



Atlantic Therapeutics is a growing organisation with an exciting product that changes people's lives. We are building a team of people with the belief, passion and expertise to make our business a success and positively influence our customer's quality of life. Our vision is to enable millions of people each year to restore their pelvic floor, and thereby restore their control, confidence and active lifestyle.

Job Title **Associate Quality Engineer (Contract)**

Responsible for supporting the AT Quality Management System with respect to new product introductions. Supporting review of design validation and verification documentation and supporting the change management process for the release of product specifications.

What's important:

Document control and engineering change management experience.
Knowledge of design control processes including design verification and validation.
Knowledge of regulatory processes for EU and FDA product clearance.
Knowledge of Software Development Lifecycles and Risk Management systems would be an advantage.

The day to day:

Support the R&D team in processing requests through the Document Control process.
Support the quality review of design control documents.
Review and update of Quality Documentation.
Support the Quality Management process.
Generate and share reports on relevant quality metrics.
Support quality audits as required.

Where you've come from:

You will have a Level 7 qualification or above in a science or engineering discipline, with 2-3 years' experience in medical devices or other similarly regulated industry with a certified quality management system.

Who you are:

Strong attention to detail.
Knowledge of product certification testing requirements for active Medical Devices.
Knowledge of maintaining a certified Quality Management System.
Experience of EN/MDD/MDR, ISO13485 and FDA requirements.
Excellent Verbal and written communication skills.
Results orientated and a self-starter with the ability to work on own initiative.
Advanced Microsoft Office and reporting tool skills.
Strong project management skills.

How you work:

We have created a list of competencies that are required at different levels, for every role within our Company:



COMPETENCY

Communication
Interpersonal skills
Adaptability/Flexibility
Accomplishments/Results Orientation
Attention to Detail
Customer Service Orientation
Sales Orientation
Decision Making, Problem Solving & Judgement
Initiative & Innovation
Leadership
Planning & Organisation
Pressure Tolerance & Resilience
Supervising & Developing Others
Teamwork/Working with Others

ADVANCED/INTERMEDIATE/BASIC

Advanced
Intermediate
Intermediate
Advanced
Advanced
Advanced
N/A
Intermediate
Intermediate
Basic
Intermediate
Intermediate
N/A
Advanced