PROTOMED

DFM Checklist

Design for Manufacturability

Key checkpoints before design transfer
ISO 13485:2016 · FDA 21 CFR 820.30

HOW TO USE THIS CHECKLIST

Review each checkpoint at every major design milestone ~~not~~ only before design freeze.
The earlier a gap is identified, the lower the cost of addressing it.

1 DESIGN INPUTS

- [ ] Manufacturing constraints documented as formal design inputs: target process, production volumes, sterilization method, supply chain requirements
- [ ] Regulatory requirements applicable to manufacturing identified and included in design inputs (ISO 13485, MDR, FDA QSR as applicable)
- [ ] A process FMEA or equivalent manufacturing risk analysis initiated alongside the product risk analysis

2 MATERIALS

- [ ] Final materials confirmed biocompatible per ISO 10993 for the intended application
- [ ] Materials compatible with the intended sterilization process (EO, steam, radiation) without performance degradation
- [ ] Material aging behavior assessed: mechanical properties, dimensional stability, and sterile barrier integrity over shelf life
- [ ] All materials sourceable from qualifiable suppliers at production volumes

3 GEOMETRY & TOLERANCES

- [ ] All critical tolerances verified as achievable with the target industrial process (injection molding, machining, extrusion.), not just prototyping processes
- [ ] Part geometry compatible with target manufacturing process: draft angles, wall thickness, parting line placement reviewed
- [ ] Mechanical properties verified with final materials and processes: flexibility, fatigue resistance, behavior under load

4 ASSEMBLY

- [ ] Assembly sequence reviewed for producibility on a manufacturing line ~~not~~ just bench assembly
- [ ] All joining, bonding, or welding operations compatible with industrial processes and cleanroom requirements if applicable
- [ ] Assembly tooling and fixtures defined

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5 DOCUMENTATION

- [ ] Design History File up to date - all design decisions recorded with justification, day by day
- [ ] Device Master Record initiated: initial manufacturing specifications, BOM, drawings with part numbers
- [ ] Work instructions for manufacturing, assembly, and packaging drafted or planned

6 SUPPLIER READINESS

- [ ] Suppliers identified for all critical components and sub-assemblies
- [ ] Supplier qualification initiated or complete according to criticality level (quality agreements, capability assessment)
- [ ] Incoming inspection criteria defined for purchased components

7 PROCESS VALIDATION

- [ ] Process validation assessment (PVA) performed to identify which manufacturing steps require formal validation (IQ/OQ/PQ)
- [ ] Process validation protocols drafted for critical processes: manufacturing, sterilization, packaging sealing
- [ ] Manufacturing staff training plan defined

8 DESIGN TRANSFER READINESS

- [ ] All risk control measures linked to manufacturing processes implemented and traceable in the risk analysis
- [ ] Labeling and IFU drafted and reviewed
- [ ] DMR documentation complete and up to date
- [ ] Design transfer checklist review scheduled with QA, R&D, and production teams before design release

PROJECT INFORMATION

Project / Device: _____ **Reviewed by:** _____ **Date:** _____