

With a strong diagnostic and microbiology experience **JENNIE BENGTSSON** can support within quality and regulatory services. Jennie has worked with global product registration, product documentation, labelling, classification, CE-marking, post market surveillance and audits within the medical device and IVD area as well as immunology, clinical diagnostics, public health, dental care cosmetics and biocides. This includes global markets, import and export with regulatory experience from manufacturing organisations as well as distributing organisations.

Jennie has been a biomedical consultant for many years and has experiences from mostly medical research and public healthcare in diverse roles including product management, marketing and sales. Always with a strong focus on delivering quality product.

On a strategic level Jennie works analytical with the goal to make it easy to implement processes close to the core business. On a practical note Jennie is determined in evaluating both clinical evidence and risk management with regards to a profitable and qualitative solution. As a consultant Jennie is social and service minded, highly focused on working efficiently with the project at hand, independently or in teams.

#### QUALIFICATIONS

Quality and Regulatory Affairs for medical devices, IVD products and clinical laboratories.

#### Tools & Methods

- Global product registration
- Regulatory analysis
- Product classification – MDR/IVDR
- CE-marking – IVD
- Risk management laboratory and patient safety
- Regulatory assessment of innovations – FDA and CE-marking
- Performance evaluation – IVD
- Clinical laboratory audits
- Product audit & reviews
- Compliance assessment: IVDD, IVDR, MDR, MDD, ISO 13485, ISO 9001, ISO 15189, ISO 22870, ISO 17025
- Cosmetic regulation 1223/2009
- Biocides regulation 528/2012

#### EDUCATION

- SIS MDR and IVDR
- B Sc in Medical Biology, Linköping University

#### LANGUAGES

- Swedish – mother tongue
- English – fluent

#### EMPLOYMENTS

- Mediteq 2019 -
- Mediq Sverige AB, 2018-2019
- Thermo Fisher Scientific, 2017-2018
- TATAA Biocenter AB, 2015-2017
- Svenska Labfab, 2010-2013
- Klin. Immunologi, Sahlgrenska 2007-2008

Mediteq  
Kanalstråket 1  
SE-433 76 Jonsered  
Sweden

+46 31 774 25 00  
+46 708 72 96 68  
[helen@mediteq.se](mailto:helen@mediteq.se)  
[www.mediteq.se](http://www.mediteq.se)



+46 702 51 50 63  
[jennie@mediteq.se](mailto:jennie@mediteq.se)