

IT/CSV Business Analyst - Pharma (GxP)

Job ID
REQ-10064760

10月 20, 2025

Switzerland

摘要

The IT/CSV Business Analyst will ensure end-to-end traceability and compliance for GxP-relevant systems in a regulated pharmaceutical environment. This role combines rigorous validation practices with advanced data proficiency to optimize processes and support decision-making, while maintaining alignment with Security, Quality, and IT governance frameworks.

About the Role

Major Accountabilities:

- Create and maintain traceability between user requirements, functional/technical specifications, test cases, and validation evidence for GxP systems.
- Lead and support test planning and execution, including risk-based test design, defect management, and objective exit criteria.
- Ensure strict adherence to Security, Compliance, and Quality policies (GxP, data integrity,

- access management) and documentation standards within Service Delivery.
- Maintain controlled documentation: URS/FRS/DS, test protocols/reports, validation plans/reports, SOPs/WIs, and change/control records aligned to DDIT governance and TT Service Portfolio.
- Apply industry best practices and reusable platforms/templates; minimize customization in favour of configuration for COTS solutions.
- Analyse and improve local business processes using advanced data analysis and digital tools to increase reliability and throughput.
- Engage business representatives and partner with DDIT teams to elicit, refine, and manage requirements; translate business needs into implementable, testable specifications.
- Ensure audit readiness: maintain complete, current validation packages; address findings and CAPAs promptly.
- Define test strategy per system risk classification (GxP impact, data integrity, cybersecurity).
- Author and review test scenarios, scripts, expected results, and acceptance criteria mapped to requirements.
- Orchestrate UAT: environment readiness, data sets, role-based testers, defect logging, and closure.
- Assure test evidence quality and traceability in the validation repository.
- Automate regression where feasible; maintain reusable test libraries for configured COTS.

Minimum Requirements:

- Experience in regulated pharmaceutical environments with GMP/QA/validation exposure.
- Demonstrated ability to structure regulatory and quality information using digital tools and data.
- Proven record of influencing without authority and managing relationships across departments and locations.
- Experience interacting with senior stakeholders in quality, operations, and IT, including workshops and reviews.
- Multi-national and cross-functional collaboration.
- Advanced data proficiency; ability to leverage digital tools for data analysis, process optimization, and decision support.
- Analytical thinking; structured problem solving under compliance constraints.
- Concise, evidence-based communication and audit-ready documentation.
- Requirements analysis and requirements gathering.
- Test design and validation documentation per GxP and security standards.
- Proficiency with Microsoft 365 toolset for documentation, tracking, and reporting.
- Degree in Pharmacy or related life-science discipline (or equivalent).
- Fluent German & English.

Preferred:

- Experience in pharmacy operations with workflow optimization.
- R&D Quality Assurance internship/placement with deviation/trending and cross-site coordination.

Commitment to Diversity and Inclusion: Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

Accessibility and accommodation: Novartis is committed to working with and providing reasonable accommodation to all individuals. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to receive more detailed information about the essential functions of a position, please send an e-mail to inclusion.switzerland@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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部门
Operations

Business Unit
Universal Hierarchy Node

地点
Switzerland

站点
Stein Aargau

Company / Legal Entity
C046 (FCRS = CH046) Novartis Pharma Stein AG

Functional Area
Technology Transformation

Job Type
Full time

Employment Type
Temporary (Fixed Term)

Shift Work
No

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