Senior Associate QC Specialist " >

Job ID
320178BR
Sep 03, 2021
India

Job Description

300! That's the approximate number of documents you will contribute to as a new QC Associate based at Novartis in Hyderabad. As part of Submission Management and Quality team you will be responsible for the clinical content review and identifying inaccuracies for preclinical and/or clinical documents (e.g. primarily Clinical Study Reports (CSRs) and High Level Documents (HLDs) contained within New Drug Applications (NDA), 120 day Safety Updates and Marketing Authorization Applications (MAA) filed by Novartis Pharmaceuticals to governmental Health Authorities around the globe.

Your responsibilities include, but are not limited to:

• To write and/or edit under guidance high quality clinical and safety documents such as non- registration Clinical Study Reports (CSR), Development Safety Update Reports (DSUR), Clinical Trial Registration Documents or Patient Narratives
• May act as documentation consultant in CTTs to ensure compliance of documentation to internal company standards and external regulatory guidelines. May act as liaison between CTTs and publishing teams to ensure timely delivery of final documents for publishing.
• Assess validity of clinical/scientific interpretation described in preclinical, clinical and device documents provided to governmental Health Authorities and identify discrepancies.
• Provide independent clinical/scientific review of clinical summary documents (such as SCE, SCS, SCP, SBP and CO) and identify content inaccuracies prior to submission to Health Authorities, e.g.: to Verify accuracy (100% review) of all factual statements within summary document text compared to post-text sources cited.
• Verify numeric accuracy (100% review) of all data cited throughout text and hand derived in-text tables compared to post-text sources cited. Verify appropriateness of all internal/external citations noted within summary document.
• Develop and provide factual evidence to support all discrepant findings for review and approval by Submission Team or document authors.
• Mentor/Train new or junior QC specialists to achieve department set goals for excellence in quality review. Provide cross-divisional support through quality review of divisional specific documents such as CSRs, CERs, Tabular Listings, etc.
• Compile comprehensive documents containing discrepancies identified from QC reviews (with corresponding factual 'Evidence') for each clinical summary document in preparation for resolution meeting. Lead resolution of discrepant findings with Submission Team or author, including documenting actions, verifying implementation of findings and archiving results.

Minimum Requirements

• Bachelor's degree required, advanced degree in scientific /health or management discipline preferred Fluent

English language capability required
• >5 years’ experience in clinical research with proven proficiency in global clinical development.
• Ability to understand, interpret complex clinical/scientific and statistical data and effectively communicate inaccuracies in clinical summary documents to authors.
• Demonstrates strong medical/scientific communications (written); Proven ability to work independently to deliver clinical summary document discrepant findings within defined timelines (e.g. 4 working days).
• Previous experience in clinical development of NDA/MAA deliverables with knowledge in world-wide regulatory requirements for drug registration (e.g., Common Technical Document)
• Solid computer technical skills (Word/Excel/PDF development) and ability to learn new systems quickly.

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!
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.
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
Division
Global Drug Development
Business Unit
GDO GDD
Location
India
Site
Hyderabad, AP
Company / Legal Entity
Nov Hltcr Shared Services Ind
Functional Area
Research & Development
Job Type
Full Time
Employment Type
Regular
Shift Work
No
Apply to Job Access Job Account

Job ID
320178BR

Senior Associate QC Specialist

Apply to Job Access Job Account

Source URL: *https://www.novartis.com/careers/career-search/job-details/320178br/senior-associate-qc-specialist*

List of links present in page

- https://www.novartis.com/careers/career-search/job-details/320178br/senior-associate-qc-specialist
- https://sjobs.brassring.com/TGnewUI/Search/home/HomeWithPreLoad?PageType=JobDetails&partnerid=13617&siteid=5260&jobid=2737130&AL=1