INTRODUCTION

Integrum AB is an innovative and fast growing company that provides innovative systems for bone-anchored prostheses to improve the quality of life for people with amputations.

Integrum is now seeking to strengthen the team with a Quality and Assurance Engineer within operations to enable future international growth. The main responsibilities are to ensure quality compliance within the fields of post-market surveillance, supply chain, non-conformity and CAPA and product release.

ROLE DESCRIPTION

- Responsible for developing systems for collecting, analyzing and providing reports on non-conformity and complaint statistics to the organization
- Identify and report any quality or compliance concerns and take immediate corrective action as required
- Drive, investigate and analyze complaint cases and work with authorities regarding vigilance/ medical device reporting
- Drive and perform vigilance/medical device reporting and ensure that deadlines in relation to authorities for vigilance/medical device reporting are adhered to
- Drive and participate in the decision forums for CRB (Complaint Review Board) meetings
- Actively participate in and drive development and continuous improvement, maintenance of and adherence to documented processes, the development and implementation of employee training where necessary
- Ensure the awareness of quality, customer and statutory requirements throughout the organization
- Authority to initiate corrections, corrective and preventive actions to ensure safe and effective products and compliance with applicable quality regulations and standards
- Responsible for reviewing and approving final product release
- Actively participate in reviewing the specification of documents for purchasing products and components
- Responsible for driving and following up supplier complaints
- Ensure quality compliance and the optimization of quality system procedures relating to CAPA, complaint handling, adverse event reporting, product field actions and final product release
- Actively participate in validation project at suppliers to secure production
- Minimum of three years' professional experience of a similar role with in-depth knowledge of ISO 13485, FDA QSR, MDD and ISO 14971
- Experience of driving process development and continuous improvements
- Hands-on experience of vigilance/medical device reporting, NB audits is a merit
- Experience of working in a global and rapidly expanding company is seen as an advantage
- Excellent oral and written communication skills in both Swedish and English
- Relevant university degree in engineering, medical device technology or scientific field

QUALIFICATIONS

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PERSONAL SKILLS/SUCCESSFUL CANDIDATE

As a Quality Assurance Engineer, you have the ability to engage and involve the people around you in quality programs and continuous improvements. You enjoy a changing environment and have a good ability to prioritize and get things done. You are versatile and like challenges at both a detail and a high level. You are thorough and have a good understanding of the medical device regulations and related standards, as this is part of the daily work. You understand and enjoy the challenges in a changing and growing organization. The right person is not afraid to take the initiative and work to develop the organization to make a difference. For the right person, this role will be rewarding, stimulating and the start of a unique journey.

PLEASE SEND YOUR APPLICATION TO:

EMAIL: info@integrum.se