SILVIA MANCINI, BSc

QUALITY ASSURANCE AND REGULATORY SPECIALIST

Silvia Mancini has a BSc in biotechnology, specializing in industrial processes. She received a certificate in aseptic processing, a master's certificate in biopharmaceutical regulatory affairs, and is in the process of completing an online master’s program in regulatory affairs, covering drugs, biologics and medical devices.

Ms Mancini’s professional experience includes various positions of responsibility, including 7 years in the United States, first with a multinational aseptic compounding pharmacy, and then with a medical device company, followed by 2 years in Canada, working with a food company. She also worked as a quality control analyst for a large multinational company in Italy. Ms. Mancini has direct experience of working with the US FDA and European Notified Bodies, including providing compliance support for EN ISO 13485:2016.

Ms. Mancini joined Donawa Lifescience Consulting in January 2019. and provides client support in the following areas:

- Medical Device/IVD Pre-Sub and 510(k) review and preparation
- Medical Device/IVD Technical Files review and preparation for CE marking purposes
- Assisting clients with EN ISO 13485:2016 compliance
- Assisting clients with US FDA, EU MDD and EU MDR quality system compliance
- Preparation and submission to national Competent Authorities (CAs) other documents related to regulatory requirements (such as Free Sales Certificates, CLIA, vigilance reports, etc.)
- Assisting clients with device registration in the Italian Ministry’s on-line databank