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Medical Device Commercialization Checklist

The following checklist lists key deliverables which should be considered for medical device commercialization. It should be used as a foundation to customize for your unique device needs.

Manufacturing Engineering Readiness

- ❍ Bill of Materials (BOMs) finalized
- ❍ Process risks and mitigations defined (pFMEA)
- ❍ Manufacturing, inspection procedures and travellers defined
- ❍ Process flow chart finalized
- ❍ Process characterization complete
- ❍ Equipment and software qualification complete
- ❍ Process validation (OQPQ) complete
- ❍ Inspection methods validated (test method validation (TMV))
- ❍ Packaging and shipping processes validated
- ❍ Labeling processes validated
- ❍ Master validation plan/report released
- ❍ Technician training complete and documented
- ❍ Comprehensive list of design and process changes for post-launch outlined

Supply Chain Readiness

- ❍ Supply chain understood & risks (if any) identified
- ❍ Has a second source for all critical components been identified?
- ❍ Supplier evaluations complete
- ❍ Supplier agreements signed
- ❍ First article inspections (FAI) complete on all critical custom components
- ❍ Incoming inspection requirements defined
- ❍ Certificates and/or compliance requirements (if required) for Import/Export understood

Production Readiness

- ❍ Cleanroom requirements understood & environmental monitoring program defined (if required)
- ❍ Layouts finalized (cleanroom, warehouse, inventory etc.)
- ❍ Assembly time studies complete
- ❍ Yield targets understood
- ❍ Standard product costs understood
- ❍ Forecasting and inventory control levels understood

Visit starfishmedical.com/tools for more medical device commercialization tools.

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