NOVARTIS

Data Integrity Lead

Job ID
REQ-10015862
Sep 03, 2024
USA

Summary

The Data Integrity Lead has ultimate accountability and responsibility for all aspects of the Millburn Site Data Integrity Program, including, creation, implementation, defining, monitoring and reporting KPIs, creating solutions for KPI improvement and continuous improvement of the program.

Location: Millburn, NJ #LI-Onsite

About the Role

Key Responsibilities:

- Proactively drives establishment of Data Integrity culture through implementation and monitoring of the Data Integrity program individually and through the both the Millburn Data Integrity network and the Global Data Integrity network.
- Serves as the site subject matter expert for all DI-related inquiries/trainings and DI assessment tools.
- Identifies and maintains a network of functional Data Integrity (DI) Subject Matter Experts (SME)/ DI Champions within appropriate GxP functional areas (e.g. Manufacturing, Maintenance, MS&T, engineering, QA Ops, QC, etc.).
- Determines strategy and collaborates with functional DI SMEs/DI Champions to drive behavioral change management activities to strengthen DI culture.
- Drives continuous/sustainable improvement in detecting and mitigating DI risk by working with SMEs to embed DI focus in existing site programs, for example, self-inspection program, continuous improvement program, Gemba walks, etc.
- Manages/Leads DI topics at site in investigations, rapid alerts, reviews and audits related to Data Integrity for both internal Novartis and external parties.
- Facilitates the identification of high-risk data processes and systems (via risk assessment, gap assessment, data mapping, etc.).
- Identify and champion opportunities for mid and long-term actions and strategies to reduce DI risk.
- Implementation of DI tools, training materials and guidance (e.g. DI Key cards, Data mapping optimization, audit trail review) at the site according to defined strategy.
- Support Production Management in creating a GMP/GDP culture on the shopfloor

Essential Requirements:

- BSc in Chemistry, Biology, Pharmacy, business, or related experience.
- Advanced Degree in Quality / Regulatory, Business, Healthcare, Pharmacy, or Scientific discipline preferred.
- 10 years' experience in Quality Systems, Quality / Regulatory Compliance, Operational GxP area(s)

(Manufacturing / Development), Quality Control, Quality Assurance, Supplier Quality and / or Post Market Quality within the pharmaceutical, diagnostic and / or medical device industries. Experience in advanced therapies (CGT, RLT, etc) is preferred.

- 5 years' of industry Data Integrity related experience.
- Prior experience with aseptic manufacturing is preferred.
- Cross-functional experience in a GxP regulated pharmaceutical industry (e.g Quality Assurance), clinical operations, PV, preclinical operations, manufacturing/engineering operations, Quality Management Departments or equivalent external consultant positions with experience in quality risk management through application of ALCOA+ principles and 21CFR Part 11 requirements. Strong operational background preferred.
- Knowledge of applicable cGMP regulations, for example, FDA Regulations (e.g., 21 CFR 4, 7, 11, 211, 212, 314, 803, 806, 820), ICH Guidelines,
- EU Pharmaceutical Regulations and Directives, ISO Standards, etc. Strong experience in supporting DI programs, risk analysis, project management, budget, communication and presentation skills.
- Ability to synthesize detailed information and provide clear communication and messaging across quality, manufacturing and supply chain.
- Prior experience successfully leading Health Authority Audits / Inspections, including, front room / back room, readiness, strategy and response to findings / observations.
- Experience working in a diverse, fast-paced, local and global SME matrix environment, with ability to drive and manage change.

The pay range for this position at commencement of employment is expected to be between $144,000 and $216,00 per year; however, base pay offered may vary depending on multiple individualized factors, including market location, job-related knowledge, skills, and experience. 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.

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Commitment to Diversity and Inclusion:

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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

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Business Unit
Innovative Medicines
Standort
USA
State
New Jersey
Site
Millburn
Company / Legal Entity
U469 (FCRS = US469) AAA USA Inc.
Functional Area

Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No
Apply to Job

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