

## Key Questions to Ask of a Potential Clinical Evaluation Report Partner

By: Medavise



### **Q: What are your areas of expertise?**

**A:** The varied clinical data sets included in a CER rely heavily on inputs from regulatory, quality, engineering, statistical and clinical areas. Since gap analyses are a critical part of the CER process, it's important to have these subject matter experts on the team.

### **Q: How much experience will my project lead have?**

**A:** CERs are a key component of obtaining and maintaining your CE mark, and they can be complex, even for the simplest of products. While junior team members can provide significant contributions, your project lead should be highly experienced both in the medical device field and in preparing CERs.

### **Q: What measures do you have in place to ensure I receive a high quality CER?**

**A:** For a document as complex as a CER, even the best writers can miss something now and then. An internal review of the deliverables by another expert team member before sending the documents helps ensure a smooth review of the finished product by you and your team.

### **Q: Do you operate under SOPs and related work instructions (WI)? Can you work using our SOPs?**

**A:** Every facet of a CER has specific requirements, and standardized procedures and work instructions help ensure that these requirements are consistently met. Your CER partner should have their own SOPs and WIs to prove that they understand the regulations and can provide you with a quality product. This level of understanding is important even if you choose to have the CER partner use your processes instead.

### **Q: Do you farm out your literature searches or other aspects of the CER?**

**A:** CERs are best prepared when the project lead is completely familiar with all of the data sets, including the literature. A lot of learning occurs during the literature search process, which can be lost when having a separate group perform this critical task. Having the project lead perform the literature search and analysis helps assure that you get the best results.

**Q: Do you appraise every clinical data set in the CER, or just the published literature?**

**A:** The MDR and MEDDEV 2.7/1 Rev 4 both emphasize that all clinical data sets should be appraised with the MDR providing specific instructions for Notified Bodies to look for the appraisals. Many consulting groups (and device manufacturers) overlook this important step.

**Q: Do you have experience preparing CERs for legacy devices or those using well established technologies?**

**A:** The MDR created a new path for showing conformity to safety and performance requirements without the need for clinical investigations. Some devices certified under MDD and others that meet the requirements for well established technologies (or both) can use this path but there are some twists and turns along the way.

**Q: My business is small and my product is new. Are you able to help younger companies?**

**A:** Understanding the resource limits and “many hats” approach of small device companies is important. A consulting team whose members have had their own experiences in start-ups or as entrepreneurs can relate best to those who are “actually in the arena”.

**About Medavise**

*Your multidisciplinary team of med-tech experts.*

Averaging more than 20 years in the medical device world, our team’s experience ranges from Principal Engineer to VP of Clinical and Engineering. We’re educated in engineering, nursing, biology, business, public health, epidemiology, veterinary medicine, manufacturing and medicine, from Bachelors to PhD and MD. Medavise is a unique collection of talent that can deliver the unique solution you need, from strategy development to planning and execution. We’re anything but average.

Medavise is led by Britt Norton, who has spent 40 years in the medical device arena as an engineer, inventor, executive and entrepreneur. His goal is to provide clients with solutions that have an immediate impact and enable long-term success.

Combined, the team has a background in a broad range of treatment areas, including:

- **Orthopedics:** spine, extremities
- **Cardiology:** electrophysiology, interventional catheters, valves, stents, CABG, guidewires, sensors
- **Urology:** implants and interventional
- **Gastroenterology / endoscopy**
- **Gynecology**
- **Infusion therapy:** catheters, ports
- **Pain management**
- **Diagnostics:** IVD, imaging
- **Prosthetics**

Interested in learning more? Our staff is committed to you and will stand by your side. **Contact us today!**

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