CareerCross

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【外資大手製薬企業】GQP/QMS シニアアソシエイト

募集職種

人材紹介会社
エンワールド・ジャパン株式会社

求人ID
1478067

業種
医薬品

雇用形態
契約

勤務地
東京都 23区

給与
500万円 ~ 700万円

勤務時間
9:00〜17:30

更新日
2024年06月27日 01:00

応募必要条件

職務経験
3年以上

キャリアレベル
中途経験者レベル

英語レベル
ビジネス会話レベル

日本語レベル
ネイティブ

最終学歴
大学卒： 学士号

現在のビザ
日本での就労許可が必要です

募集要項

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

スキル・資格

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

会社説明