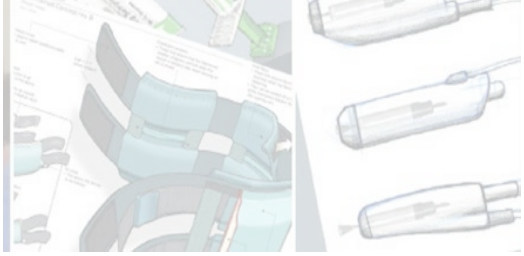


Manufacturing Quality Plan Authority and Responsibilities Checklist

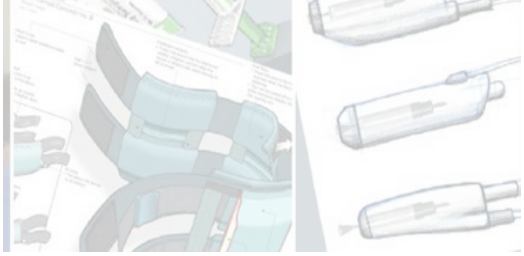
Use the following checklist to identify and assign authority and responsibility between client and contract manufacturer for implementing and enforcing the medical device manufacturing quality plan.

A medical device quality plan is intended to ensure that relevant quality standards are met when manufacturing a medical device, and that the medical device is equivalent to the approved device submitted to regulatory bodies. The Quality Plan indicates relevant standards for the medical device and describes in detail how these how these standards will be met.

A Medical Device Quality Plan should:

- Describe how the requirements for quality will be met during the manufacture of the medical device, product accessories and shippable components
- Specify the relevant quality and regulatory standards/regulations that apply
- Define roles and responsibilities

Item	Contract Manufacturer	Company	N/A	Comments
Design				
Design History File	☐	☐	☐	
Device Master Record	☐	☐	☐	
Design Plan	☐	☐	☐	
Requirements Documents	☐	☐	☐	
Risk Management	☐	☐	☐	
Design Specification	☐	☐	☐	
Bill of Materials	☐	☐	☐	



Design Verification	☐	☐	☐	
Design Validation	☐	☐	☐	
Process Validation	☐	☐	☐	
Change Control	☐	☐	☐	
Regulatory				
3rd party Test Results (Safety & EMC)	☐	☐	☐	
Technical File (CE)	☐	☐	☐	
Regulatory Submissions	☐	☐	☐	
Manufacturing				
Quality Plan	☐	☐	☐	
Manufacturing Procedures/Forms	☐	☐	☐	
Training	☐	☐	☐	
Manufacturing Validation	☐	☐	☐	
Device History Records	☐	☐	☐	
Shipping	☐	☐	☐	
Service Procedures/Forms	☐	☐	☐	
Service/Complaints	☐	☐	☐	

StarFish Medical provides award-winning design, development, and flexible manufacturing outsourcing services —100% dedicated to the medical device and life science marketplace. StarFish partners with innovative companies to create and manufacture breakthrough products for a full range of medical specialty areas including: Cardiovascular, Digital Health, IVD, Ophthalmology, Optics, and Ultrasound. StarFish expertise includes electronics, mechanical, human factors and software systems engineering.

Our proprietary Pathfinder™ process for medical device product definition saves clients time and resources throughout the technology and product development phases to commercialization. Prototype and low volume complex electro-mechanical production are delivered in an ISO 13485 certified facility with FDA registration, including cleanroom capabilities.

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