



On behalf of our client, one of the biggest biopharmaceutical companies, we are looking for a

Validation Engineer

Location: Bern (CHE, Switzerland)



DESCRIPTION

For a project rolling from ASAP until end of 2022, we are looking for a Validation Engineer.

This person will be in charge of **Computer System Validation (CSV) activities for Technical Services department** in order to **ensure that Validation phases are performed according to global and local company policies** and Validation Master plans are up to date and established for all ongoing projects.

Tasks:

- **Plan, coordinate and execute all phases for computer system validation** of production and QC Lab systems including but not limited to, **Validation plans, FMEA, RTM, DQ, IQ, OQ, PQ test scripts**
- Prepare, review, and approve technical and GMP related **documentation**
- **Coordinate and execute FAT/SAT**, commissioning activities focused on CSV for new systems in collaboration with internal and external partners
- Ensuring completion of CSV Periodic Review activities and assessment of the required corrective actions
- Validation planning for base business including interaction with IT, Maintenance Automation and Quality Operations groups
- Operational handling of Change Controls, CAPAs and Non-Conformances related to CSV
- Support Technical Services department KPI
- Ensure the CSV process related procedures and life cycle management are up to date according to international GMP standards and internal procedures

QUALIFICATIONS

- A minimum of 3 years of working experience within pharma or a biotech company
- A minimum of 4 years of working experience with CSV
- Know-how of CSV requirements according to FDA 21CFR part 11/ EUGMP Annex 11 regulations and ISPE GAMP 5 guidelines
- Basic know-how of quality assurance principles



Additional information:

Actual End Date	30/12/2022
Education Required	Bachelor or Master's Degree in technical or natural sciences
Work Experience	A minimum of 4 years of working experience with CSV
Non Technical Skills and Additional Details	<ul style="list-style-type: none">• Excellent communication skills• Analytical thinking and problem-solving ability• Ability to effectively work as part of a multidisciplinary, international team• Self time management <ul style="list-style-type: none">• Business fluency in English• German language is a plus



To apply, please write an e-mail to: candidature@adeodata.eu