



Achieving Maximum Benefit from Consultants

Presentation for the Medical Development Group
(MDG Boston)



David Connor

David Connor, President of Striper Solutions LLC, is a seasoned IEEE product consultant with over three decades of experience in product development for domestic and international markets. He specializes in product regulatory compliance, guiding businesses through the complexities of regulatory standards and providing solutions for critical EMC and safety product issues.

David has over 20 years in engineering management, developing optical imaging equipment for a global market.

A Manager's Story

Sometimes, you just can't see the forest for the trees

- ▶ Seeking external expertise can be difficult, it's easy to think you already have the best team
- ▶ No prior specific knowledge is not necessarily a bad thing -a fresh perspective can often bring insight



Why Use a Consultant?

► Risk Reduction:

- Technology risk (need for specialized knowledge)
- Design safety and hazard reduction (FMEDA)
- Schedule risk (additional resource requirements)

Reduction of Project Complexity:

- Technology feasibility (investigation, specification, modeling, limited design)
- Cross-functional collaboration (working through issues with engineering teams)
- Quality Management System integration for new products and update for new design methods

Reduced Regulatory Burden

- Regulatory compliance expertise (FDA, MDR, ISO 13485, FCC, CE, etc.)
- Regulatory documentation and submissions
- Interpretations of regulations, translating complex regulatory language into actionable items

Limited Overhead

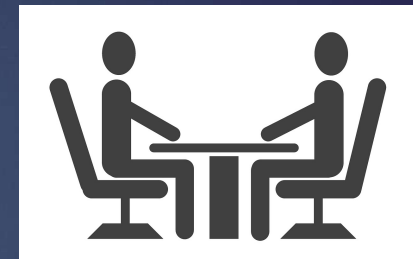
- Scale up or down as needed without hiring full-time employees for temporary or specialized needs
- Some consultants have specialized tools (such as design or modeling)



Effective Consulting Projects

► Projects With a Time-Limited Scope

- Technology and product strategy, feasibility, proof-of-concept
- Modeling or troubleshooting complex technical issues
- QMS implementation and optimization



► Projects Requiring Specialized Expertise

- Embedded systems or ASIC design
- Medical software
- Image processing, artificial intelligence, or machine learning algorithms
- Product safety and regulatory compliance

► Projects With Fluctuating Resource Needs

- Providing extra capacity during critical development phases, such as prototyping, testing, or regulatory submissions
- Investigating and exploring new technological approaches for future products



Regulatory Compliance

Compliance to Safety Standards:

- ▶ Working directly with design teams to address complex product safety issues and meeting global standards

EMC Compliance (FCC, ISED, CE,...)

- ▶ Circuit design and modeling for emissions
- ▶ Resolving Emissions and immunity issues found during testing
- ▶ High-level support during product testing, providing feedback to the design team

Product Certification and Marking (UL, ETL, CSA,...)

- ▶ Interface between engineering and NRTL to clearly identify requirements
- ▶ Provide a technical interface during NRTL testing
- ▶ Design and build of specialized manufacturing test fixtures to meet regulatory requirements

FDA Process

- ▶ Implementation of regulatory safety controls for product certification
- ▶ Ensuring manufacturing processes and controls meet regulatory safety requirements for certification and validation.



Accelerating Medical Device Development Using a Consultant

- ▶ **Reduce Development Risk:**
 - ▶ Consultants expedite the development process by providing specialized knowledge, streamlining design, and identifying potential pitfalls early on, working directly with the development team
- ▶ **Access to Specialized Expertise:**
 - ▶ Consultants bring in-depth knowledge in niche areas, often unavailable in-house
- ▶ **Low-Overhead Solution:**
 - ▶ Medical device manufacturing requires lots of specialized equipment and highly-skilled people. Consultants provide a solution for low-overhead short-term projects.





Thank you

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