

MedTech LAUNCH

by Genesis Plastics Welding

QUICK START QMS

Identifying your ideal **Quality Management System**
for a faster, successful medical device launch.

OBJECTIVES

- ✓ Increase your chances of a **profitable** medical device launch.
- ✓ Minimize risks, costs and delays.

KEY SUCCESS COMPONENTS

- QMS setup matches my business size/scope/objectives
- Risk analysis
- Regulatory compliance management
 - FDA 21 CFR 820
 - ISO 13485
- Management responsibility
- Resource management
- Control of documents & records
- Product realization (device requirements, design specs, process control and more)
- Access to training, expert guidance
- Provider's track record in managing or guiding successful medical device launches

AVOIDING A COMMON PITFALL

Often, quality management systems are built too complex to be useful, cost more than they're worth, and take a long time to implement. What's more, wasteful delays and regulatory slip-ups tend to follow quality management systems that are misaligned with your business size, scope and objectives.

MedTech Launch helps you avoid those pitfalls by providing **scope-limited, tailored quality management systems** so you get exactly what you need — no more, no less.

THE OFFSHOOT: Faster medical device launches without sacrificing quality, needless spending, or regulatory compliance.

COMPLIMENTARY STRATEGY SESSION

We'll help you clarify next steps and pinpoint the best solution for you — whether or not we end up working together. You'll walk away with actionable

insights to minimize risks and spending in your medical device launch.

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