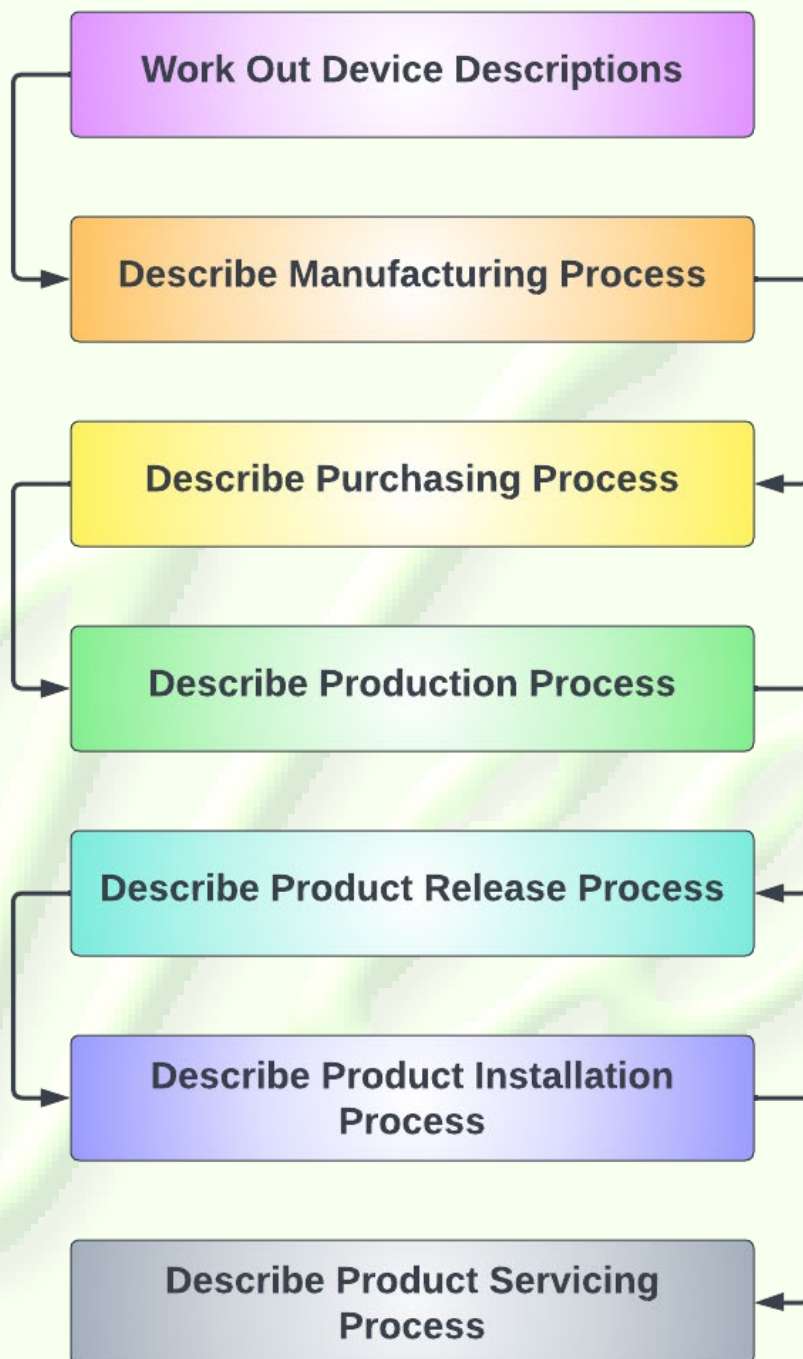


## DESIGN MASTER RECORD PROCESS



## **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