Director, Global Sterility Assurance

Job ID
REQ-10032098

12月 16, 2024

Spain

摘要

As Director, Global Sterility Assurance you will:
· Be Key functional Expert for Aseptic processing within the Novartis manufacturing network (includes Large Molecules and Advance therapies / CMO sites with focus on Large Molecule manufacturing sites.
· Ensure and verify 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:

- 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.)
- Ensure quality actions are executed and the overall plans are closed per the required timelines and that future quality plans are aligned with global initiatives.
- 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
- Aseptic operations support for ramp up of new production facilities and microlabs
- SME in microbiological topics, provide ad-hoc support to the sites of the platform and within the 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)
- Setup system to capture lessons learned (e.g. topics discussed, near misses) during internal and external audits and define appropriate actions.
- Share best practices between the different sites and ensure cross platform communication with aseptic sites (e.g by authoring Novartis position papers)
- Manage 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.
- Ensure that quality and technical issues across the platform are resolved consistently in line with international & global cGMP-standards
- Aseptic KPI trending
- Act as a Quality System Owner for Sterile Operations and responsible person for Functional Representative
- Act as owner of Sterility Assurance Expert Network as platform for knowledge exchange, support of discussion and decision making for aseptic processing topics
- 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
- Engagement in external industry forums (cross industry exchange as e.g. in Biophorum). Proposing strategy for external engagement.
- 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
- 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; capable in convincing people, negotiation and communication/escalation skills).
- 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

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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.

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部门
Operations

Business Unit
Innovative Medicines

地点
Spain

站点
Barcelona Gran V í a

Company / Legal Entity
ES06 (FCRS = ES006) Novartis Farmac é utica, S.A.

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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