NOVARTIS

MS&T Asia Projects & Expansions Lead

Job ID
REQ-10012008
Juni 16, 2024
China

Summary

This is a temporary role ends by 2026 end, to support RLT local product manafucturing launch in both China Haiyan Site and Japan Sasayama Site, with operationally reporting to Project Director RLT CN, and functionally reporting to MS&T Site Head & AAA MS&T Head at RLT platform.

About the Role

- This is a temporary role ends by 2026 end, to support RLT local product manafucturing launch in both China Haiyan Site and Japan Sasayama Site, with operationally reporting to Project Director RLT CN, and functionally reporting to MS&T Site Head & AAA MS&T Head at RLT platform.
- Equipment qualification and validation:
  - Input, review and approval of equipment URS, changes, design documents, risk assessments (e.g. SRA and FRA), change controls, deviations and design reviews
  - Prepare, review and approve commissioning, qualification and validation master plans
  - Review, approval and execution of FAT/SAT, validation documentation including cleaning validation, shipment validation, process validation, technical transfer, filter validation, leachable and extractable, mixing validation, VHP, smoke tests and any other validation activity
  - Documentation preparation, review and approval for qualification and validation
  - Input on layout, pressure cascades, environmental monitoring strategy and parameters, contamination control strategy based on process and product knowledge
- Process development and validation
  - Assessment of equipment and line set-up for manufacturing
  - Definition of process improvements
  - Identify parameters for manufacturing under new technology
  - Develop, define, and validate new manufacturing process with new technologies, new batch sizes, liaising with TRD and sites.
  - Counterpart with development for implementation of new processes, batch size increase, new components implementation, etc.
  - Manage change control for expansions, new buildings, process transfers and process adaptations and modifications
  - Prepare regulatory submission, generation and review of source documents and CMC sections of the dossier
  - Drafting and approval of SOPs and WI related to process, in alignment with Operations and Quality
  - Process design: approval of aseptic processing steps within manual/semi-automated process, including media fills, smoke studies, etc.
  - Ensure technology transfer across the organization
  - Site readiness for technology acceptance

    - Knowledge transfer to operations
- Cross functional activities:
    - Planning of PQ and validation activities
    - Project management collaboration to ensure equipment readiness for process validation
    - Expansion and new technology implementation on all sites according to plan
    - Alignment of proposed validation strategy with operations, quality, regulatory and supply chain
    - New components must be validated for use
    - Project execution and commercial readiness according to plan
- New sites:
    - Influence in the site layouts and equipment needed for each of the sites
    - Adopt state of the art technology for new projects
    - Ensure compliance to regulations (e.g. Annex 1)
- People:
    - Develop site capabilities to adopt new technologies
    - Ensure knowledge transfer for each new project and site
    - Establish an organization to support the implementation of the developed process, qualification and validation documentation preparation and execution

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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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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