



CSV Engineer - Life Sciences (DE)

Bern

Referenznummer:

ALTEN is a leader consultancy company divided in **3 different business units: IT, Engineering and Life and Science**, operating in more than **30 countries** worldwide by now. We have around **54,000 employees (88% engineers)** working with our clients. ALTEN group has **6,500 Clients** in various sectors such as pharmaceutical sector, aerospace, telecoms, finance, energy, automotive, public sector and more... As a company we support them with their expertise. In ALTEN Switzerland we have **450 Employees** and **100 clients**.

Are you passionate about technology and like to take on complex technical challenges? Do you want to work in exciting projects at renowned clients? At ALTEN we believe that knowing and meeting the expectations of our consultants is a key factor in our success. Our consultants make the difference. Do you want to make the difference too?

- Assess and lead specific assigned CSV package(s)
- Hands on: Plan, coordinate and execute all phases for computer system validation of production and/or 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 (URS, impact/risk assessment, Master plans, qualification/validation documentation)
- Understand customer needs and define electronic records requirements for computerized system adhering to regulation and company standards
- Coordinate and execute FAT/SAT, commissioning activities focused on CSV for new systems in collaboration with internal and external partners
- 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
- Contribute to ensure that changes introduced in the organization of systems, procedures, processes and formulas are managed so that all aspects of the equipment / computerized systems commissioning, and qualification process are assessed and resolved.

- Bachelor / Master degree in Life Sciences, biotechnology, chemistry or related field
 - Significant experience in computerized system validation (CSV) in a GMP environment
 - Know-how of CSV requirements according to FDA 21CFR part 11/ EUGMP Annex 11 regulations and ISPE GAMP 5 guidelines
 - Strong analytical thinking and problem-solving ability
 - Excellent communication and teamwork skills
 - Fluent in English and/or German
 - Multiple options for locations: Bern, Zurich, Basel, Schaffhausen
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Ihr Ansprechpartner

ALTEN Switzerland

What

we offer you

Apply now and be a part of our amazing journey - we believe in growing together!

What we offer you

We at ALTEN Switzerland strongly believe that every employee is equally valuable for our company's success. We are driven by making people grow, which is why we offer you the opportunity to do what you are truly passionate about. We partner with some of the leading companies in Switzerland in a number of different sectors. Furthermore, we offer both national and international growth opportunities for our employees, which means that you would have the freedom to build your career path and achieve your goals.

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