Assignment Brief

for the position of

Director of Project Delivery, Europe

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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

Context of the role

Approximately two years ago, the decision was taken to create a new role within the global operations function focused on the development and management of PRA's key customers and oversight of international trials and programmes. The thinking behind this strategy was to provide a dedicated resource to strategic clients at a global level thereby ensuring PRA could develop a deep knowledge of the client, their portfolio, pipeline, culture and vision. Additionally, the client could benefit from a single point of contact for their operational and commercial needs. In executing this strategy, PRA set out to build a team of Project Delivery professionals who would work alongside operational and commercial groups to coordinate activities relating to specific accounts.

Over the last 18 months, PRA have targeted experienced global study management and clinical operations professionals, both internally and externally, who have sought to leverage their clinical research knowledge and experience in a client facing role. Today, the Project Delivery team is 13 strong and is led by six General Partners worldwide. Their remit is to provide client management, leadership and project mentorship with the goal of providing outstanding customer delivery and developing a strong, long-term relationship with the customer.

In the last few months, PRA have been awarded preferred provider status with a global pharmaceutical company and the need has arisen to recruit an additional **Director, Project Delivery** to the team. Reporting to the UK based General Partner, the role can be based at one of PRA's European offices or may be home based for the right candidate. PRA are seeking a professional with a life sciences degree who brings extensive experience in global phase I-IV clinical trial management and strong commercial skills. You will already be liaising with clinical research and procurement professionals at a senior level within the pharmaceutical industry and comfortable with managing a portfolio of multi-centre international studies.

This is a unique opportunity to join a dynamic and growing business unit within one of the leading global CROs in a role which offers tremendous scope for career development and enhancement.

Job Description

Primary Purpose of the Role

Accountable for maintaining relationships (i.e. maintaining repeat business) with assigned Customer(s)/projects through excellence of project delivery of awarded projects whilst maintaining bid profitability.

Accountabilities

- Frequent and routine (e.g. weekly) face-to-face and remote liaison with Customer contacts to review and discuss status (e.g. project successes, issues, opportunities) of awarded projects.
- Networking within Customer to extend contacts and develop business opportunities for PRA.
- Leads Project Status Reviews (PSRs) for assigned projects including risk assessment.
- Ensures maintenance of bid profitability through thorough review of projections of revenue, estimates of cost to complete and timely execution of contract modifications for awarded projects. Create action plans to minimize inefficiencies when recovery from the customer is not possible.
- First point of escalation (internal and external) for resolution of issues and conflicts (e.g. escalation from PSRs).
- Member of Executive Oversight/Operations Committees for assigned Customers as requested.
- Ownership of strategy development for proposals.
- First reviewer/approver for proposals.
- Owner of content of materials to be used at bid defense meetings. Logistics of bid defense meeting (slide preparation, attendance requests and preparation meeting) will be responsibility of the Sales personnel provided by Business Development.
- Mentor Project Managers (all levels) leading assigned projects and provides feedback on performance to line-managers of Project Managers (Director of Project Managers).

Education

- An undergraduate degree in health sciences from an accredited institution or international equivalent degree. An advanced degree (M.S., Ph.D., Pharm.D., M.D.) preferred
- Business related coursework (management, marketing, accounting, budgets, personnel management, negotiation skills, etc.) preferred
- Masters of Business Administration from an accredited institution or related coursework and/or employment experience is preferred
- Demonstrated experience with clinical project development process, financial management tools, regulatory compliance (International Conference on Harmonization (ICH)-Good Clinical Practices (GCP)), data management, project scheduling and resource management, coordinating and scheduling team activities.
- Read, write, and speak fluent English, fluency in the language of the host country required

Package - Dependent upon location

- Competitive basic salary
- Bonus – to 15% of base salary
- Company Car or Car Allowance - £7,200
- 5% non-contributory pension
- Private healthcare
- Life Assurance (4 X base salary)
- 25 days holiday