

# Senior Process Expert CGT - temp

Job ID

REQ-10024679

08. Oktober 2024

Schweiz

## Summary

As Senior Process Expert CGT you will act as subject matter expert for all process-specific issues to ensure execution of processes on time, continuously improving in quality and productivity, performed in compliance to cGMP, SOPs and applicable guidelines and functional standards. Supports processes and standards to maintain and improve existing and to implement new innovative concepts and strategies.

## About the Role

### Why join Cell & Gene Therapy?

Novartis is pioneering the way in the class of cell and gene treatment and has developed the first CAR-T cell therapy approved for pediatric and young adult patients with relapsed/refractory B-cell acute lymphoblastic leukaemia (ALL). The patient is at the center of the process for CAR-T cell therapy. The process begins with the patient at autologous T-cell collection and ends with the patient at infusion.

### Key Responsibilities:

- Provide front line support to manufacturing, working with the shift teams, focusing on manufacturing each batch safely, on time, in compliance with the batch instructions and quality requirements.
- Responsible for maintaining the master manufacturing documents of assigned products (e.g. Master Batch Record, Bill of Material (BOM) & Recipe, Quality Risk Assessment).
- Support steward for assessment of technical changes and process changes (task manager ACC/PCC).
- Collect data for ongoing process verification (OPV), support product steward in tracking and evaluation of product performance and implementation of CAPAs.
- Support the execution of process validations and qualifications, and short-term improvement projects, liaising with all the relevant parties at shop floor to ensure accurate execution.
- Perform first line evaluation of product and process related issues, perform root-cause investigations (uncritical, major and critical deviations, complaints, OOS, OOE) and implement effective CAPAs.
- Ensure that technical batches generate sufficient process knowledge by thoroughly testing critical variables.
- Support technology trainings and education programs for production operators and others.
- Act as Subject Matter Expert for Audits.

### Minimum Requirements:

- Minimum BSc. or MSc. in Biotechnology, Engineering, Pharmaceutical Technology, Chemistry, Pharmacy or equivalent scientific degree with some years of experience in a technical process support role on the

shopfloor of GMP manufacturing.

- Or: PhD in Biotechnology, Engineering, Pharmaceutical Technology, Chemistry, Pharmacy or equivalent scientific degree with less experience in a technical process support role on the shopfloor of GMP manufacturing.
- Fluent English language skills (written and oral).
- German language skills are desirable.
- Experience working in a GMP environment.
- Knowledge of Cell & Gene topics.
- Root cause investigation skills.

### **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>

### **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>

### **Commitment to Diversity and Inclusion / EEO:**

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

### **Accessibility and accommodation:**

Novartis is committed to working with and providing reasonable accommodation to all individuals. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to receive more detailed information about the essential functions of a position, please send an e-mail to [diversity.inclusion\\_ch@novartis.com](mailto:diversity.inclusion_ch@novartis.com) and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

### **Join our Novartis Network:**

If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here:

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

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Aufteilung

Operations

Business Unit

Innovative Medicines

Location

Schweiz

Site

Stein Aargau

Company / Legal Entity

C046 (FCRS = CH028) Novartis Pharma Stein AG

Functional Area

Technical Operations

Job Type

Full time

Employment Type

Temporary (Fixed Term)

Shift Work

No

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