

# JOB ADVERTISEMENT FOR MEDICAL REGULATORY AND COMPLIANCE OFFICER

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## JOB TYPE

- Entry-level
- Permanent
- Full Time

## INTRODUCTION

Cell Path Services (Pty) Ltd is looking to employ a Medical Regulatory and Compliance Officer. The successful candidate will be responsible for ensuring that all employees are compliant with the rules and regulations of the South African Health Products Regulatory Authority (SAHPRA). The Compliance Officer will also be responsible for ensuring that the company Code of Conduct is in line with the Code ratified by our association bodies, the South African Medical Technology Industry Association (SAMEDI) and the Southern African Laboratory Diagnostics Association (SALDA). This role will require the successful candidate to update and implement company policies and procedures outlined by our ISO 9001:2015 Quality Management System.

As this is a small company, job roles will also extend into administration duties, such as compiling tenders, maintaining instrument service records, and assisting with quoting, invoicing, ordering and filing.

## DUTIES & RESPONSIBILITIES

- Preparation of regulatory documentation to ensure compliance with medical device regulations, as well as collate the necessary documentation for product market authorisation
- Implement and oversee the company ISO 9001:2015 Quality Management System
- Implementation of ISO 13485 before license renewal
- Product registration for SAHPRA and compilation of STED files
- Maintaining customer and supplier databases
- Compilation of technical dossiers and product files for CE-Marked products
- Compilation/filing of MSDS sheets and all product related essential documentation, including technical documentation
- Compilation of product risk analysis
- Attending compliance meetings and regulatory forums, and relaying the information to fellow employees
- Filing and keeping records of Certificates of Analysis and Certificates of Origin
- Compiling government tender documents, both hard copy and online
- Maintaining instrument service records, and liaising with engineers and customers
- Maintaining social media accounts

- Assisting with office administration
  - Taking phone calls
  - Quoting and invoicing customers
  - Placing product orders
  - Filing
  - Stock take
  - Completing waybills and delivery notes

## DESIRED EXPERIENCE & QUALIFICATION

- National Senior Certificate (Matric)
- Relevant Tertiary Qualification (BSc with experience in Business Science or a BCom with knowledge of a laboratory environment)
- 2 – 3 Years relevant experience

## SKILLS & REQUIREMENTS

- Excellent grasp of the English language
- Excellent Computer literacy
- Proficient in all Microsoft Office Software, specifically Word, Excel, PowerPoint, Access, and Outlook
- South African driver's license
- Interpersonal, communication and document drafting skills
- Ability to work independently and as part of a team
- Self-sufficient with the ability to take initiative on a task
- Knowledge of the QuickBooks Accounting System advantageous
- Prior experience in medical compliance advantageous

## REMUNERATION

R180 000 – R200 000 pa depending on experience and qualifications.

## APPLY

Please send your CV and cover letter to [sales@cellpathservices.co.za](mailto:sales@cellpathservices.co.za)  
Applications close on 20 October 2020