

# Medical Device Remediation Expertise:

## *Build or Buy?*

Regulatory changes are accelerating globally. Today, it's the European Union's Medical Device Regulations (EU MDR) and phasing out ethylene oxide (EtO) sterilization. Tomorrow, it will be strict cybersecurity and artificial intelligence requirements.

Medical device companies that excel in proactive compliance and remediation will have a competitive advantage.

They can choose to build an in-house competency and/or establish strong partnerships with expert advisors. Each approach brings advantages and challenges. The choice will depend on a company's long-term strategic priorities, expertise, size, budget, and more. Here, several considerations for making an informed decision.

### **Take the next step:**

If your company doesn't have the experience and expertise to manage the next big regulatory program, or if you're working to build an in-house remediation competency, download

**[Apply Lessons from EU MDR to Upcoming Regulatory Changes.](#)**



**Build an in-house competency**



**Partner with consultant(s)**

	<b>Build an in-house competency</b>	<b>Partner with consultant(s)</b>
<b>Control</b>	Full strategic control	Shared
<b>Cost</b>	High initial investment Recurring cost Cost effective long term Fixed cost	Immediate value Short-term nonrecurring expense Variable
<b>Timing</b>	Takes time to build	Quicker to start
<b>Knowledge base</b>	Institutional knowledge Product knowledge	Deep specialized knowledge Industry best practices Specific remediation experience and expertise
<b>Training</b>	Steep learning curve, ongoing investment	Short learning curve May serve as trainer or mentor
<b>Resources</b>	Shared with NPD, other initiatives Overworked at peak times	Scalable Dedicated Focused
<b>Tools</b>	Custom Take time, experience to build	Advanced Proven tools tailored to fit
<b>Culture</b>	Existing relationships Potential politics, silos	Objectivity Fresh perspective Bridges silos
<b>Sustainability</b>	Long-term adaptability Agility Institutional knowledge	Organizational capability built and knowledge transferred before program completion