

# 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>

**Join our Novartis Network:** Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up:

<https://talentnetwork.novartis.com/network>

**Benefits and Rewards:** Read our handbook to learn about all the ways we'll help you thrive personally and professionally: <https://www.novartis.com/careers/benefits-rewards>

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

[Apply to Job](#)

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

Job ID

REQ-10045596

**Computerized Systems Validation (CSV) Engineer**

**Source URL:** <https://prod1.novartis.com/nl-nl/careers/career-search/job/details/req-10045596-computerized-systems-validation-csv-engineer>

**List of links present in page**

1. <https://www.novartis.com/about/strategy/people-and-culture>
2. <https://talentnetwork.novartis.com/network>
3. <https://www.novartis.com/careers/benefits-rewards>
4. [https://novartis.wd3.myworkdayjobs.com/en-US/Novartis\\_Careers/job/Baarle-Nassau/Computerized-Systems-Validation--CSV--Engineer\\_REQ-10045596-1](https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Baarle-Nassau/Computerized-Systems-Validation--CSV--Engineer_REQ-10045596-1)
5. [https://novartis.wd3.myworkdayjobs.com/en-US/Novartis\\_Careers/job/Baarle-Nassau/Computerized-Systems-Validation--CSV--Engineer\\_REQ-10045596-1](https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Baarle-Nassau/Computerized-Systems-Validation--CSV--Engineer_REQ-10045596-1)