

**Assignment Brief**

**for the position of**

**Director Clinical Operations**

**- Germany -**

**Ref: PSL4009**

### Prepared by:

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**The Organisation**

PRA International is one of the world’s leading Global Clinical Research Organisations.

With an established presence, spanning more that 30 years, they have enjoyed continual growth and success, currently employing 3,200 staff globally.

PRA have managed to continually build and enhance their reputation through delivering a service that is reliable, with a high level of therapeutic expertise and global access to knowledge. This is enhanced by having a wealth of CRO, clinical and product development expertise within their senior management, all of whom work closely alongside their customers.

**PRA International - History**

* Established in the late 1970’s with name changed to **Pharmaceutical Research Associates Inc**., in 1981 with focus on data management in Virginia, USA.
* In 1991, **PRA** expanded its service offering to include clinical trial management and opened their first European location.
* 1996 saw the company name change to **PRA International** as the company moved towards becoming a global CRO with 333 employees.
* In 1997, **PRA** acquired International Medical and Technical Consultants (IMTCI), a CRO based in Lenexa, Kansas. This increased **PRA International’s** clinical trials leadership, expertise and experience within the key therapeutic areas of allergy and respiratory. Additionally they gained a Phase I facility.
* In 1999, **PRA** acquired Valorum (UK) Ltd, based in Reading, UK. This acquisition enhanced their regulatory expertise and expanded **PRA’s** trial management footprint in Europe.
* In 2000, **PRA** acquired ARCAM, an international CRO based in Paris, France. This further enhanced PRAs capability in Europe, across a number of therapeutic areas within clinical trial management, project management and quality assurance. This enhanced PRAs European footprint to in excess of 250 employees.
* In 2002, **PRA** acquired Staticon International Espana, an established CRO in Madrid, Spain, further developed their service offering in Europe and in particular bringing enhanced capability in electronic data capture and management.
* In 2002, **PRA** acquired CroMedica, a CRO headquartered in Canada with key expertise in the CNS therapeutic area and global operations. Several of their offices now represent **PRA** in Victoria, British Columbia; San Diego, California; Sao Paulo, Brazil; Johannesburg and Cape Town, South Africa; and Sydney, Australia.
* In November 2004, **PRA** became a publicly traded company on the NASDAQ exchange.
* In June 2006, **PRA** acquired Pharma Bio-Research, an early phase clinical development and bioanalytical laboratory company based in The Netherlands, forming the basis for the group within **PRA** now known as **Early Development Services**.
* In October 2007, **PRA** acquired Pharmacon, a clinical research organisation based in Berlin, Germany. Specialising in Phase I studies with patients in several Central European countries, this was an important step in **PRA’s Early Development Services** plan to further strengthen its position as an industry leader.
* **PRA** returned to being a privately held company when it was reacquired by Genstar Capital, LLC in December 2007. Genstar had been **PRA’s** largest investor before the initial public offering in 2004.

**PRA International’s mission: ‘Our people commit to provide innovative solutions that our clients rely upon to introduce new drugs and to improve lives’**

**PRA International – Core Values**

* Unquestionable ethics and integrity
* Consistent and measurable quality in all they do
* Outstanding service and flexibility to meet customer requirements
* Commitment to staff development and collaboration
* Demonstrated technical and therapeutic excellence throughout the company

**PRA International – Key Services**

**Trials Management Services**

* Protocol and Case Report Form design
* Feasibility study
* Project Management
* Investigator site selection and qualification
* Investigator handbook and meetings
* Investigator site management
* Investigator site monitoring
* Medical monitoring and drug safety
* Data management
* Analysis and reporting
* Medical and scientific publications
* Regulatory filings

**Early Development Services**

* First in man studies
* Single and multiple dose safety and tolerability studies
* Food effect
* Proof of concept studies
* Interaction studies with drugs and food
* Mass balance / ADME studies
* Micro dosing studies
* Single and multiple dose bioavailability studies
* QTc – prolongation and intensive ECG studies
* PK studies in renally impaired patients
* PK studies in hepatically impaired patients
* Special population studies
* Special formulations
* Vaccine studies
* Studies with biotechnology-derived therapeutic products

**Late Phase Services**

* Safety surveillance
* Post-authorisation safety studies (PASS)
* Restricted access programs
* Retrospective studies

**Drug Safety Management**

* Reporting of serious adverse events
* Processing and reporting of adverse drug reactions (ADRs)
* Periodic safety update reports
* Safety and Pharmaco-Epidemiological Studies
* Global database pooling and integrated summaries of safety
* Consulting and system analysis

**Electronic Regulatory Submissions**

* Protocol and Case Report Form design
* Feasibility study
* Project Management
* Investigator site selection and qualification

For further information, please go to www.prainternational.com

**Primary Purpose of the Role**

Responsible for clinical operations activities and staff within the unit(s). Mentors and leads the clinical operations management team, maintains appropriate resources to achieve maximum staff billability and adheres to quality management practices. Provides leadership in the implementation of PRA’s quality initiatives and business processes, achievement of management goals within the framework of the company mission, policy and philosophy. Provides strategic direction to the Clinical Operations department.

**Accountabilities (Responsibilities)**

* Sets overall direction, strategy and performance standards for multiple job disciplines to ensure that project profitability targets are achieved
* Schedules and reviews project tasks to ensure high quality product is delivered on time and within budget
* Ensures services provided to clients are compliant with PRA’s policies, procedures, SOPs, ICH-GCPs, client contractual expectations and country specific regulatory requirements
* Manages operation budget for the unit (s)
* Mentors and develops employees to expand employee performance levels and ensure retention of high performing PRA employees
* Ensures appropriate employee resources are available to meet corporate/ client/ project objectives while achieving optimal billability of clinical operations staff
* Accurately projects resource needs to ensure timely hiring of clinical operations staff
* Adjust resource allocation for project work as appropriate to ensure corporate billability targets are maintained while assuring client/project objectives are achieved
* Establishes processes and participates in PRA’s Quality Process Management continuous improvements by assuring that project quality metrics align with company, client and clinical operations objectives
* Provides input to central proposals for project bids to ensure all projects can and will be managed within contractually agreed upon schedules and budgets
* Provides guidance/ insight on aspects of clinical operations, as well as contingency planning, to accommodate project or therapeutic specific nuances while identifying potential impacts of the same to budget
* Participates in client presentations and/ or bid defence meetings, as required
* May function as legal representative for PRA in selected countries as appropriate
* Broader focus on moderate to complex projects. Less supervision by VP or Exec Director
* Strategic focus for all projects independent of degree of complexity. Works under general guidance by VP, but minimum oversight required

**Qualifications**

* Undergraduate degree, or its international equivalent, in clinical science or health-related field from an accredited institution, or equivalent work experience required
* Advanced degree, or its international equivalent, preferred
* Extensive experience using computerised information systems required, experience with PC-Windows, word processing, and electronic spreadsheets required
* Substantial clinical trials development experience is required
* International clinical development experience preferred
* Substantial experience supervising or managing professional staff in a clinical research environment required
* Thorough knowledge of ICH and local regulatory authority regulations regarding drug research and development is required
* Read, write and speak fluent English, fluent in host country language

**Package - dependent upon location**

* Competitive basic salary
* Bonus
* Company Car or Car Allowance
* 5% non-contributory pension
* Private healthcare
* Life Assurance (4 X base salary)
* 25 days holiday

If you are interested in this role, please visit our website [www.pharma-search.co.uk](http://astralisgroup.com/?p=1334) or send your CV to grant@pharma-search.co.uk