CareerCross

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【外資大手製薬企業】GQP/QMS シニアアソシエイト

Job Information

Recruiter
en world Japan K.K

Job ID
1478067

Industry
Pharmaceutical

Job Type
Contract

Location
Tokyo - 23 Wards

Salary
5 million yen ~ 7 million yen

Work Hours
9:00〜17:30

Refreshed
November 14th, 2024 03:00

General Requirements

Minimum Experience Level
Over 3 years

Career Level
Mid Career

Minimum English Level
Business Level

Minimum Japanese Level
Native

Minimum Education Level
Bachelor's Degree

Visa Status
Permission to work in Japan required

Job Description

Responsibilities will include, but are not limited to the following:

- Ensure accurate and thorough compalint intake information, replacement need, troubleshooting with compainant, complainant follow- ups, product complaint investigations. trachking and trending of complaint data. Accurate reporting into the internal software system/QMS system, follow-up, communication to complaints, identification of trends, assisting with determining CAPA's
- Review each compaint assigned for accurate/missing information, comoplaint details further regulatory complaince actions, replacement needs, or unreported adverse events.
- Act as technical product subject matter expert and trouble shoot complaints with complainants
- Contact complainants for complaint follow up information, trouble shooting, and medical device replacement and returns
- Perform complaint investigations to determine root cause, identify resolution and respond to the complainants
- Issue complaint close-out notifications to complainants.
- Ensure Adverse Events reported through the complaint system or at patient follow-up are reported within one business day

- Ensure the reconciliation between the complaints report and Safety/Customer reports
- Support product/supplier changes, deviations and CAPAs, assisting with technical write up, impact assessment, and root cause analysis.
- Assist in maintaining the applicable GQP and QMS SOPs. • Check quality progress on a monthly basis as they relate to batch release, complaints, deviations, CAPAs', change requests or other relevant quality metrics. Powered by Purpose
- Asist internal process audits and external supplier audits as necessary.
- Actively work on Global and local Quality projects
- Support 3 officer activities and authority inspection

Experience/Knowledge/Skills

- Minimum 3 years' experience in a similar role within pharmaceutical or medical device industry
- Thorough knowledge of GMP, GQP and good documentation practice
- Experience in quality related complaint handling is preferred • Experience in working with an electronic Quality Management system is desired.
- Must have excellent communication skills (verbal and written).
- Must have ability to meet tight deadlines and be efficient, detail oriented, flexible, and a self-starter.
- Highly organized with a strong attention to detail, clarity, accuracy and conciseness.
- Works effectively across functions as a team player
- Highly proficient in Microsoft Office (Word, Excel, PowerPoint, Outlook).
- An uncompromising ethical standard and level of conduct are essential

Required Skills

Qualification/Certificate

- Bachelor's degree in life sciences or equivalent through experience

Other

- Must successfully exhibit Insmed's five (5) core corporate competencies of: Collaboration, Accountability, Passion, Respect and Integrity; along with any other position specific competencies
- Individuals must demonstrate the ability to interact successfully in a dynamic and culturally diverse workplace
- Non-smoker
- Travel up to 10% (domestic and international), some of which will be overnight in nature

Company Description