DIRECTOR REGULATORY AFFAIRS & QUALITY ASSURANCE

Reporting directly into the Chief Executive Officer, the QA & RA Director is responsible for maintaining and ensuring that the Company’s Quality Management System complies with FDA, ISO 13485 and international medical device regulatory standards.

Duties and Responsibilities

- The QA & RA Director will act as the management representative for Proxy Biomedical Ltd. The duty of this task is to act as the point of contact for all regulatory communication in the company, including incident reports, audits, registrations, etc.
- Establish, manage and maintain compliance with FDA QSR, including establishment registration, new product submissions, CAPA System.
- Establish, manage and maintain compliance with MDD 93/42/EEC directive, including CE Mark applications via Technical Files.
- Responsible for the quality and regulatory control for products in which Proxy Biomedical is the Legal Manufacturer.
- Manage and maintain compliance to ISO13485 requirements.
- Responsible for responding and reporting incidents to all approved markets.
- Responsible for the Customer Complaint System.
- Responsible for managing product failures and appropriate corrective actions.
- Responsible for defining the Company’s quality goals each year.

Managerial responsibilities

- Manage the Quality Assurance and Regulatory department.
- Develop yearly target budget and capital plan.
- Manage QA & RA expenditure against budget.

Education and Experience

- A bachelor of Science Degree with 10+ years’ experience in Quality Assurance and Regulatory affairs within the medical devices field of use.
- At least 2 years management experience