

Senior Site Management Coordinator/ Regulatory and Start-Up Specialist at IQVIA

Join us on our exciting journey!

IQVIA™ is The Human Data Science Company™, focused on using data and science to help healthcare clients find better solutions for their patients. Formed through the merger of IMS Health and Quintiles, IQVIA offers a broad range of solutions that harness advances in healthcare information, technology, analytics and human ingenuity to drive healthcare forward.

Within this position, you will perform tasks at country level associated with Regulatory, Start-up (RSU) and Maintenance activities in accordance with applicable local and/or international regulations, standard operating procedures (SOPs), project requirements and contractual/budgetary guidelines. Furthermore, you may participate in feasibility and/or site identification activities.

Your typical responsibilities might include:

- Under general supervision, serve as Single Point of Contact (SPOC) in assigned studies for investigative sites, Start Up Team Lead, Clinical Operations, Feasibility, Site Identification, Project Leadership. Ensure adherence to standard operating procedures (SOPs), work instructions (WIs), quality of designated deliverables and to project timelines.
- Perform Regulatory, Start-up and Maintenance activities according to applicable regulations, SOPs and work instructions. Distribute completed documents to sites and internal project team members.
- Prepare and review site regulatory documents, negotiate site contracts and budgets with sites.
- Ensure accurate completion and maintenance of internal systems, databases and tracking tools with project specific information.
- Review, establish and agree on project planning and project timelines and provide feedback to management on site performance metrics. Ensure monitoring measures are in place and implement contingency plan as needed.
- Inform team members of completion of regulatory and contractual documents for individual sites.

- Review, track and follow up the progress, the approval and execution of documents, including contracts, regulatory, ethics, Informed Consent Form and Investigation Product Release documents, in line with project timelines.
- Perform quality control of documents provided by sites.

You should have:

- A Master's or higher-level degree, preferred in health care or other scientific discipline; or equivalent combination of education, training and experience
- General awareness clinical trial environment and drug development process
- Computer skills including proficiency in use of Microsoft Word, Excel and PowerPoint
- Fluent written and verbal communication skills in Dutch and French including good command of English language
- Good organizational and problem-solving skills and effective time management skills

If you want to make an impact in the global research market, where we are working to make a real difference in patient health, we ask you to **apply now and join our team.**

We know that meaningful results require not only the right approach but also **the right people.** Regardless of your role, we invite you to reimagine healthcare with us. You will have the opportunity to play an important part in helping our clients drive healthcare forward and ultimately improve human health outcomes.

Whatever your career goals, we are here to ensure you get there!

We invite you to join IQVIA™.