

RSVP Management Consultants AG, one of the leading HR and management consultancies in the life science market, combines three business divisions under the brand name RSVP GROUP: Executive Search, Leadership Services and Management Consulting. Our services are illustrated in an efficient and transparent fashion - in compliance with the overall concept of the company "Visions for Change". RSVP GROUP maintains offices in Frankfurt, London, New York, Princeton, Wiesbaden and Zurich and has been active for over 40 years in servicing prominent companies in the life science industry. This accounts for our excellent placement rate which well exceeds the average market rate.

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Our client, a global biotherapeutic and biotechnology company that discovers, develops and produces critical care treatments (plasma-derived therapeutic proteins) for people with life-threatening disorders in a variety of therapeutic areas including immunology, pulmonology, and hemostasis,

is looking for a

Project Coordinator Clinical Research/ CRA

at their European Headquarter in the Rhine-Main Area, Germany

Position Purpose:

- The Clinical Research Associate (CRA) will be responsible for the operational aspects of scientific projects running throughout Europe. These include Investigator Initiated Trials (IITs), post marketing surveillance studies (AWBs), national and international registry projects as well as scientific awards
- As such the CRA is interfacing with internal and external partners on organization of meetings, setting up of contracts and tracking of project progress

Major Tasks:

Projects/ IITs/ AWBs/ awards

- Provide assistance in specific tasks relating to the preparation of the project/study (e.g. preparation of protocols; Informed consent form, case report forms, internal documents)
- Assist with ethics committee submissions where required
- Manage contracts on scientific contracts including communication with external/institutional legal departments
- Ensure collection of required essential documents for study start-up and throughout conduct of project/study
- Liaise with doctors/consultants (or investigators) in Germany and EU on conducting the project/study or other site staff members during the course of projects, to ensure all is proceeding to agreed protocols and time schedules
- Responsible for project related tasks as appropriate



- Prepare final reports and assist with abstracts/manuscripts for publication occasionally
- Management of communication and operational details including contracts and meetings of scientific awards (eSPIN and eALTA) together with responsible medical advisors
- Communicates with global IIT approval committee all such incoming scientific funding requests and directs follow up activities regarding approved protocols

External partners

- Locate and assess the suitability of external partners (e.g. biometry, medical writing) for approval
- Work with external service providers (e.g. data management, biometry, medical writing) to ensure a seamless data analysis and publication
- Responsible for contract management with investigators/consultants/speakers and other external partners

Internal project management

- Prepare all operational project details (e.g. budgets, supplies, etc.) for approval
- Monthly tracking of project costs in close cooperation with the Medical Leader and Controlling
- Assist with the development of local SOPs for approval by line management
- Track study/project progress and provide a report of status of each of the projects for which he/she is responsible
- Maintain effective communication with other members of the clinical team and management.
- Maintain awareness of local regulatory requirements, and to conduct studies in accordance with local SOPs, guidelines and ICH Good Clinical Practice guidelines.
- Interface with regulatory department on regulatory authority applications and approvals of studies/projects
- Interface with Sales forces on AWBs (communication of project status, exchange on key customers)

Work Interactions:

- Internal close cooperation with the Medical Team Europe, Sales and Marketing
- Directly reporting into the Medical Leader Immunology
- Interactions with Controlling for Budget Tracking

Major Opportunities:

- Due to the small size of the company and the multitude of usually smaller projects the incumbent will encounter a variety of projects and follow them through. The position offers the opportunity for a diverse set of tasks across projects/studies with EU key opinion leaders and challenges. To achieve good working results in a dynamic and challenging business environment very good project management skills are required



Capabilities:

- Degree in a life science (e.g. Biology, Pharmacy)
- With a minimum of two years of experience as CRA in a similar position in the pharmaceutical industry or CRO
- Strong communication skills (German & English)
- Project management and organizational skills with attention to detail
- Must have the ability to understand, interpret and communicate scientific information and data
- Computer skills (MS office, data analysis tools)
- Knowledge of GCP guidelines, medical terminology and clinical trial processes

For further information please contact:

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