

Process Expert

Job ID
REQ-10018579
Aug. 23, 2024
Schweiz

Zusammenfassung

A new and exciting opportunity has presented itself in CGT Stein. Join our team as a Process Expert, where you will providing front line technical and scientific expert support for all process-specific issues to ensure execution of processes on-time (business continuity); in compliance to cGMPs, SOPs and applicable guidelines and functional standards (e.g. HSE, NOSSCE) and to allow continuously improving in quality and productivity efficiency.

About the Role

Why join Cell & Gene Therapy?

In the Cell & Gene Therapy network we are operating on a daily basis (including weekend days) to deliver our life changing medicines the most rapidly to the patient.

Individualized CAR T therapy uses a patient's own immune system to fight certain types of cancers. A patient's T cells are extracted and reprogrammed outside of the body to recognize and fight cancer cells and other cells expressing a particular antigen.

Key Responsibilities:

- Provide front line expert support for all process-specific issues to production.
- Act as Subject Matter Expert (SME) for the product and process.
- Coordinate and ensure the completion of all production operations on time, in accordance with the documentation and in compliance with GMP, SSE and 5S rules.
- Ensure real time shop floor support as an expert on technical problems and ensuring that appropriate immediate corrective/remediation actions are implemented.
- Perform real time batches follow-up and batch records technical review.
- Ensure that all production documents are systematically up to date and that the production documents necessary for the validation / revalidation of processes are available.
- Execute validations when/where needed.
- Manage the preparation and execution of change over activities between campaigns by ensuring availability of equipment, consumables, raw materials, documentation and providing Change Over

training to technicians.

- Ensure timely treatment of deviations, complaints, OOE, OOS, and the implementation of effective CAPAs within agreed timelines.
- Lead thorough Root Cause Investigation process using investigation tools and methodology.

Minimum Requirements:

- Desired experience in GMP manufacturing process support role.
- Advanced English is a must.
- University degree in Science is desirable, Pharmacy or Chemical Engineering, Pharmaceutical Technology or equivalent job experience.
- Good scientific and technical (automation) understanding.
- Good working knowledge/understanding of manufacturing execution systems (MES, SAP, or relevant...).
- Good understanding or capacity to quickly understand production processes.

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 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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Abteilung

Operations

Business Unit

Innovative Medicines

Ort

Schweiz

Website

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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