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# Associate pirector, startup solution Lead

Work Your Magic with us!

Ready to explore, break barriers, and discover more? We know you've got big plans – so do we! Our colleagues across the globe love innovating with science and technology to enrich people's lives with our solutions in Healthcare, Life Science, and Electronics. Together, we dream big and are passionate about caring for our rich mix of people, customers, patients, and planet. That's why we are always looking for curious minds that see themselves imagining the unimaginable with us.

United As One for Patients, our purpose in Healthcare is to help create, improve and prolong lives. We develop medicines, intelligent devices and innovative technologies in therapeutic areas such as Oncology, Neurology and Fertility. Our teams work together across 6 continents with passion and relentless curiosity in order to help patients at every stage of life. Joining our Healthcare team is becoming part of a diverse, inclusive and flexible working culture, presenting great opportunities for personal development and career advancement across the globe.

**Your role:** Collaborate with internal and external business partners for country protocol feasibility (if applicable) and site feasibility assessment; drive the development of the Country & Site Activation Strategy Plan at the study level across Phase I-IV, with internal and external business partners; serve as start-up delivery expert and oversee the activities from protocol feasibility, site selection, EC/IRB submission, Regulatory green-light to site activation and subsequent amendments activities; serve as the point of escalation to study teams for start-up process issues and facilitate resolution to issues identified; evaluate translation procedures and strategies to accelerate regulatory submissions & site activations; accountable and perform regular reviews of start-up performance and quality metrics at a portfolio level and identify trends/gaps within the start-up processes, which may impact key deliverables (eg. timelines/ quality/costs) and work closely with internal stakeholders and/or external partners to ensure action or

## Associate Director, Start-up Solution Lead Job Details | Merck KGaA Darmstadt, Germany

mitigation plans are defined and implemented at a portfolio or program level; accountable for raising awareness of such trends/issues in overall feasibility and start-up processes and facilitating solutions, working closely with relevant internal partners and/or external business partners, to ensure CAPA are defined and implemented. Raise awareness of trends/ issues (within and across the program) with key internal/external partners, department Leadership Team and/or senior management as appropriate; work closely with internal business and service providers to improve or develop a country study start-up plan, to support the acceleration of country study start-up.

## Who you are:

- Medical or Life Sciences degree or equivalent qualification. PM certification (CPM, PMP) is desirable
- At least 10 years in clinical research in a CRO or Pharmaceutical/Biotechnology Industry environment
- Understanding of the overall clinical development paradigm, especially in the area of clinical study operations and have global or regional experience
- Passionate about bringing the latest scientific discoveries to life, supporting the start-up phase of our Development Clinical Trials
- 3-5 years of project management and experience in study start-up activities, preferred
- Experience in oversight of external service providers
- Thorough knowledge of ICH-GCP and applicable laws and regulations for key countries
- Experience in multiple Therapeutic Areas, especially in oncology and immuno-oncology
- Fluent in English

**What we offer:** We are curious minds that come from a broad range of backgrounds, perspectives, and life experiences. We celebrate all dimensions of diversity and believe that it drives excellence and innovation, strengthening our ability to lead in science and technology. We are committed to creating access and opportunities for all to develop and grow at your own pace. Join us in building a culture of inclusion and belonging that impacts millions and empowers everyone to work their magic and champion human progress!

Apply now and become a part of our diverse team!

# Job Requisition ID: 283080 Location: Madrid Career Level: E - Professional (10+ years) Working time model: Full-time

#### **North America Disclosure**

The Company is committed to accessibility in its workplaces, including during the job application process. Applicants who may require accommodation during the application process should speak with our Candidate Services team at 844-655-6466 from 8:00am to 5:30pm ET Monday through Friday. If you are a resident of a Connecticut or Colorado, you are eligible to receive additional information about the compensation and benefits, which we will provide upon request. You may contact 855 444 5678 from 8:00am to 5:30pm ET Monday through Friday, for assistance.

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