

## Global Statistics / PAT Lead

Job ID  
REQ-10018736

9月 03, 2024

India

### 摘要

Provide leadership on the development and deployment of statistics strategy for the manufacturing network. Provide excellence in statistical support to the platform / sites and within the global network to drive the application of advanced and state-of-the-art statistical principles, tools and methodologies to improve process understanding, quality and compliance of the products, efficiency and capability of the processes and profitability of the organization. Interact with key stakeholder groups such as Operational Excellence to develop and deploy statistical applications.

### About the Role

Global Statistics / PAT Lead

Location - Hyderabad / Ljubljana

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## Key Responsibilities:

- Support definition of Internal Release Limits (IRL) and Out-of-Expectation (OOE) limits
- Develop best practices roadmap and harmonize application for NTO / platform, in alignment with corporate and regulatory guidelines.
- Perform statistical analysis of process validation data for demonstrating validity and equivalence.
- Plan and evaluate Design of Experiments (DoEs) in the frame of the Novartis Quality by Design (QbD) validation strategy.
- Perform trending analysis in the frame of Ongoing Process Verification (OPV):
  - Implement and apply Statistical Process Control principles, e.g. control charts, and other pattern recognition techniques. Contribute to the development of fit-for-purpose platform to comply with long term OPV requirements.
  - Support the standardization and automated statistical evaluation of APQRs.
  - Support the introduction of Process Analytical Technology (PAT) by facilitating and enabling (multivariate) process monitoring and control principles, e.g. by Multivariate Data Analysis (MVDA).
  - Support development and deployment of new requirements, such as definition of Internal Release Limits (IRL), in line with corporate and regulatory expectation.
- Establish global / platform procedures & templates for statistical analysis.
- Enable process improvement initiatives in alignment with OPEX organization and methodologies (e.g. IQP, Six Sigma, Lean Manufacturing) such as capability and stability assessments, hypothesis testing, MVDA, computational Fluid Dynamics (CFD), multi linear curve fitting etc.
- Deploy state of the art modelling and simulation techniques across the network to improve quality, supply chain performance and profitability.
- Define and implement strategy for PAT, develop and validate MVDA models for on-line PAT methods, support the design of an analytical robustness test, perform statistical assessment of method validation data and technology and process transfer across sites.
- Interact with internal and external Regulatory bodies and Health Authorities, as well as internal functions as appropriate (e.g. during inspections, investigations etc.) in statistical aspects of data analysis and rationales.
- Use statistical knowledge to analyze data to provide process understanding, and to identify root causes of product and process failures, provide technical expertise together with local statistical experts.

## Essential Requirements:

- Minimum 10 year experience, of which min. 2 year experience in manufacturing.
- Proven process understanding (Pharma, GMP, Regulatory aspects).
- Proven experience of applied statistics is a must, e.g. in the field of .DoEs and multivariate data analysis. Experience in the following software is a plus: SAS, R, Minitab, SIMCA-P+, Modde, JMP, SPSS.
- Experience in deploying divisional strategy and leading in a matrix organization

## Desirable Requirements:

- MSc. in Statistic, Mathematics, natural science or Chemical Engineering.
- Desirable PhD. or equivalent experience.

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Innovative Medicines

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India

站点  
Hyderabad (Office)

Company / Legal Entity  
IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Alternative Location 1  
Ljubljana, Slovenia

Functional Area  
Technical Operations

Job Type  
Full time

Employment Type  
Regular

Shift Work  
No

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