Geistlich

注册经理 RA Manager

部门：　注册部
Department：　RA Department

工作城市：　北京
Work Location：　Beijing

工作内容

- Local project management for product and product change registration (new submissions, re-certifications and changes) in China
- Continuous control of ongoing regulatory actions and regular reporting to and alignment with Geistlich Pharma Headquarters (GPAG HQ)
- Active exchange with GPAG HQ and other legal manufacturers during the submission process and communication with NMPA
- Authoring submission documents (e.g. statements, reports) for registrations in China, based on information from GPAG HQ and other legal manufacturers
- Translations (Chinese-English, English-Chinese)
- Professional judgment with regard to reporting of changes and variations
- Work out regulatory strategies for China including localization and local partnerships
- Regulatory Intelligence for China and education of HQ in this regard
- Active networking with regulatory professionals, associations and NMPA
- Plan and realize product testing (evaluate Chinese testing centers, select and support the process)
- Process Owner for Adverse event management at Geistlich Trading (Beijing) GPCN in coordination with Quality Assurance GPAG HQ
- Process Owner for product recalls at GPCN in coordination with Quality Assurance GPAG HQ
- Support and coordinate product recalls and FSCAs
- Represent RA during local audits and inspections
- Assist GPAG HQ during audits and NMPA inspections in CH
- Release and reg. approval of marketing materials (control of claims)
- IP and TM registration in China
- Management of department budget

任职要求

- University degree with related subjects
- English skills: business proficiency (written and verbal)
- Above 8 years of regulatory work experience in healthcare/medical device/pharma industries. MNC working experience is preferred.
- Good team management experience and ability.
- Strong sense of responsibility and learning ability.
- Good communication and cross-functional collaboration.