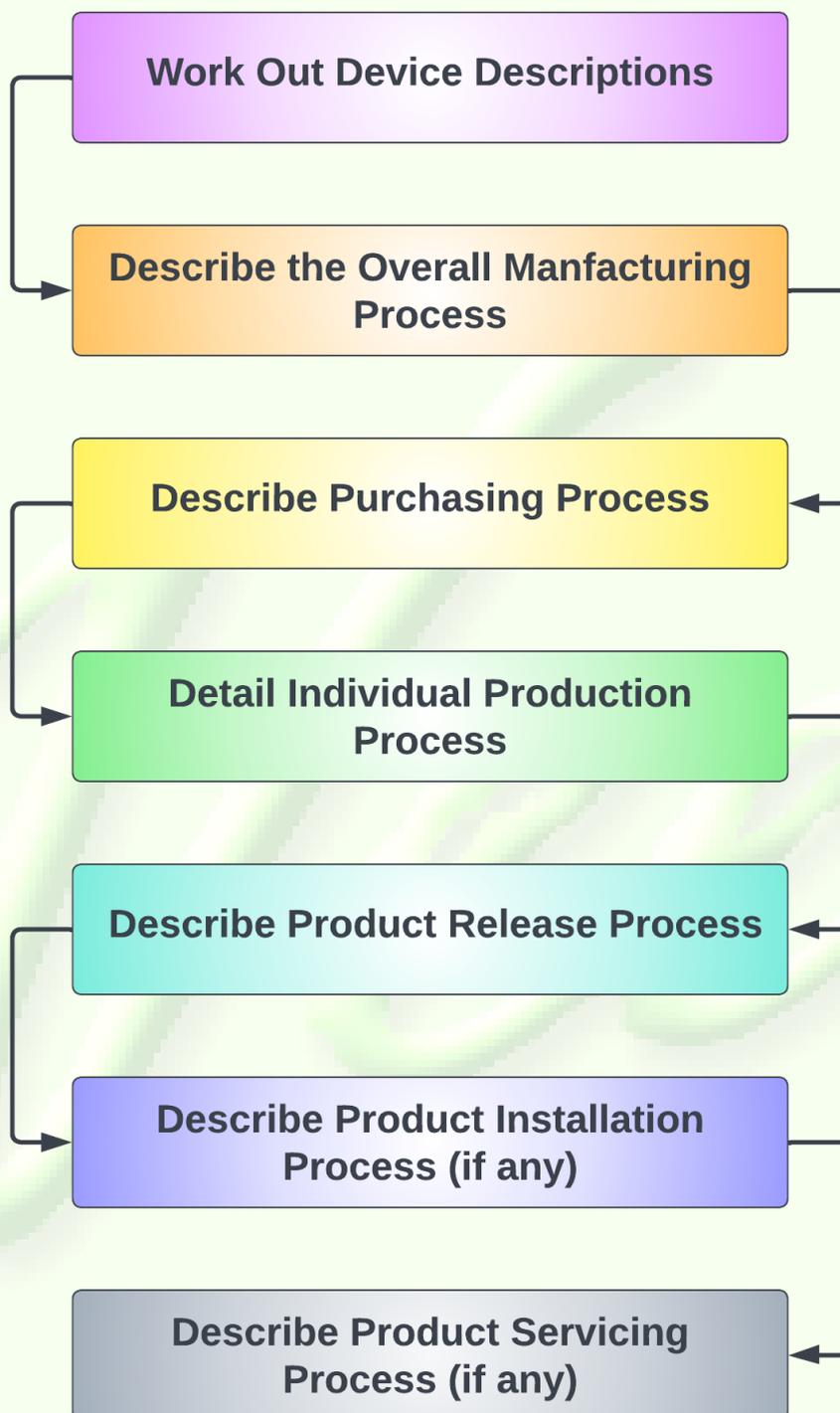


DESIGN MASTER RECORD PROCESS



DEVICE MASTER RECORD DOCUMENTATION

1. DEVICE DESCRIPTIONS

- Over Descriptions
- Intended Uses
- Product Specifications
- Raw Materials/ Components
- Udi
- Labelling
- Packaging And Storage

2. OVERALL MANUFACTURING FLOWCHART

- Production Flowchart
- Floor Plan with Goods/Personnel Flow Diagram

3. PURCHASING PROCESS

- Purchasing Procedures
- Raw Materials and Suppliers Information

4. PRODUCTION PROCESS

- Production Related Procedures
- Production Process
 - Input Specifications
 - Production Method
 - Production Equipment
 - Output Specifications
 - In-Process Inspections Process and Criteria

5. PRODUCT RELEASE PROCESS

- Finished Product Inspection Work Instruction
- Finished Product Inspection Criteria

6. INSTALLATION PROCESS

- Product Installation Work Instruction
- Installation Requirements

7. SERVICING PROCESS

- Product Servicing Work Instruction
- Servicing Requirements