Mitelos
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08009 Barcelona
Spain
www.mitelos.com

Quality & Regulatory Affairs Technician (Barcelona / On-site)

The selected candidate will join a team responsible for ensuring compliance with applicable requirements for our medical devices and cosmetic products, in accordance with Regulation (EU) 2017/745 (MDR), EN ISO 13485, and other applicable regulatory requirements in the markets where the company operates.

Main Responsibilities:

- Activities related to the maintenance and continuous improvement of the Company Quality Management System (QMS) in compliance with EN ISO 13485.
- Collaboration in the preparation, review, and update of Technical Documentation for medical devices and Product Information Files (PIFs) for cosmetic products.
- Ensuring ongoing compliance with the requirements of Regulation (EU) 2017/745 (MDR).
- Preparation and management of documentation for audits, certification activities, and regulatory assessments.
- Providing regulatory support for the entry into new international markets.
- Preparation, review, and approval of product labelling, Instructions for Use (IFU), and packaging materials, in collaboration with clients, translators, and designers where applicable.

Candidate Profile:

- Degree in Life Sciences, Pharmacy, Biotechnology, Quality Management, or related disciplines.
- 2–3 years of experience in Quality Assurance and/or Regulatory Affairs within the medical device and cosmetic sector.
- Solid knowledge of MDR 2017/745, EN ISO 13485, and cosmetic regulation (Regulation (EC) No 1223/2009).
- Strong command of English (written and spoken).
- Highly organized, team-oriented, detail-oriented, proactive, solution-driven, and capable of working autonomously.
- Advanced user of Microsoft Office Suite, particularly Word and Excel.

Interested candidates must write to esoler@mitelos.com and jcolome@mitelos.com