

# 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

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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Division

Operations

Business Unit

Innovative Medicines

Location

Netherlands

Site

Baarle Nassau

Company / Legal Entity

NL42 (FCRS = NL042) IDB Holland BV

Functional Area

Technical Operations

Job Type

Full time

Employment Type

Temporary (Fixed Term)

Shift Work

No

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