Compliance Engineer

Job ID
REQ-10036341
Jan 17, 2025
Japan

Summary

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About the Role

- Supports projects in all matters of Qualification (Risk Management), Documentation, GxP Training to comply with external regulatory requirements, Novartis quality manual and Novartis GPE standards.
- Conducts project reviews and vendor quality audits where required and ensures that the standard global quality procedures are implemented and followed.
- Participate NTO Best Practice Network in Engineering Compliance.
- Networks with divisional quality functions.
- Provides engineering compliance by GMP training.
- Conducts Rolling Engineering Assurance to strengthen and improve Engineering Compliance in the sites.
- Enables and facilitates the sharing and leveraging of local best practices equipment qualification.
- GPE GxP
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- NTO
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- GMP
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- Possesses knowledge in areas of regulatory compliance in engineering(projects,
- lifecycle management) in regulated pharmaceutical Engineering.
- Has knowledge in GxP regulations, Qualification, Validation, CSV, GPE standards.

- Possesses business acumen to internal & external knowledge and external guidelines.
- Maintains knowledge in quality management principles, regulatory and legal requirements
- Able to build Internal and external networking smoothly
- Good communication skills (Fluent Japanese and Business level of English is required)
- Degree in Engineering Local and English essential, others helpful
- Preferable of Engineering (Mechanical, Electrical, Chemical) degree in university or equivalent professional education certificate.
- Several years of experience Validation / Qualification in regulated
- Experience working pharmaceutical firm is required
- Project Management experience is helpful.
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- GxP CSV GPE
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- midcareer-r.japan@novartis.com

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

Division
Operations
Business Unit
Innovative Medicines

Location
Japan
Site
Sasayama
Company / Legal Entity
JP99 (FCRS = JP005) Ciba-Geigy Ltd.
Functional Area
Technical Operations
Job Type
Full time
Employment Type
Regular
Shift Work
No
Apply to Job

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Compliance Engineer

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