Site Head Manufacturing Science & Technology

Job ID
REQ-10022416
Sep 13, 2024
Estados Unidos

Resumen

At Advanced Accelerator Applications, a Novartis company, we are committed to leading innovation in nuclear medicine and delivering the next generation of targeted radioligand therapy (RLT) to cancer patients. We are looking for a skilled pharmaceutical industry professional with experience building teams in start-up environments to lead the Manufacturing Science and Technology (MS&T) function at our new Carlsbad site.

As the Site Head MS&T, you will lead the site's MS&T organization and activities, including Commissioning and Qualification (C&Q) activities. You will be responsible for maintaining and improving scientific oversight of the manufacturing processes and technical changes, technical knowledge and capabilities, and ensuring product and technical stewardship across functions at the Carlsbad Site.

This role reports operationally into the Carlsbad Site Head and will be part of the Site Leadership Team. The role has functional reporting to both the Global MS&T and site Engineering organizations.

About the Role

Key Responsibilities:

- Ensure robust product stewardship for all products manufactured at the site, and end-to-end technical oversight of product manufacturing processes, at all stages of the commercial lifecycle.
- Set objectives and develop vision for department. Manage the MS&T career path, succession planning, training program and career progression within the site. Drive a culture of quality and compliance across the MS&T team.
- Lead site activities related to technology transfer, change management and process improvement. Encourage the identification and implementation of new and innovative technologies. Propose business cases as needed.
- Ensure oversight of technical changes and lead end-to-end change control management related to relevant technical issues, working cross-functionally as required. Contribute to change records as impact assessor and action owner per Novartis change management requirements. Support deviation closure as a technical resource to ensure effective product impact assessment and root cause analysis. Own CAPAs as appropriate to ensure compliant and timely closure.
- Support excellence in manufacturing by setting standards and technical capability development and deployment. Identify and address process issues, maintaining the state of control of the products. Ensure technical excellence in operational start-up for new manufacturing equipment and areas. Ensure technical

expertise for manufacturing equipment operation is taken into account for CAPEX projects.

- Lead execution and maintenance of site Validation Master Plan activities including the annual revalidation activities such as: aseptic processing, media fills, equipment requalification, and continuous improvement. Support C&Q activities related to the site build and initial start-up.
- Act as the interface for the site with the relevant Health Authorities for technical issues. Review and release regulatory proposals or information required for regulatory filings.
- Work with the other Site MS&T teams and networks of the relevant platform/cluster, driving reapplication of standard work processes, reapplication of best practices. Ensure that quality and compliance improvement and savings opportunities locally implemented are rapidly re-applied globally.
- Work collaboratively with functional management in the global MS&T organization as well as Technical Research and Development, to ensure that Technical Life Cycle Management (TLCM) projects are identified, prioritized and delivered with excellence.

Essential Requirements:

- BSc degree in engineering, biology, chemistry, or related field or equivalent relevant experience
- 7+ years' experience in pharmaceutical MS&T roles with demonstrated experience driving quality, compliance and process improvement in an organization.
- Direct experience in an aseptic manufacturing setting.
- Expert in reviewing and writing technical reports.
- Fundamental understanding of standard pharmaceutical analytical testing

Desirable Requirements:

- Prior experience with radio pharmaceuticals is a plus.
- Additional relevant experience such as pharmaceutical formulation, process development, or manufacturing technology, is preferred.

Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: novartis-life-handbook.pdf

Commitment to Diversity and 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 $144,000 and $216,000 per 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

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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.

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