Manager, Quality Assurance TRD " >

Job ID
328816BR
Sep 30, 2021
USA

Job Description

2 weeks after the birth of your child you realize they aren't meeting critical developmental milestones and after months of doctor's appointments you are told your baby has a rare neurological disease that would impact how they would live their lives. This is the reality of parents whose children have Spinal Muscular Atrophy (SMA) and it's the reason why we at Novartis Gene Therapies are laser focused on bringing hope and possibility to those devastated by rare genetic diseases.

The Manager, QA Technical Research Development, manages projects and processes to support departmental portfolio, projects and objectives according to agreed timelines and standards.

Your Key Responsibilities:
• Leads or supports early phase projects or support more complex projects with mentoring.
• Ensures that compliance with cGMP is maintained in TRD CGT.
• Supports a discipline and/or provide a service individually or within a team of associates.
• May provide functional expertise to Line Unit and other QA Units in area of responsibility.
• Writes, reviews, decides on approval and/or release of GMP-relevant deliverables and or/ related tools as per area of responsibility in order to ensure compliance with cGMP and project quality deliverables.
• Manages project related activities (e.g. TRD product portfolio, development of new tools, processes, Quality initiatives, Quality Manual implementation, Quality Plans, Quality Risk Assessments, training activities, qualification and facility upgrade activities, IT validation projects) as per area of responsibility.
• Supports Project management functions as a project team member.
• Provides quality support and guidance to TRD line functions in GMP related topics as per area of responsibility.
• Provides support and guidance to TRD line functions to implement TRD Development Quality Practices (DQP) for non-GMP activities.
• Complies with internal and external guidelines regarding quality and safety (Quality Manual, regulatory cGMP guidelines, Health Authority guidance, SOPs etc.).
• Other relates duties as assigned.

Diversity & Inclusion / EEO

The Novartis Group of Companies are Equal Opportunity Employers and take pride in maintaining a diverse environment. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, gender, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status. We are committed to building diverse teams, representative of the patients and communities we serve, and we strive to create an inclusive workplace that cultivates bold innovation through collaboration and empowers our people to unleash

their full potential.

Minimum Requirements

What You'll Bring to the Role:
• Bachelors in biology or biochemistry with 7 years' relevant experience in pharma industry.
• Masters preferred.
• Good knowledge of cGMP, working knowledge in technical development, production or QA. Good knowledge in the CGT space.
• Sound scientific, technical and regulatory knowledge.
• Good organizational and decision-making skills.
• Good and proven ability to analyse and evaluate cGMP compliance.
• Fluent English required (oral & written). Good skills in site (local) language desired (oral).

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!

Novartis Gene Therapies Benefit Summary:
Annual bonus, long term incentive, health insurance, paid vacation/holidays, potential flexible working arrangements (based on role) and an employee recognition program are available for this position, among many other benefits provided to employees of Novartis Gene Therapies.

Please note this job description is not designed to cover or contain a comprehensive listing of activities, duties or responsibilities that are required of the employee for this job. Duties, responsibilities and activities may change at any time with or without notice.
Division
Global Drug Development
Business Unit
QA GDD
Location
USA
Site
San Diego, CA
Company / Legal Entity
Novartis Pharmaceuticals
Functional Area
Quality
Job Type
Full Time

Employment Type
Regular
Shift Work
No
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Job ID
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