QA Validation Specialist

m/f/d, Wallis

The QA Validation Specialist is responsible for ensuring that GMP equipment, facilities, and systems are properly qualified, validated, maintained in a compliant state, and supported through change control, documentation review, audits, and regulatory inspections to guarantee product quality and patient safety.

Key responsibilities

- Must possess a full grasp of the duties of Qualifications (CQV) and Validation.
- Perform QA oversight of the Validation review and qualification activities to ensure GMP equipment, facility and/or systems are continuously maintained in a validated/qualified state.
- Schedule own tasks to be performed as well as tasks for Level 1 as determined by the Validation Manager.
- Perform change control assessments for GMP equipment, facility and/or systems and associated validation activities to ensure compliance with regulatory requirements.
- Demonstrate a thorough understanding of Cell and Gene manufacturing equipment, facility and/or system and validation procedures for Installation Qualification (IQ), Autoclaves, Clean Utilities, Shipping Validation, Temperature Mapping Controlled Storage Rooms and Equipment.
- Develop validation protocols from Validation plans (if applicable).
- Provide strong technical expertise when reviewing and approving SOPs, protocols, reports, change controls, deviations and other records.
- Perform assigned Quality Systems activities including: Document Management System (DMS), Laboratory Information Management System (LIMS), Validation and Qualification Management System (Kneat) and Trackwise system (Change Control, Deviations, CAPA, etc.).
- Perform other duties as assigned, like participate to Audits and inspections to demonstrate the compliance of the facility, equipment and systems with both European and US (FDA) regulations, and continuous improvement initiatives.

Job profile

- Life Sciences - Engineering
- Wallis
- Contracting
- Full Time
- Qualification

Sounds interesting?

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Your background

- GMP-regulated pharmaceutical, biotech, or cell & gene therapy environment.
- 2–6 years Validation / Qualification Experience in IQ, OQ, PQ, maintenance
- Must have experience reviewing and approving: SOPs , Validation protocols, Validation reports, Deviations, CAPAs, Change controls
- Familiar with EU GMP and FDA regulations
- English Proficiency (German a strong plus)

Sounds like a great job?
Then we look forward to receiving your complete application documents through our online application form.

When applying by email, the sender agrees that his or her data will be used in accordance with our data privacy policy.

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