

Computerized Systems Validation (CSV) Engineer

Job ID
REQ-10045596

Apr 03, 2025

Netherlands

Summary

We are seeking a : Computerized Systems Validation (CSV) Engineer

About the Role

Key Responsibilities:

- Owning the computerized system validation site masterplan.
- authoring user requirements, validation plans, protocols, reports and risk
- Assessments regarding computerized systems.
- Execute the required tests in collaboration with Production department, QC
- department or external suppliers where applicable
- Perform periodic reviews on existing validated systems to ensure systems are in a validated stat during the complete life cycle.
- Supports audits

- Authors and updates SOPs, WIs when required
- Participate in design checks and reviews to guarantee the required quality.
- Being a thought partner for Capital Investments, equipment validation and process engineering
- Develop partnership with Global Novartis Engineering teams ensuring consistence and standardization of Engineering process.
- Lead or participate on the assessment or implementation of special projects or initiatives with cross-functional teams.

Essential Requirements:

- Degree in Engineering, Medical/Pharmaceutical sciences, Biotechnology (Dipl. Ing. / M. Sc. / B. Sc.) or equivalent.
- Minimum 3 years of working experience within (pharmaceutical) GMP and or isotope manufacturing.
- Good understanding of related guidelines GAMP 5 (ISPE), USFDA 21 CFR Part 11 en Eudralex Annex 11
- Good command of Dutch and English language, both written and speaking.
- Attention to safety, able to work in an organized and structured manner through protocols and standards
- Attention to detail, ability to look at the process through the eye of the end-user as well as an engineer
- Project management skills with the ability to handle multiple projects at one time
- Basic IT skills
- Analysis capability and reporting skills

Commitment To Diversity And Inclusion

Novartis is committed to building an outstanding, inclusive work environment and diverse teams representative of the patients and communities we serve.

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients ' lives. Ready to create a brighter future together? <https://www.novartis.com/about/strategy/people-and-culture>

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部門
Operations

部門
Innovative Medicines

国
Netherlands

勤務地
Baarle Nassau

Company / Legal Entity
NL42 (FCRS = NL042) IDB Holland BV

Functional Area
Technical Operations

職種
Full time

雇用形態
Temporary (Fixed Term)

Shift Work
No

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