

Biosample Operations Lead (50%)

m/f/d, Basel-Stadt

The Biosample Operations Lead (BOL) is accountable for the execution of the biosample chain of custody, which includes the planning and coordination of all operational activities required for the collection and delivery of clinical trial samples (e.g. Safety, Chemistry, Biomarker, PK and PD) across the portfolio of trials. The BOL is an integral part of the Clinical Trial Team and provides operational/ project management expertise as it relates to sampling, site and patient logistics, and vendor management to ensure deliverables to the CTT or biomarker scientist. The BOL works closely with the Clinical Trial Lead, CRO partners, Trial Monitors, Data Management, Biomarker Scientist, etc. to ensure the trial protocol and overall program deliverables are met.

Contract duration: until 31.12.2026 (possible extension)

Location: Basel

Workload: 50%

Responsibilities:

- * Contribute to the trial protocol development as it relates to biosample management requirements.
- * Translate protocol requirements into laboratory operational planning and set up.
- * Initiate contracts and budget negotiations with laboratory trial vendors, facilitate discussions with stakeholders, and push through with deliverables to ensure finalization is within appropriate timelines.
- * Oversee activities outsourced to laboratory vendors as it relates to biosample tasks
- * Develop a Sample Chain of Custody as part of the Trial Oversight Plans.
- * Secure documentation evidencing high quality Sample Chain of Custody within the TMF.

Job Profil

 Life Sciences - Clinical & Safety

 Basel-Stadt

 Contracting

 Vollzeit



Immediately - 31.12.2026 (possible extension)

 GLP, Biomarker, biosample



Klingt interessant?

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- * Liaise with clinical development, translational and pharmacokinetic scientists and clinical teams to establish analysis needs with clinical feasibility
- * Establish productive working relationships with sites, vendors, business partners, and other stakeholders.
- * Serve as an active member of the Clinical Study Team to obtain and provide updates on the progress of the trial regarding sample management
- * Must be able to identify and mitigate risks (and issues) to ensure accuracy in sample collection, delivery, and analysis
- * Keep track of follow up items for sample activities within clinical studies
- * Draft and review laboratory manuals to ensure accuracy and consistency with the study protocol and clinical needs
- * Oversee Lab delivers on sample delivery, query resolutions, negotiating with couriers and external vendors to streamline sample collection and shipment
- * Facilitate sample shipments and query resolutions among vendors to ensure timely data delivery as needed
- * Manage biobank if relevant
- * Identify issues and be proactive in urgently escalating and resolving them
- * Track and manage all sample related activities or PK, PD, and Biomarkers routinely and provide updates when appropriate
- * Have a strong understanding of scientific needs as well as clinical processes to bridge the needs between these functions
- * Understand and assist in data reporting needs for each clinical study
- * Drive the development of necessary Biosample Operations SOPs, Templates, and tools by assessing the need for creation of, change to, and removal of procedural documents
- * Maintains current knowledge of and ensures all functional work team activities are conducted in compliance with the full range of related internal and external systems, technology, regulatory, GxP requirements and related policies and procedures. Advocates for full legal compliance and ethical conduct in all business transactions.

Experience:

- * Life sciences degree and at least minimum of 6 years working experience in the biotech/pharma industry. **A good proportion of that experience must be in biosample operations**

management and securing biosample chain of custody through outsourced laboratory vendors.

- * Clinical or biological laboratory experience with evidence of involvement in the processing and/or analysis of biological samples.
- * Proven clinical development experience working in teams running clinical studies, monitoring clinical studies or working in clinical studies at an investigator site
- * Proven critical reasoning skills including the identification and resolution of complex problems working independently and in a team environment
- * Proficient in Microsoft Office Applications including Excel, Word, and PowerPoint
- * Knowledgeable and experienced in GLP
- * Excellent written and verbal communication skills.
- * Experience in controlled procedural document principles, process design and leading process improvements.

Sounds like a great job?

Then we look forward to receiving your complete application documents through our online application form.

When applying by email, the sender agrees that his or her data will be used in accordance with our data privacy policy.

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