

## GCP Bioanalysis Lab Operations Expert

Job ID  
REQ-10022958

10月 04, 2024

Switzerland

### 摘要

As a GCP Bioanalytical Lab Operations Specialist, you will oversee the equipment and sample management operations of a bioanalytical laboratory adhering to GCP guidelines. Your responsibilities include instrument fleet management, asset management, sample management, data management, computerized system validation, and continuous process improvement. You will collaborate with cross-functional teams and effectively communicate with internal and external stakeholders. A degree in a related field and experience in a GCP-regulated environment are preferred. Strong knowledge of GCP guidelines, FDA regulations, and ICH guidelines is required. Novartis offers a flexible working environment, a collaborative culture, and opportunities for growth and development. Competitive salaries and benefits provided.

### About the Role

As a Good Clinical Practice (GCP) Bioanalytical Lab Operations Specialist, you will be responsible for the equipment and sample management operations of a bioanalytical laboratory that adheres to GCP

guidelines. Your role will involve ensuring the highest standards of quality and compliance in the laboratory's operations, leading a team of sample managers, and effectively communicating with internal and external stakeholders.

Your main responsibilities will include but are not limited to:

- Instrument fleet management: be responsible for overseeing preventative maintenance/repairs and software updates in compliance with SOPs and regulatory requirements, and maintain logbooks in accordance with GCP standards. Write/edit/review SOPs for general instrument usage and maintenance.
- Asset management: responsible for purchasing CAPEX and low-value assets, in close collaboration with the lab scientists, facilities, and finance teams.
- Sample management: lead a team of sample managers, supervising the proper handling, labeling, storage, and disposal of clinical trial samples according to GCP guidelines, SOPs, and protocol requirements. Ensure the integrity and chain of custody of samples throughout their lifecycle.
- Data Management: Implement data management systems and ensure that data is properly recorded, stored, and backed up.
- Computerized System Validation and Management: Development and implementation of validation plan for computerized systems used in the bioanalytical lab, ensuring compliance with GCP guidelines and regulatory requirements, and managing system installation, configuration, training, data integrity, security, and system updates.
- Continual improvement: ongoing evaluation and improvement of laboratory processes, workflows, and efficiencies related to sample management and equipment operations. Implement automation and technology solutions to enhance productivity and data quality. Stay updated with industry trends, regulations, and advancements in bioanalytical sciences.
- Collaboration and communication: Collaborate with cross-functional teams, including lab staff, vendors, facilities, reconciliation specialists, and archivists to support bioanalytical activities in clinical trials. Communicate effectively with internal and external stakeholders. Foster a culture of collaboration, operational excellence, and continuous improvement within the team.

Essential requirements:

- Degree in biochemistry, chemistry, pharmaceutical sciences, or a related field with 7+ (bachelor) or 5+ (master) years of experience. Previous experience as a bioanalytical lab operations specialist in a GCP-regulated environment is preferred.
- Strong understanding of GCP guidelines, FDA regulations, and ICH guidelines related to sample management, laboratory documentation, and lab operations. Familiarity with GLP (Good Laboratory Practice) is a plus.
- Laboratory operational excellence, and a strong desire to continuously improve efficiency, quality and automation.
- Familiarity with sample collection, labeling, storage, disposal, and archiving practices in a regulated laboratory environment. Understanding of sample chain of custody and documentation requirements.
- Ability to work independently and/or supervise a small team, and organize work across multiple projects to meet timelines.
- Eagerness to take on additional responsibilities when required; flexibility to adapt to changing

priorities and strategies.

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Functional Area  
Research & Development

Job Type  
Full time

Employment Type  
Regular

Shift Work  
No

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