Director, Global Sterility Assurance Team Lead

Job ID
REQ-10032140
Dic 16, 2024
Austria

Resumen

As Director, Global Sterility Assurance Team Lead you will:
• Lead a team (4-6 direct reports, 20-30 indirect) of Key functional Expert for Aseptic processing within the Novartis manufacturing network (includes Large Molecules and Advance therapies and third parties producing for Novartis).
• Ensures and verifies that all actions related to FDA and other health authority inspections are understood and implemented by the sites in the platform, avoiding re-occurrence of 483's and Warning Letters.
• Assure that key projects are implemented in the manufacturing sites as per committed plan to FDA and other health authorities
• Ensure implementation of changes to support GMP updates (i.e. Annex 1) within all the sites in scope in order to assure ongoing compliance for the upcoming years. In this regard supports the gap assessment process and respective remediation and action tracking.
• Liaise with TechOps to ensure implementation, follow up and completeness of all related Quality/ Compliance programs, documentation and Quality reporting of Aseptic related projects / metrics.
• Ensure adequate Health Authority Inspection preparation of the Sites in scope and successful inspection outcomes. Interactions with sites mainly require interpretation of complex information and persuasion both internally with other areas of the business and the site leadership team and externally.

About the Role

Major Accountabilities:

- Overall team leader that has the responsibility of 4-6 individual contributors hosted in US, Spain and Austria, plus 20-30 indirect reports located within the manufacturing sites performing sterile operations.
- Lead cross site/platform and network projects and harmonization initiatives as assigned
- Provide expert advice and appropriate technical support to ensure site readiness for Health Authority and GGA inspections by supporting sites in their preparation, up to and including hands on preparation of materials (i.e. storyboards for complex cases, etc.)
- Primary Responsible for optimization of aseptic processes (as e.g. cleaning and disinfection programs, microbiological monitoring and sterilization techniques) between sites and platforms within the Novartis manufacturing network
- Support escalations for specific topics (i.e. Microbial contaminations, sterility issues, etc.) with the manufacturing sites if needed, and in collaboration with the other members of the platform (i.e. QA operations, QA compliance lead, QC/AS&T lead)
- Own, Monitor and act as Primary contact for the sterility assurance from the sites and define improvement plans as appropriate.
- Build fit for purpose aseptic governance and training program in collaboration with engineering and MS&T

to support sites in development, training and understanding of aseptic topics
- Provides input for the selection, training, people development and performance evaluation, development planning and participating in recruiting process of the Aseptic experts within the manufacturing sites / global functions.

Obligatory requirements:

- Education: Graduate in Chemistry, Pharmacy, Microbiology or another related science; desirable: Ph.D. in science or related discipline
- 12 - 15 years experience in management and leadership roles in the pharmaceutical industry, preferably in a FDA-regulated environment and in QA Operations & Compliance of a strategic Site or a global role. Pharma production experience indispensable. Quality Assurance / cGMP regulations in USA, EU (Self Inspections, Auditing of 3rd parties, Complaint/Deviation Handling, GMP-Training, SOP-Systems).
- Deep understanding of microbiology and aseptic processes
- Solid People Management / Communication skills (To explain difficult business processes and related GMP-requirements to a community of very diversely oriented and educated people from a multitude of different units.
- Excellent Project Management skills, especially with crossfunctional projects.
- Fluent English written and spoken.

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

You will receive: Competitive salary, Annual bonus, Pension scheme, Share scheme, Health insurance, 27 days annual leave, Flexible working arrangements, subsidized dining facilities, Employee recognition scheme, learning and development opportunities.

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

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

Operations
Business Unit
Innovative Medicines
Ubicación
Austria
Sitio
Schaftenau
Company / Legal Entity
AT33 (FCRS = AT033) Novartis Pharmaceutical Manufacturing GmbH
Alternative Location 1
Barcelona Gran Vía, España
Alternative Location 2
Durham, North Carolina, Estados Unidos
Alternative Location 3
Ljubljana, Eslovenia
Alternative Location 4
Morris Plains, New Jersey, Estados Unidos
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No
Apply to Job

Adjustments for Applicants with Disabilities

If because of a medical condition, physical disability or a neurodiverse condition you require an adjustment during the recruitment process, please reach out to disabilities.austria@novartis.com and let us know the nature of your request as well as your contact information. The support which we can provide will include advice on suitable positions as well as guidance at all stages of the application process. Austrian law provides candidates the opportunity to involve the local disability representative, Behindertenvertrauensperson (BVP), in the application process. If you would like to request this, please let us know in advance as a note on your CV.

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

Job ID

REQ-10032140

Director, Global Sterility Assurance Team Lead

Apply to Job

Source URL: *https://www.adacap.com/careers/career-search/job/details/req-10032140-director-global-sterility-assurance-team-lead*

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://www.novartis.com/about/strategy/people-and-culture
5. https://talentnetwork.novartis.com/network
6. https://www.novartis.com/careers/benefits-rewards
7. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Schaftenau/Director--Global-Sterility-Assurance-Team-Lead_REQ-10032140-2
8. mailto:disabilities.austria@novartis.com
9. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Schaftenau/Director--Global-Sterility-Assurance-Team-Lead_REQ-10032140-2