

December 5th, 2025

To whom it may concern,

I highly recommend Caroline Webster as a trusted partner in medical device innovation. Her philosophy, that successful devices emerge from the alignment of technical insight, structured product development, and regulatory strategy, is not just a belief but a proven practice in her work.

- Her Insight: She brings a deep expertise in translating complex engineering concepts into practical, patient-focused solutions.
- Structured Product Development: With a disciplined approach to design controls, risk management, and dFMEA, she ensures that innovation is balanced with reliability and manufacturability.
- Regulatory Strategy: Her mastery of ISO 14971, ISO 13485, and 21 CFR 820 allows her to anticipate regulatory challenges and integrate compliance seamlessly into the development process.

What sets her apart is her ability to bridge functions, connecting R&D, quality, and regulatory teams into a unified vision. This alignment accelerates timelines, reduces risk, and ultimately delivers devices that are safe, effective, and market-ready.

If you are seeking a consultant who can transform complexity into clarity and guide your team from concept to commercialization, Caroline Webster is the ideal choice.

Best regards,

Kristin Gordon

Kristin Gordon
Independent Quality and Regulatory
Compliance Consultant