Medical Device Manufacturing Checklist

Below you will find a short checklist to use as you prepare to bring your medical device products to market. This list should be used as a general guide; your contract manufacturer will work with you to ensure all of your specific medical device requirements are completed.

- I have a stable and complete design which has been verified and validated to meet device specifications and documented in an approved Design History File.
- My trusted manufacturer has in-house regulatory experience.
- A full risk assessment and analysis of the product's benefit/risk balance has been completed and documented.
- My manufacturer and I have agreed on a Formal Manufacturing Control Plan that includes a PFMEA.
- My manufacturer has ensured all tools and processes used in manufacturing have been identified, documented, and validated where required.
- All vendors have been qualified and documented via an Approved Vendor and Procedure List. Critical components have been identified and incoming inspection criteria identified and documented.
- My test development and documentation includes test fixture software validation. All test system design has been completed with formal medical device development procedures that are QSR compliant.
- My manufacturer's packaging and shipping has been documented and validated to ensure medical device products will not be damaged during shipment.
- I have a robust corrective action and preventive action process.
- I have a plan for ongoing monitoring and data collection for finished products.
- I have a plan for collecting field information that includes warranty and field return information.
- I am prepared for an FDA inspection at my facility or at my contract manufacturer's FDA registered facility.