Associate Director - Impurity Safety Expert

Job ID
REQ-10054887

6月 16, 2025

United Kingdom

摘要

Are you passionate about advancing pharmaceutical research and ensuring drug safety at Novartis? The Preclinical Safety (PCS) department at Novartis BioMedical Research (BR) is seeking an experienced Impurity Safety scientist to join our dynamic team.

More than 100,000 people across 140 countries are working for Novartis to discover, develop, and successfully market innovative products to prevent and cure diseases, ease suffering, and enhance the quality of life. As an Impurity Safety expert at Novartis, you will play a key role in supporting non-clinical safety assessment throughout drug discovery and development, as well as for established medicines, with state-of-the-art regulatory compliance. Utilizing your expertise, you will collaborate with cross-functional teams to ensure the delivery of high-quality and compliant research. The position can be located in the US (Cambridge, MA or East Hanover, NJ) or UK (London).

We are unable to offer permit support for this role.

About the Role

Key Responsibilities**:**

- Conduct safety assessment of impurities in drug substances and medicinal products spanning all therapeutic modalities and disease indications (including extractable and leachables, elemental impurities, degradation products, and excipients)
- Perform ICH M7 in silico assessments to evaluate the presence of potential mutagenic impurities
- Provide expertise to support Nitrosamine impurity evaluations
- Provide expert opinions on impurity safety assessments to support drug discovery and development project teams, regulatory submissions, due diligences, and life-cycle management of established medicines.
- Develop innovative interdisciplinary approaches to advance the field of impurity safety assessment across all therapeutic areas and advanced modalities (e.g. Bx, GTx, xRNA, RLT)
- Maintain state-of-the-art scientific and regulatory expertise in Impurity Safety.
- Lead cross-functional teams; represent the PCS line function on internal and external boards; actively share and communicate information back to the Impurity Safety team
- Engaging and collaborating with key internal and external customer partners
- Ensure compliance with relevant regulatory guidelines and standards.

Essential Requirements:

- PhD, DVM or equivalent
- Broad knowledge in toxicology and chemistry
- Knowledge of the drug development process
- Minimum of 5 years of experience in regulatory impurity safety assessment
- Experience in health authority interactions
- Knowledge of design and application of impurity safety databases, experience in the area of QSARs
- Strong analytical skills and a commitment to scientific excellence.
- Excellent communication and team collaboration skills.

Desirable Requirements:

- Strong data exploration and analysis skills.

Why Novartis: Our purpose is to reimagine medicine to improve and extend people ' s lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

Commitment to Diversity and Inclusion:

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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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部门
Biomedical Research

Business Unit
Universal Hierarchy Node

地点
United Kingdom

站点
London (The Westworks)

Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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