NOVARTIS

Director, Regulatory Affairs (Digital Medical Devices)

Job ID
REQ-10064222
мар 17, 2026
Великобритания

Сводка

Office Location: London (The Westworks), United Kingdom
#LI-Hybrid (12 days per month on-site if living within 50 miles to our London office)
#LI-Remote (if living beyond 50 miles to our London office)

We're looking for a seasoned regulatory expert to lead global strategy and execution for digital medical devices, including Digital Health Technologies (DHTs) and Software as a Medical Device (SaMD). This role drives regulatory direction across development, registration, and post-approval, ensuring timely, compliant decisions that balance patient safety and business needs.

About the Role

Major accountabilities:

- Develop and communicate digital medical device regulatory strategies for projects across the life cycle (Development and On-Market).
- Ensure digital device regulatory risks and key issues are communicated in a timely manner to project teams and other stake holders. Represent de-partment in cross-functional project teams as appropriate.
- Provide Novartis technical and clinical functions clear, concise guidance on current digital device regulatory requirements to support planning and decision making.
- Lead and implement global digital device submission activities (planning, authoring, reviewing, coordination, submission) for assigned projects/products
- Lead the identification of the required documentation and content, compliance and timelines issues for global digital device submissions and work collaboratively with cross-functional teams for the delivery of technical source documents in accordance with project timelines.
- Author and/or review compliant digital device documentation for HA submissions, applying agreed digital device global regulatory strategies, current regulatory standards and guidelines.
- Lead, prepare and communicate digital device risk management assessments, contingency plans, and lessons learned on major submissions and escalate as appropriate.
- Drive digital device related interactions with Health Authorities globally.
- Knowledge sharing, e.g. provide coaching within Regulatory Affairs and other functional areas.
- Development of new digital device regulatory guidance, policy, and processes.

Minimum requirements:

- Science Degree (e.g. Engineering, Chemistry, Pharmacy, Biochemistry, Biotechnology, Biology) or equivalent.
- Significant experience in the digital device industry or regulatory agency with responsibility for digital devices.
- Significant knowledge/experience in digital device regulatory submission and approval processes.
- Demonstrated practical experience in digital device regulatory affairs (e.g. IDE/510(k)/PMA filings; application of digital device quality management systems, software validation, human factors, design verification/validation requirements).
- Experience of leading regulatory health authority interactions, inspections and/or external advocacy/regulatory policy.
- Ability to critically evaluate data from a broad range of scientific disciplines.
- Knowledge of digital device development and life cycle management.
- Ability to work independently and successfully with global project teams and prioritize activities considering timelines and workload.

Commitment to Diversity & Inclusion

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

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)

Дивизион
Development
Business Unit
Development
Место
Великобритания
Сайт
London (The Westworks)
Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.
Alternative Location 1
Home Worker, Великобритания
Functional Area
Research & Development

Job Type
Full time
Employment Type
Regular
Shift Work
No

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