteer studies
- Performs pre-study medical, monitors pre-study, interim and post-study lab test results and other clinical data
- Liaises with project team regarding design and safety of protocols
- Monitors, assesses, records adverse events
- Provides on-call medical cover
- May act as principal investigator for studies

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - Low
- Technical - High - Expert

CROS 50.10 **Project Manager – Clinical Pharmacology**

Survey Level 7

Experience 5 years' CRO/Pharma experience – at least 12 months' PM experience

Qualifications BSc degree

Responsibilities

- Responsible for the project management of assigned studies
- Advises on study conduct, design and timelines
- Represents Company at client and supplier meetings
- Responsible for client liaison, ensuring effective information flow to all interested parties
- Financial tracking of project
- Produces study documents including protocol, informed consent documents, CRFs and report
- Responsible for the quality and integrity of all documents and data generated in the course of a study
- Approves all study documentation
- Supervises and mentors Clinical Research Monitors, trains junior staff

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - Medium
- Technical - High - Expert

CROS 50.11 **Senior Clinical Research Scientist/Manager Technicians**

Survey Level 7

Experience 5+ years' Phase I experience

Qualifications BSc

Responsibilities

- Contributes to the planning and execution of clinical studies
- Supervises the Clinical Pharmacology Unit surrogate laboratory facilities with respect to the day-to-day running, equipment maintenance, and staff
- Provides technical support for the equipment used in the Unit

Level Responsibility

- Line Management - Medium - 1-5
- Project - Low - 1 Country
- Financial - Low
- Technical - High - Expert

CROS 50.12 **Pharmacy Supervisor**

Survey Level 10

Experience 5 years' post–qualification in hospital or industrial pharmacy

Qualifications Qualified Pharmacy Technician BTEC or equivalent in pharmaceutical sciences

Responsibilities

- Preparation, maintenance and control of complete records with respect to test articles
- Receipt, inventory, and acknowledgement of test articles
- Correct storage and handling of all materials used on site
- Accurate and timely completion of file notes to document deviations from the study protocol
- Provision of a Pharmaceutical service to the Unit
- Provision of a suitable supply of medication for use in emergency situations
- Preparation of dispensing instructions and labels
- Dose preparation functions as appropriate for all trials
- Ensure relevant licences are held for the storage and use of controlled drugs

Level Responsibility

- Line Management - Medium - 1-5
- Project - Low - 1 Country
- Financial - Low
- Technical - High - Expert

CROS 50.13 **Pharmacist**

Survey Level 9

Experience 12 months' post qualification experience

Qualifications Qualified Pharmacist

Responsibilities

- Responsible for all drugs kept and used in the Unit, including storage, record-keeping, drug preparation, dispensing, disposal and ordering
- Writes Working Practices and SOPs for all aspects of Pharmacy practice
- Ensures all pharmacy equipment is kept in good order and validated where necessary

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - Low
- Technical - High - Expert

CROS 50.14 **Clinical Training Officer – Qualified**

Survey Level 8

Experience 2 years' relevant experience

Qualifications Match this job where the job holder is a qualified Nurse providing training to clinical staff (in GCP) and training on wards.

Responsibilities

- Orientation and training of all new Clinical Operations Nursing and Technical employees
- Training on Unit procedures and processes, GCP and Standards
- Maintains training records

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - Low
- Technical - High - Expert

CROS 50.15 **Clinical Training Officer – Non-Qualified**

Survey Level 9

Experience 12 months' relevant experience

Qualifications Graduate level education

Responsibilities

- Orientation and training of all new Clinical Operations Nursing and Technical employees
- Training on Unit procedures and processes, GCP and Standards
- Maintains training records

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - Low
- Technical - Medium

CROS 50.16 **Volunteer Co-ordinator and/or Screening Co-ordinator**

Survey Level 10

Experience 2+ years' Phase I experience

Qualifications UKCC Registered

Responsibilities

- Accountable for all aspects of volunteer recruitment and screening
- Management of the volunteer panel
- Manages the screening and recruitment team

Level Responsibility

- Line Management - Medium - 1-5
- Project - Low - 1 Country
- Financial - Low
- Technical - High - Expert

CROS 50.17 **Nurse Manager**

Survey Level 6

Experience Minimum of 5 years' post-registration experience. Supervisory experience. Appraisal training

Qualifications RGN – Part 1/12 of NMC Register

Responsibilities

- To manage and lead the nursing group, maintaining the Clinical Unit to the highest standard, facilitating change and working collaboratively with all members of the multidisciplinary team
- To be responsible for ensuring that all the activities of the Clinical Unit are conducted to the highest standards set by company policy and external requirements
- To be a specialist in the Clinical Unit, demonstrating advanced knowledge and skill in relation to a range of clinical, research-based, educational and managerial responsibilities
- To be ultimately responsible for the nursing element of clinical studies
- To develop strategies for the successful recruitment and retention of nurses, as well as direct their selection and training

Level Responsibility

- Line Management - High - 6+
- Project - Low - 1 Country
- Financial - Low
- Technical - High - Expert

CROS 50.18 **Clinical Research Nurse (Recruitment and Screening)**

Survey Level 8

Experience 12 months' post qualification experience/ ideally 12 months' Phase I experience

Qualifications UKCC registered

Responsibilities

- Recruits and carries out health screening on subjects prior to studies
- Assists in the conduct of individual Phase 1 studies across all therapeutic areas

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - Low
- Technical - High - Expert

CROS 50.19 **Senior Clinical Research Nurse**

Survey Level 7

Experience 4+ years' Phase I Experience

Qualifications UKCC registered

Responsibilities

- Plans and implements the conduct and administration of multiple studies in a wide range of therapeutic areas
- Organises and carries out studies in specialist areas
- Manages more junior staff
- Ensures optimal scheduling of study work and routine workload

Level Responsibility

- Line Management - Medium - 1-5
- Project - Low - 1 Country
- Financial - Low
- Technical - High - Expert

CROS 50.20 **Clinical Research Nurse**

Survey Level 8

Experience Minimum experience - 12 months' post qualification

Qualifications UKCC registered

Responsibilities

- Assists in the conduct of clinical trials in accordance with agreed protocols
- Prepares equipment and study areas
- Assists in the administration of drugs

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - Low
- Technical - Medium

CROS 50.21 **Senior Clinical Research Monitor**

Survey Level 8

Experience At least 3 years' experience in Clinical Research

Qualifications Degree in Life Sciences or equivalent

Responsibilities

- To be line manager and mentor to Assistant/Clinical Research Monitor(s) assessing workload and individual training and development needs
- To work with management to test and develop systems to improve the quality of data collection and the development of applicable SOPs
- To ensure regular reports on Data Quality collection are generated and provided to management at agreed intervals
- To act as an internal Monitor generating and adhering to study specific monitoring schedules and ensuring compliance with SOPs, ICH GCP and sponsor requirements
- To host sponsor CRF monitoring visits

Level Responsibility

- Line Management - Medium - 1-5
- Project - Low - 1 Country
- Financial - Low
- Technical - High - Expert

CROS 50.22 **Clinical Research Monitor**

Survey Level 9

Experience

Qualifications BSc Degree

Responsibilities

- Assists with project management of assigned studies
- Advises on study conduct and design
- Represents Company at client meetings
- Assists with writing informed consent documents
- Monitors quality and integrity of documents and study data
- Assists with production and collation of all documentation for IEC submission
- Monitors project milestones

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - Low
- Technical - High - Expert

CROS 50.23 **Clinical Technical Officer**

Survey Level 9

Experience

Qualifications Degree qualified

Responsibilities

- Ensures technical equipment is maintained. calibrated and available for trials as required
- Liaises with equipment suppliers and ensures maintenance contracts are adhered to

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - Low
- Technical - Medium

CROS 50.24 **Volunteer Telephone Recruiter**

Survey Level 12

Experience

Qualifications

Responsibilities

- Conducts telephone screening of volunteers
- Provides relevant information about the study to prospective volunteers
- Ensures study panel requirements are met
- Ensures volunteer database is maintained

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - Low
- Technical - Medium

CROS 50.25 **Unit Receptionist/Administrator**

Survey Level 13

Experience 12 months' administration experience

Qualifications

Responsibilities

- Ensures reception area is manned at all times and that all visitors and calls are dealt with promptly and in an efficient and friendly manner
- Assists with the administrative requirements of the volunteer and screening departments
- Provides a comprehensive and efficient secretarial service to staff

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - Low
- Technical - Low

CROS 50.26 **Volunteer Recreation Officer**

Survey Level 12

Experience

Qualifications

Responsibilities

- Ensures the highest standard of Patient/Volunteer social welfare is maintained whilst they are resident in the Unit
- Ensures an interesting and varied programme of activities is readily available, providing an enjoyable and interesting residential stay in the Clinic

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - Low
- Technical - Low

CROS 50.27 **Lab Manager - Clinical Pathology**

Survey Level 7

Experience At least 4 years' experience in a senior medical technical role

Qualifications FIMLS

Responsibilities

- To supervise all staff and ensure that departmental standards are maintained
- To allocate and co-ordinate the routine work of all sections
- To be responsible for the production and quality of scientific data
- To implement and monitor quality assurance programmes for both internal and external schemes and advise staff accordingly
- Responsible for discipline, organisation, training and development of staff
- Assists in recruitment and induction

Level Responsibility

- Line Management - High - 6+
- Project - Low - 1 Country
- Financial - Low
- Technical - High - Expert

CROS 50.28 **Senior Clinical Research Technician**

Survey Level 11

Experience 3-5 years' relevant experience

Qualifications 'A' Level science/HNC

Responsibilities

- To co-ordinate and prioritise activities within the Clinical Preparation Area to ensure that all studies are prepared for in an accurate and timely manner and that samples are handled in accordance with protocol requirements
- To assist with recruitment of Clinical Unit Technicians
- To be Line Manager to the permanent Clinical Research Technicians
- To be responsible for the training of Clinical Unit Technicians (Locum and permanent) in sample handling and shipping procedures including documentation
- To monitor and review working procedures within the Clinical Preparation Area daily and complete the relevant monitoring and compliance reports
- To be responsible for the maintenance of safety, hygiene and general tidiness within the Clinical Preparation Area
- To be responsible for the equipment in the Clinical Preparation Area

Level Responsibility

- Line Management - High - 6+
- Project - Low - 1 Country
- Financial - Low
- Technical - Medium

CROS 50.29 **Clinical Support Assistant/Technician (Development/Established)**

Survey Level 13

Experience 1 year +

Qualifications Secondary Education

Responsibilities

- Supports Clinical Operations group by doing general clinical duties:- collection of urine and faecal samples, taking blood, etc.
- Provides care and support to patient/volunteers

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - Low
- Technical - Medium

CROS 50.30 **Clinical Support Assistant/Technician (Entry Level)**

Survey Level 14

Experience Training programme (0-12 months' experience)

Qualifications Secondary Education

Responsibilities

- Supports Clinical Operations group by doing general clinical duties:- collection of urine and faecal samples, taking blood, etc.
- Provides care and support to patient/volunteers

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - Low
- Technical - Low

CROS 50.31 **Business Development Manager**

Survey Level 6

Experience Experience in Phase I service provision including managerial experience. Research background with concentration in pharmaceutical/biotech area helpful. Requires experience of client interaction and ability to assess client's needs. Excellent communication skills would be required and knowledge of specific personnel in client companies would be an advantage

Qualifications Bachelors degree in science or business

Responsibilities

- To secure and retain business for the company through professional, consultative, proactive sales activities directed at decision-makers and decision influencers at existing and new clinical sponsors
- To position the company as a primary or preferred provider for all clinical development work to be outsourced
- To liaise between sponsor and company on all business development activities and requirements

Level Responsibility

- Line Management - Low - 0
- Project - Low - 1 Country
- Financial - High - Primary Responsibility
- Technical - High - Expert

CROS 50.32 **Quality Manager**

Survey Level 7

Experience

Qualifications Thorough knowledge of Quality Management as well as experience in a quality related area (i.e. Quality Assurance, Quality Control, Compliance), preferably within the CRO industry.
Thorough knowledge of applicable international and local guidelines (e.g. ISO 9001, GCP, GLP, GMP). Ability to lead and motivate functional groups to achieve objectives (i.e. groups with members from diverse backgrounds created to complete short term projects)

Responsibilities

- To act as the primary interface between the Phase 1 Unit and all internal/external QA auditors as well as regulatory inspectors
- To manage the follow-up of all QA audits and regulatory inspections to ensure that findings are addressed
- To conduct regular quality assessments of deliverables as well as systems
- To analyse and improve systems
- Keep abreast of changes in regulatory climate and focus. Inform staff of such changes
- Co-ordinate training and maintain the Training Management System

Level Responsibility

- Line Management - High - 6+
- Project - Low - 1 Country
- Financial - Medium
- Technical - High - Expert

CROS 50.33	**Quality Officer**
Survey Level	10
Experience	At least 1 year's experience in Clinical Trial activities. Knowledge in the field of GxP Guidelines International Conference on Harmonisation, Good Clinical Practice (ICH GCP), Good Manufacturing Practice (GMP), legal requirements for clinical studies, SOPs, Quality Control, Quality Assurance and Quality Management
Qualifications	Educated to at least A level standard

Responsibilities

- To verify quality in the conduct of clinical trials to the satisfaction of clients throughout effective management and performance of internal quality control processes at the Phase 1 Unit
- To manage and conduct quality control systems to confirm that the clinical trials are performed in accordance with all Good Practices and internal requirements
- To perform regular quality assessments of deliverables as well as systems
- To participate in evaluation and improvement of these systems
- Review all relevant study documents
- To verify adherence of the study team and other personnel to the study protocol, SOPs, and other internal or sponsor standards

Level Responsibility

- Line Management – Low - 0
- Project - Low - 1 Country
- Financial - Low
- Technical - Medium