Aston Life Sciences is the proud leading company in Consulting, Recruitment and Executive Search for the Pharmaceutical, Biotechnology, Medical Devices and Diagnostics industry. Based in Switzerland we serve Eastern and Western Europe, North America and Russia. Life Sciences is our passion and we are committed to successfully support our clients in their quest to improve patient's health all around the world.

For one of our client based in Switzerland we are looking for

CSV Senior Engineer - DeltaV/Syncade

Your role:

Due to the sustainable increase of activities for one of our clients, we are looking for CSV Senior Engineer (permanent position with our client). The main responsibility and accountability of the CSV (Computer System Validation) Senior Engineer is to perform computer systems validation activities associated with establishing the business processes required to implement, qualify, change and manage a highly automated & integrated large scale bio-production facility.

Your tasks:

- Perform validation activities at the site and ensures the approach and execution aligns to the company's expectations. Scope includes IT, Execution Systems, and Laboratory Analytical systems.
- Provide input on improvement of life cycle documentation. Provide input on SOP (Standard Operations Procedures) development.
- Act as a high-level technical resource for implementation of policy in partnership with the quality organization(s) to ensure alignment in approach and desired acceptance criteria.
- Support the implementation and adoption of the global CSV program and remediation. Support data integrity implementation and remediation for systems within CSV program. Participate in continuous improvement efforts related to CSV program.

Your profile:

- Bachelor's Degree (BS) with as emphasis in Engineering/Sciences or equivalent.
- 7/10 years of experience in CSV and validation
- Experience with **DeltaV or MES Syncade systems is a must**
- Understanding of regulations governing computer systems and control such as FDA's 21 CFR Part 11, EMA's Annex 11, and MHRA's data integrity guidance
- Understanding of risk based validation executions
- Background in Lifesciences and/or Pharma/Biotech industries (or understanding of bioprocessing and support processes)
- Direct experience with IT and Manufacturing automation systems supporting GMP (Good Manufacturing Practices) manufacturing

Starting date: 30 April 2019

Location: German part of Switzerland

Level: Middle

Domain of experience: CSV

Category: Biotechnology

Closing date: 01 January 1970