Expert Regulatory Writer (80-100*) " >

Job ID
329360BR
Oct 22, 2021
Switzerland

Job Description

160+ projects in development including over 60 new molecular entities, 26 major approvals, reaching over 769 million patients! And that's just in 2020. This is your chance to help reimagine medicine in 2021.
Novartis is looking for dedicated individuals to join our Regulatory Writing team and contribute to developing our pipeline of drugs and biologics into innovative therapies for our patients worldwide. Read on for details about the role and how you can join a world-class organization at the forefront of the industry and how you can further your career In this role, you will write, review and/or manage the production of high quality clinical and safety documentation for submission to regulatory authorities in support of marketing applications. You will provide authoritative documentation-related consultancy to other line functions. You will coach/mentor and/or train less experienced writers.

Your responsibilities will include:
• Author, review and/or independently manage high quality clinical and safety documents for health authorities.
• Lead writing team for complex submissions, contributing to key messaging and pooling strategy, providing expert content guidance for) clinical submission documents, contributing to statistical analysis plans and presentation of outputs, and ensuring compliance of documentation to internal company standards and external regulatory guidelines.
• Provide content and strategic expertise on the clinical portions of the CTD to cross-functional teams.
• Program Writer for large and/or complex programs ensuring adequate medical writing resources are available for assigned program and consistency between documents.
• Lead process improvement in Regulatory Writing and Submissions and cross-functional initiatives and/or activities.
• Coach and/or mentor less experienced writers.

Diversity & Inclusion / EEO

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

Minimum Requirements

What you'll bring to the role:
• Min 6+ years medical writing experience or other relevant pharma industry experience combined with scientific and regulatory knowledge, plus expert knowledge of medical writing processes.
• Expert knowledge of the global registering of drugs, and repeat experience and demonstrated record of leading complex submissions.
• Excellent communication skills.

• Proven ability to prioritize and manage multiple demands, projects and cross-functional teams.
• Future-oriented perspective and strong ability to define and solve complex problems.

*Some restrictions on flexible working options may apply and will be discussed during interview if applicable.

WHY NOVARTIS?

769 million lives were touched by Novartis medicines in 2020, and while we're proud of this, we know there is so much more we could do to help improve and extend people's lives.

We believe new insights, perspectives and ground-breaking solutions can be found at the intersection of medical science and digital innovation. That a diverse, equitable and inclusive environment inspires new ways of working.

We believe our potential can thrive and grow in an unbossed culture underpinned by integrity, curiosity and flexibility. And we can reinvent what's possible, when we collaborate with courage to aggressively and ambitiously tackle the world's toughest medical challenges. Because the greatest risk in life, is the risk of never trying! Imagine what you could do here at Novartis!

Join our Novartis Network:

If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here:
https://talentnetwork.novartis.com/network
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Global Drug Development
Business Unit
GDO GDD
Location
Switzerland
Site
Basel
Company / Legal Entity
Novartis Pharma AG
Functional Area
Research & Development
Job Type
Full Time
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Regular
Shift Work
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