



**Maintaining quality and
regulatory compliance in
Medical Device companies:**

**Outsourcing the QA/RA
responsible role**



Introduction

In the rapidly changing medical products sector, regulatory and quality standards are constantly evolving due to new technologies and innovative devices. This dynamic environment poses challenges for companies, making a strong regulatory strategy and quality management system crucial. Quality Assurance and Regulatory Affairs (QARA) professionals play a key role in ensuring compliance with stringent standards and aligning with business goals.



WHAT IS THE ROLE OF THE QA/RA RESPONSIBLE IN A MEDICAL DEVICE COMPANY?

The QA/RA (Quality Assurance and Regulatory Affairs) responsible in a medical device company plays a critical role in ensuring that products meet all regulatory standards and quality benchmarks. This position entails a broad range of functions that cover both quality assurance and regulatory compliance.

**QUALITY
ASSURANCE**

**REGULATORY
AFFAIRS**



WHAT ARE THE QA/RA RESPONSIBLE PERSON'S ACTIVITIES?

Among the responsibilities that come with the position, the following are the main activities that will ensure the correct implementation and maintenance of the requirements applicable to medical device companies:

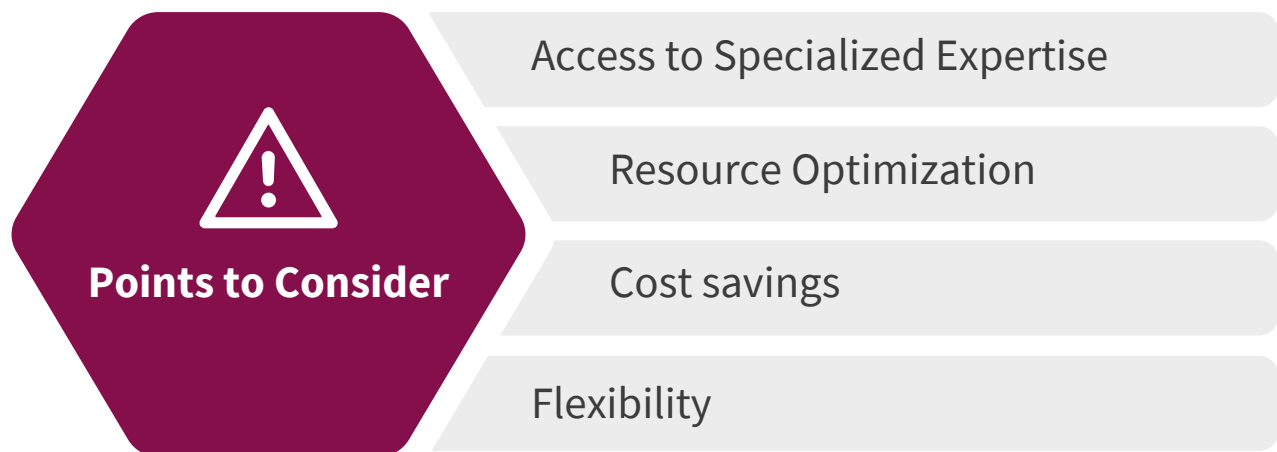


Overall, the QARA Responsible is essential in guaranteeing that a medical device company operates within the regulatory framework and maintains high standards of quality, ultimately ensuring the safety and efficacy of its products.



WHY OUTSOURCE QA/RA ACTIVITIES?

Outsourcing QARA functions can be a strategic decision to improve a company's agility, reduce operational costs and ensure compliance with the challenging regulatory requirements of the medical device industry.



Outsourcing QARA responsibilities can offer several advantages to a medical device company. Here are some key points to consider:

- **Access to Specialized Expertise:** Outsourcing allows tapping into a pool of professionals who are experts in national and international medical device regulations and quality management systems, ensuring compliance with complex standards.
- **Efficient Use of Resources:** By delegating QARA responsibilities, the company can concentrate on core activities such as product development and market expansion, while experts handle the quality and regulatory aspects.
- **Cost Efficiency:** It reduces the need for in-house training and hiring specialized staff, leading to significant cost savings, especially for companies that may not require full-time QARA staff.
- **Flexibility:** External QA/RA support can be summoned on an as-needed basis, offering a solution to handle excess workload during peak times without long-term obligations.



WHY WORK WITH US?

ASPHALION's experts have delivered solutions to over 1,000 Pharmaceutical, Biotechnological and Medical Technology companies from more than 50+ countries in over 5,000 projects covering non-clinical and clinical development, CMC, dossier writing, regulatory procedures, vigilance, eSubmissions and data management for both medicinal products and medical devices.

Reasons to outsource QARA responsible with Asphalion:

1. High Experience in Medical Devices
2. Highly qualified personnel
3. ISO 13485 certified
4. Adaptability to meet the unique needs of each company
5. Confidentiality



Multidisciplinary team:
clinical & regulatory affairs
and quality assurance



Pragmatic approach to
guide medtech
developers



Experience with a wide
variety of medical
technologies



Flexible collaboration
model for start-ups, SMEs
and large companies



Optimization of
Time to Market



Tailored services

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www.asphalion.com



medtech@asphalion.com



+34 93 238 59 45



Author

Itxaso Beltrán de Guevara
Medical Device Officer