

AD, Cell Therapy Operations Manager

Job ID
REQ-10022718
Sep 27, 2024
USA

Summary

As an Associate Director, Cell Therapy Operations Manager, you will develop, coordinate and support implementation of the plan to train and qualify apheresis and treatment centers to be able to treat patients with Novartis Cell Therapy products both in commercial and clinical trial setting. In this role, you will manage CAR-T center operations supporting qualified key staff including HCPs and study nurses as well as apheresis unit and cell laboratory staff, ensuring that the centers are operating to safely and efficiently treat patients with our products and supporting continuous operations improvements.

#LI-Remote

About the Role

The AD, Cell Therapy Operations Manager requires up to 60-70% travel to cover the territory of Ohio, Michigan, Indiana, West Virginia and Pennsylvania. This role can be based remotely anywhere in the U.S., if the employee is based near a major airport (there may be some restrictions based on legal entity). Please note that this role would not provide relocation as a result. The expectation of working hours and travel (domestic and/or international) is defined by the hiring manager.

Key Responsibilities:

- Build strong relationships with internal and external territory key stakeholders to provide best in class customer support. Partner and execute a One Team approach with commercial onboarding teams, including Strategic Account Managers, Kymriah CARES and Apheresis Quality to support implementation of site onboarding as a supplier and end-user of commercial manufactured product.
- Coordinate and guide a One Team approach adhering to GCP with internal and external stakeholders in clinical trial support & site onboarding across teams to include Novartis Medical, Novartis Trial Management, Clinical Customer Support, Apheresis Quality and assigned site Clinical Research Associates to ensure successful clinical trial site participation.
- Provide highly engaged site operations support to approved external site staff with a focus on providing guidance as well as continued training based upon approved Novartis messaging through customer facing with ordering physicians, clinical trial Primary Investigators, BMT coordinators, pharmacy, Infusion Nursing Teams, Clinical Trial Coordinators, as well as apheresis units and cell laboratory staff.
- Ensure that sites provide a high-quality consistent supply of starting material for the GMP manufacturing of Cell Therapy products through assessment, approval, initiation, and monitoring of incoming material batches from assigned territory sites.
- Conduct investigations in partnership with Apheresis Quality within the Novartis quality platform through assigned deviations related to incoming specifications, chain of identity breaches, and other related

deviations of Novartis manufacturing specification as well as investigating manufacturing results when requested. Oversight of the end-to-end process of deviations in close coordination with all relevant functions to ensure closure of deviation within the due date assigned to each deviation.

- Deliver onsite support for first order, or any time after due to site inactivity; recent site deviations, or due to significant changes in Novartis processes requiring site refresher training. Onsite activities for first collection or any time after will be dependent upon assessments and can be related to cell collection, cell processing and/or shipment of starting material as well as the receipt of final product through the administration of the final product according to Novartis specifications and processes as well as local laws and regulations
- Ensure best practice sharing amongst Cell Therapy Operations and escalate impediments to onboarding in a timely manner to leadership.
- Conduct Periodic Quality Reviews of sites in accordance with Novartis Standard Operating Procedures and meet all timelines associated (PQRs). Manage follow-up of internal and external activities in collaboration within the Novartis One Team approach.
- Complete internal training as a Certified Novartis Investigator and function fully within the Novartis quality tracking program, in partnership with the Apheresis Quality team to ensure all investigations and/or quality events to site activities are completed/evaluated while providing follow-up including, but not limited, to onsite refresher training to the sites supplying the cell material as appropriate.
- Partner with internal stakeholders in relation to management of final product deviations/issues and implement trainings plans

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Essential Requirements:

- Bachelor's degree required in science and/or medical, business, or nursing
- Minimum of 7 years external partner (supplier, customer, contractor) facing role experience and/or leadership experience in healthcare which may include Pharmaceuticals
- Experience in at least one of the following areas: 1) interacting and supporting external partners (e.g., clinical site coordinator, external supplier relations, key account manager); 2) hospital stakeholder management role or a customer facing role in pharmaceuticals; or 3) working in a pharmaceutical or hospital GxP environment (e.g., Medical, clinical, manufacturing, marketing, market access, patient services, hospital, cell processing, or apheresis)
- Demonstrated ability to engage and train groups/individuals with confidence while balancing an operational and strategic mindset
- Proven project management experience, with ability to manage several deliverables in parallel
- Comfort with navigating interactions with various subject matter experts across medical and administrative personnel at all levels and in large numbers
- Strong negotiating, observational, listening skills to engage stakeholders at all levels with humbleness and openness
- Ability to travel up to 60%-70% within North America and the ability to arrange travel quickly to meet customer/patient needs onsite at certified treatment centers. Flexibility to work outside regular business hours, including evenings and weekends to attend meetings/conferences as well as site support due to transport of material from different time zones

Desirable requirements:

- Direct experience/knowledge related to apheresis, blood or tissue collection, or cryopreservation operations is preferred
- Residency in the territory of Ohio, Michigan, Indiana, West Virginia and Pennsylvania is preferred

Field role with a company car: Driving is an essential function of this role, meaning it is fundamental to the purpose of this job and cannot be eliminated. Because driving is an essential function of the role, you must have a fully valid and unrestricted driver's license to be qualified for this role. The company provides reasonable accommodations for otherwise qualified individuals with medical restrictions, if an accommodation can be provided without eliminating the essential function of driving.

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

The pay range for this position at commencement of employment is expected to be between \$151,200 and \$226,800/year; however, while salary ranges are effective from 1/1/24 through 12/31/24, fluctuations in the job market may necessitate adjustments to pay ranges during this period. Further, final pay determinations will depend on various factors, including, but not limited to geographical location, experience level, knowledge, skills and abilities. The total compensation package for this position may also include other elements, including a sign-on bonus, restricted stock units, and discretionary awards in addition to a full range of medical, financial, and/or other benefits (including 401(k) eligibility and various paid time off benefits, such as vacation, sick time, and parental leave), dependent on the position offered. Details of participation in these benefit plans will be provided if an employee receives an offer of employment. If hired, employee will be in an "at-will position" and the Company reserves the right to modify base salary (as well as any other discretionary payment or compensation program) at any time, including for reasons related to individual performance, Company or individual department/team performance, and market factors.

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>

EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers who are focused on building and advancing a culture of inclusion that values and celebrates individual differences, uniqueness, backgrounds and perspectives. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, sex, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status. We are committed to fostering a diverse and inclusive workplace that reflects the world around us and connects us to the patients, customers and communities we serve.

Accessibility & Reasonable Accommodations

The Novartis Group of Companies are committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the application process, or to perform the essential functions of a position, please send an e-mail to us.reasonableaccommodations@novartis.com or call +1(877)395-2339 and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

Division

US

Business Unit

Innovative Medicines

Location

USA

Site

Field Non-Sales (USA)

Company / Legal Entity

U014 (FCRS = US014) Novartis Pharmaceuticals Corporation

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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