Product Steward

Job ID
REQ-10067567

11月 25, 2025

Italy

摘要

The Product Steward owns the process knowledge of the product(s) assigned throughout the commercial lifecycle, maintains the oversight on process capability, through data trending and statistical analysis of critical variables, ensuring process(es) are robust, in continued state of validation and continuously improving.

Ensures seamless flow of knowledge and information across functions, and with other Sites when applicable, with focus on the assigned product(s).

Provides second line technical/scientific process support.

About the Role

Major accountabilities:

- Maintain the oversight and knowledge for entire manufacturing process performed on site and throughout the entire commercial lifecycle, since transfer from development to date, act as SPOC.
- Create and maintain a product specific Quality Risk Analysis (QRAs).
- Monitor all critical variables and key variables as appropriate using statistical analysis and conducting regular product specific data trending.
- Track and evaluate product performance, trending, detect issues, implementation of CAPAs.
- Lead / support root cause investigation of process failures, initiate and lead product improvement projects, involving cross-functional teams.
- Present product performance and status of product improvement projects in site Manufacturing Robustness Review Board (MRRB).
- Assess impact of technical changes, assess their technical feasibility and determine scope / design of technical batches, challenge technical risk and business benefit of technical changes proposed.
- Responsible for ensuring the continued state of validation (process, cleaning, ongoing verification etc.).
- Provide the necessary data for the technical activities involved in transferring out a product, focusing on existing knowledge, through the appropriate documentation and supporting at the receiving site as needed.
- Provide SME expertise to perform process characterization of pharmaceutical processes to increase robustness and sustainability.

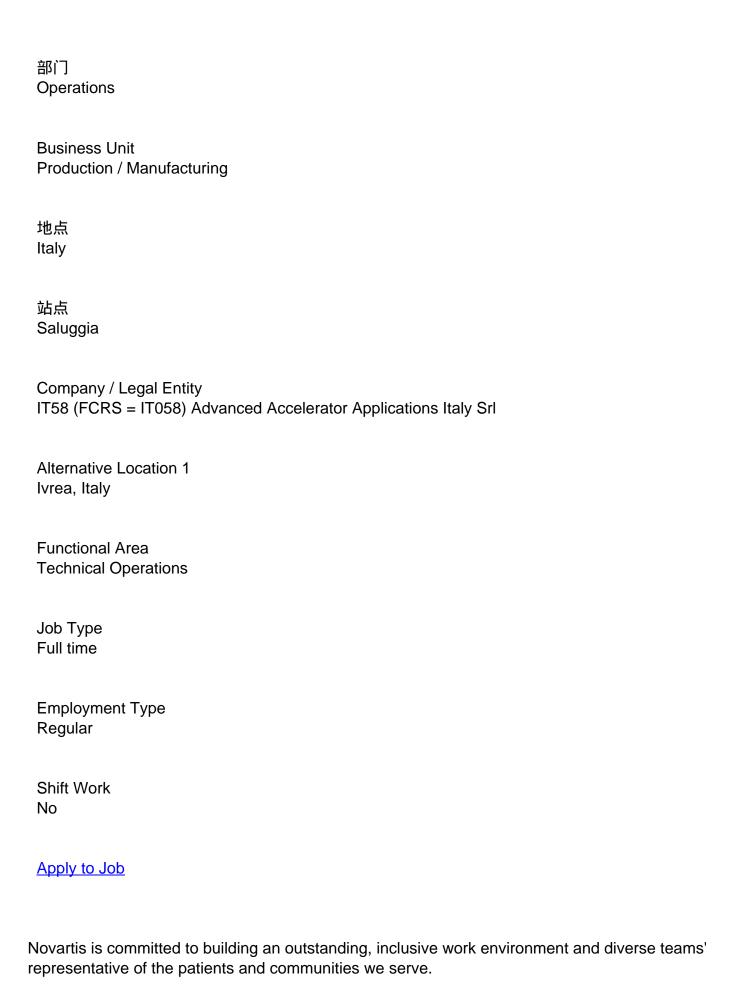
Essential requirements:

- Scientific Degree.
- Previous experience in a similar role within manufacturing/quality/MS&T department of a pharmaceutical/biotech company.
- Strong technical knowledge.
- Fluent in Italian and English.

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List of links present in page

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