NOVARTIS

Associate Director Medical Device Process Innovation and Excellence (f/m/d)

Job ID
REQ-10025665
Nov 04, 2024
Switzerland

Summary

Location: Basel, Switzerland,
Type: Hybrid Working #LI-Hybrid, Temporary for two years

With the increasing diversity of Novartis' portfolio, the need for drug-device combination product documentation packages is increasing. As such, we are searching for an Associate Director with combination product development experience to lead the creation of strong documentation-packages.

Job Description
As a member of the device sub team for your project(s) you will be the main contact & coordinator for all project-specific documentation tasks related to data driven, innovative documentation approaches with a focus on challenging projects and platforms.

About the Role

Your responsibilities include but are not limited to:

- Leading documentation strategies for highly complex, pioneering Drug-Device combination products including pilot documents fulfilling the current Health Authority (FDA, EMA) expectations.
- Leading data driven improvements enabling the conversion of regulatory expectations to solid source documentation using existing systems such as Polarion
- Building the link between technical development and Regulatory Affairs to enhance the mutual understanding
- Leading timely evaluation and implementation of design changes
- Contributing to technical development and regulatory relevant decisions
- Authoring pilot documents that fulfil the current Health Authority expectations
- Leading x-functional overarching initiatives; mentoring (senior) experts
- Contributing to and reviewing regulatory documents, supporting product registrations, presenting to Health Authorities.

Essential Requirements:

- Master or PhD in engineering or functional/chemical/bio analytics or equivalent and minimum 20 years' experience in pharmaceutical industry, including drug-device combination product development
- Demonstrated experience of technical development of medical devices/device constituent parts of combination products (e.g. autoinjectors)

- Demonstrated experience of current Health Authority expectations for combination products (contributing to and reviewing of submission relevant documentation)
- Strong knowledge of and working experience with EU Medical Device Regulations, ISO 13485 and US regulations 21 CFR Part 4 and 21 CFR Part 820
- Strong experience and interest in driving improvements of development/documentation approaches and/or Quality Mgmt System (e.g. design control)
- Leading and influencing in global matrix organization; strong communicator & listener, actively reaching out, able to understand and connect across functions
- Collaborative spirit, self-driven attitude, high level of learning agility • Fluent in English (oral and writing)

Commitment to Diversity and Inclusion: Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

Accessibility and accommodation
Novartis is committed to working with and providing reasonable accommodation to all individuals. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to receive more detailed information about the essential functions of a position, please send an e-mail to inclusion.switzerland@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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

Division
Development
Business Unit
Innovative Medicines
Location
Switzerland
Site
Basel (City)
Company / Legal Entity
C028 (FCRS = CH028) Novartis Pharma AG
Functional Area
Research & Development
Job Type
Full time
Employment Type
Temporary (Fixed Term)

Shift Work
No
Apply to Job

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

Job ID
REQ-10025665

Associate Director Medical Device Process Innovation and Excellence (f/m/d)

Apply to Job

Source URL: *https://prod1.id.novartis.com/careers/career-search/job/details/req-10025665-associate-director-medical-device-process-innovation-and-excellence-fmd*

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
2. https://talentnetwork.novartis.com/network
3. https://www.novartis.com/careers/benefits-rewards
4. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Basel-City/Associate-Director-Medical-Device-Process-Innovation-and-Excellence--f-m-d-_REQ-10025665
5. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Basel-City/Associate-Director-Medical-Device-Process-Innovation-and-Excellence--f-m-d-_REQ-10025665