Sr. Manager Computerized Systems Validation - BES

The main responsibility of the Senior Manager, Computerized Systems Validation – BES (Biogen Execution Systems) is to lead activities associated with establishing the business processes required to implement, qualify and change manage a highly automated & integrated large-scale bio-production facility in Solothurn, Switzerland. The new facility and the production process in Solothurn are envisioned to be highly automated with data being shared across multiple platforms to support production, from raw material receipt to disposition of the produced drug substance. Data generated at each stage of production will be shared across business information and control systems, including the multivariate analysis to support predicative models for process control and disposition support.

Primary Responsibilities

In this function, you are required to have expert level knowledge of change management and change control of highly integrated recipe & IT systems to:

- Lead the implementation in how computerized systems become validated to ensure the approach and execution aligns to industry as well as Biogen expectations (Scope includes IT, Execution Systems, and Laboratory Analytical systems)
- Provide guidance, and where required, lead the development of life cycle documentation
- Provide guidance in SOP development
- Act as a high-level technical resource for interpretation of policy in partnership with the quality organization(s) to ensure alignment in approach and desired acceptance criteria.
- Support internal and external audits as the point of contact for computerized systems validation
- Lead and ensure local periodic review as well as required schedule tasks conform to the developed schedule
- Support the implementation and adoption of the global CSV program and remediation. Support data integrity implementation and remediation for systems within CSV program
- Drive and participate in continuous improvement efforts related to CSV program

Qualifications/Skills

- Master's Degree in Sciences/Engineering or Engineering School
- 8-10 years' experience within a Pharmaceutical or Biotech environment
- Depth of 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
- Ability to translate regulatory guidance (GMP), laws, and Biogen directives into executable and defendable lifecycle documentation
- Direct experience with IT and MFG automation systems supporting GMP manufacturing
- Fluency in English and excellent communication skills across all different levels of an organization

Please apply online: http://biogen-solothurn.ch/karriere/

Please note that only online-applications will be accepted. Biogen will not retain paper application submitted.