

Hoff & Lowendahl



PRRC Person Responsible for Regulatory Compliance

A must to meet IVDR or MDR. You can outsource this function if the company meets the definition of small or micro company (<50 employed persons <10 MEuro). The full definition can be found in 2003/361/EC .

Typical smaller companies have their hands full with many different activities. Often with one or max two persons dedicated to quality or regulatory activities. To bring in an experienced outside person to ensure that you meet the regulatory requirements can be critical for long term success.

Our Experience

We have long experience in handling QA and regulatory matters and are acting as PRRC for many companies in the EU.

Many of our customers are startups why we also can bring valuable experiences into your company when it come to how to get to the market!

Our offerings

We have 3 different levels of agreement. All includes the PRRC role.

All inclusive: All QA&RA activities included, Typical the best choice if you want to outsource the complete function.

Extended: Company that needs to develop systems and technical documentation.

Basic: Additional services with separate pricelist. Typical best choice for class I and A products



Postal Address:
Högåsvägen 125
SE 741 41 Knivsta
Sweden

Hoff & Lowendahl

Phone: +46 (0) 722313355
E-mail: info@lowendahl.eu

Visiting Address:
Forsbyvägen 1B
SE-741 40 Knivst