AusDiagnostics

Regulatory Affairs Associate – Devices

About AusDiagnostics
Headquartered within Sydney Australia, AusDiagnostics is a leading manufacturer of a range of molecular diagnostic instrumentation and reagents servicing human, veterinary and food diagnostics markets. We are committed to achieving excellence in all that we do, with the primary goal of improving patient healthcare within society.

JOB TYPE: Full Time
LOCATION: Mascot, Sydney NSW
MAIN DUTIES/RESPONSIBILITIES: • Assisting with all product registrations processes globally   • Driving compliance for all regulation requirements throughout the organization   • Advising on regulatory pathways and strategies for product submissions   • Conducting regular internal and external analysis to ensure adherence to all global regulatory directives for legal supply of IVD products   • Managing document control and approval processes for all QA/RA documentation, including SOPs   • Collecting, collating and evaluating scientific data   • Conducting QMS training   • Achieving corporate quality objectives of the business   • Building productive collaborative interactions with all stake holders within the business   • Managing product compliance and non-conformance reporting functions   • Supporting in R&D product translation to commercialization   • Managing customer advisory notification process   • Regulatory liaison for international matters relating to product file compliance / labelling   • Supporting in external audit preparations   • Conducting regular scheduled internal audits to ensure compliance to accreditation standards
ESSENTIAL SKILLS & REQUIRNMENTS   • Minimum Bachelor's Degree in related field   • 3 years previous experience in a similar role/industry   • Expertise in CE, IVDR, FDA and TGA regulations   • Previous work experience in RA supporting function within IVD manufacturing   • ISO 13485 compliance experience   • ISO14971:2019 Medical Devices   • ISO9001 Quality Management System

DESIREBALE SKILLS AND REQUIRNMENTS

- Immaculate attention to detail and organization skills
- Ability to communicate effectively with all key stake holders internally and externally
- Confident decision maker
- Aptitude for working with complex scientific data
- Excellent communication skills both written and oral
- Strategic minded
- Effective writing skills
- Critical thinking and data analysis skills
- Effective time management skills
- The ability to work well cross-functionally and to develop productive and collaborative relationships
- Proactive and Solutions Focused
- Ability to work automatously and as part of team