NOVARTIS

Associate Manager - MS&T

Job ID
REQ-10080194
июл 23, 2026
Индия
Available in: English

Сводка

#LI-Hybrid
Location: Hyderabad, India

Bring your expertise in advanced statistics to the forefront of pharmaceutical manufacturing. In this role, you will play a key part in applying advanced statistical methodologies and process analytical technologies to improve process understanding, strengthen product quality and compliance, and enhance manufacturing performance. You will partner with manufacturing sites, quality, technical, and regulatory teams across the global network to transform complex data into actionable insights, applying statistical science to support risk-based decision-making, process optimization, root cause investigations, lifecycle management, and continuous improvement.

About the Role

Key Responsibilities:

Statistics

- Operate as a statistical subject matter expert, leveraging statistical principles and data-driven methodologies to support scientific decision-making, risk assessment, investigation conclusions, and process improvements.
- Represent the statistical function in cross-functional and regulatory interactions, including discussions with Health Authorities, to communicate, defend, and justify statistical approaches, analyses, and conclusions.
- Provide advanced statistical support for deviation investigations by applying techniques such as Regression Analysis, ANOVA, Multivariate Data Analysis (MVDA), Principal Component Analysis (PCA), and Partial Least Squares (PLS) to identify critical factors, evaluate process variability, and accelerate root cause investigations.
- Apply statistical process control and process capability methodologies to support Ongoing Process Verification (OPV), monitor process performance, identify trends, and evaluate manufacturing consistency. Guide cross-functional teams in the correct interpretation and application of statistical concepts.
- Provide statistical expertise for dissolution similarity assessments, including method selection, data analysis, reporting, and regulatory justification.
- Provide statistical expertise in equivalence testing across process validation, site transfers, formulation changes, analytical method changes, and lifecycle management activities, applying appropriate methodologies to demonstrate comparability and support technical and regulatory decisions.
- Support statistical assessment of pharmaceutical quality attributes, including Blend Uniformity (BU), Content Uniformity (CU), assay, process capability, and validation studies to enable data-driven manufacturing and regulatory decisions.
- Develop and justify internal release limits, stability acceptance criteria, and stability models using statistical principles, regression analysis, historical data, process capability, and regulatory expectations to support product lifecycle management.
- Design, execute, and evaluate experiments using Design of Experiments (DoE) methodologies within Quality by Design (QbD) frameworks to support process understanding, optimization, and control strategy development.
- Conduct statistical training and capability-building sessions for manufacturing sites, quality, technical, and regulatory teams to strengthen the application of statistical methods across the product lifecycle.
- Build statistical capability across teams through training, coaching, mentoring, and collaboration with global stakeholders, site statisticians, and regulatory teams.
- Proficiency in statistical and PAT software tools, including Minitab, JMP, SIMCA, Unscrambler, and MATLAB, etc.

Process analytical technologies (Good to have)

- Lead the development, validation, implementation, and lifecycle management of Process Analytical Technology (PAT) solutions, including multivariate calibration models, Real-Time Release Testing (RTRT), and advanced process monitoring strategies.
- Apply chemometric techniques for spectral preprocessing, variable selection, model optimization, model transfer, robustness assessment, and equivalency evaluations.
- Develop and maintain multivariate models, batch evolution models, and multivariate control charts to monitor process performance, detect variability, and support data-driven manufacturing decisions.
- Collaborate with manufacturing sites, quality, technical, and regulatory teams to define and deploy PAT strategies, support regulatory submissions and inspections, and defend PAT models, RTRT applications, and control strategies before Health Authorities.

Essential Requirements:

- Master’s degree in Statistics, Mathematics, Chemical Engineering, or a related field.
- Proven experience in Manufacturing Science & Technology and manufacturing environments within Small Molecule, Biologics / Large molecule setups.
- Proficiency in few of statistical and PAT software tools, including Minitab, JMP, SIMCA, Unscrambler, and MATLAB, Modde, JMP, SPSS etc,
- Solid understanding of GMP and pharmaceutical manufacturing processes, including regulatory requirements.
- Experience in Data & Digital solutions, including multivariate analytics, machine learning, and statistical programming using R and Python, is an added advantage.

Commitment to Diversity and Inclusion

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

Accessibility and Accommodation

Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a

reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversityandincl.india@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally.
Read our handbook (PDF 30 MB)

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Business Unit
Production / Manufacturing
Место
Индия
Сайт
Hyderabad (Office)
Company / Legal Entity
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Functional Area
Technical Operations
Job Type
Full time
Employment Type
Regular
Shift Work
No

Accessibility and accommodation

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