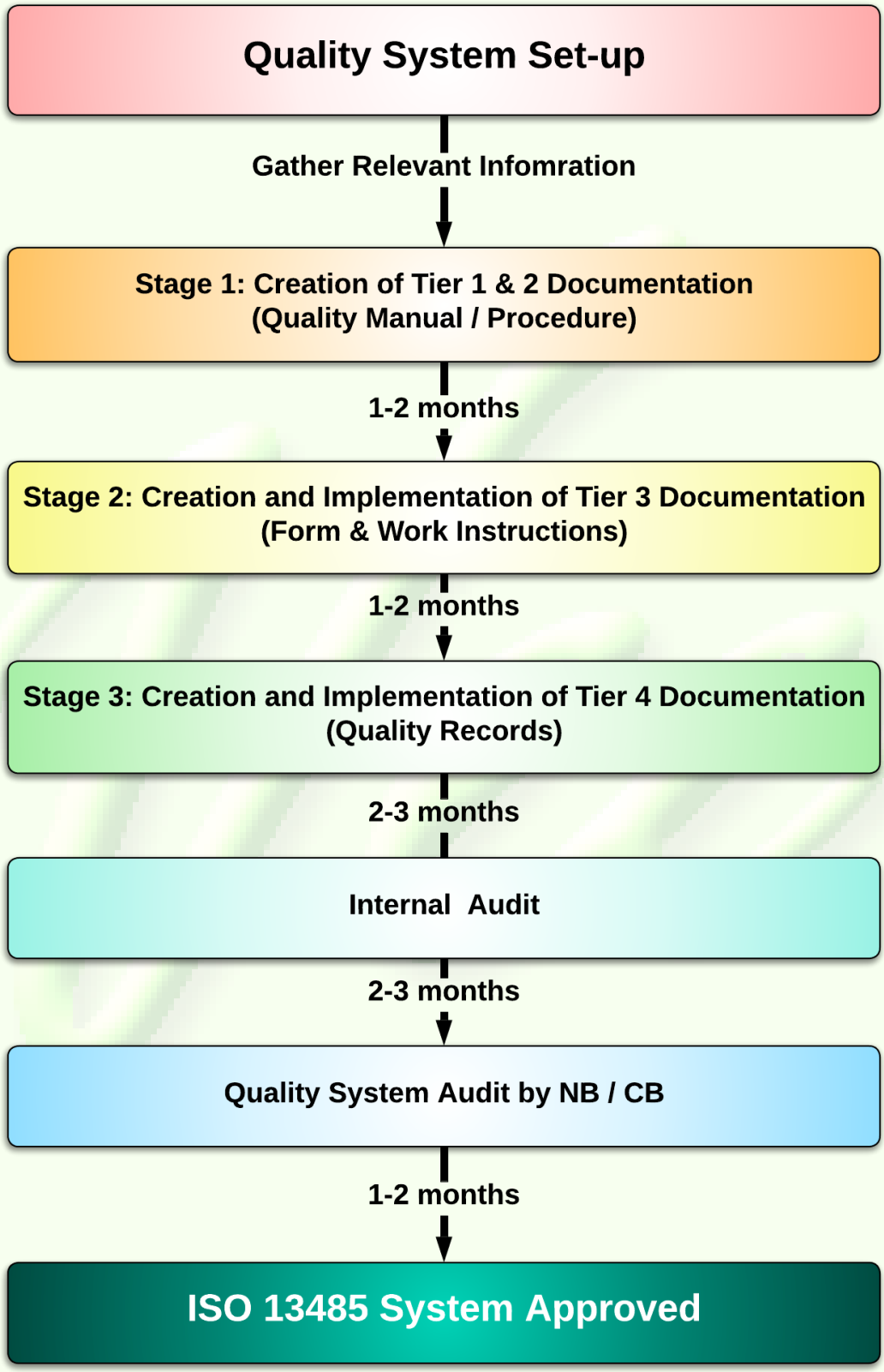
QUALITY SYSTEM SET-UP PROCESS



QUALITY SYSTEM DOCUMENTATION

1. Tier 1-2 Documentation

- Document the role(s) undertaken by the organization
- Procedure for the validation of the application of computer software
- Quality manual
- Quality policy / quality objectives
- Procedure for document control
- Procedure for record control
- Responsibilities and authorities
- Procedure for management review
- Procedure for competence, training, and awareness
- Procedure to monitor and control the work environment
- Procedure for design and development
- Procedure for purchasing
- Procedure and methods for the control of production
- Procedure for servicing activities of medical devices
- Procedures for validation of processes
- Procedure for the validation of processes for sterilization
- Procedure for product identification (UDI)
- Procedure for traceability
- Procedure for preserving the conformity of product
- Procedure for monitoring and measuring equipment
- Procedure for post marketing surveillance
- Procedure for complaint handling
- Procedure for reporting to regulatory authorities
- Procedure for internal audit
- Procedure for control of nonconforming product
- Procedure for rework
- Procedure for analysis of data
- Procedure for corrective actions and preventative actions

2. TIER 3 DOCUMENTATION (if applicable)

- Written quality agreements with outsource partners
- Annual Quality objectives
- Master Document Master List
- Responsibilities and authorities
- Organization Chart
- Position Skill Matrix
- Requirements for the infrastructure
- Requirements for the maintenance activities
- Requirements for the work environment

- Requirements for health, cleanliness, and clothing of personnel
- Arrangements for the control of contaminated or potentially contaminated product
- Requirements for control of sterile medical device contamination
- Risk Management Documentation
- Arrangements for communicating with customers
- Approved Product List
- Approved Supplier List
- Requirements for cleanliness of product
- Management Review Form
- Post Marketing Surveillance Plan
- Post Periodic Safety Update Plan
- CAPA Form
- Design History File
- Device Master Record
- Device History Record (Batch Record)
- Internal Audit Report

3. Training

- Design Control
- EN/ISO 13485:2021 Quality System
- EN/ISO 14971:2019 Risk Management
- CAPA

4. Internal Audit

- Creation of Internal Audit Plan
- Conduction of Internal Audit (audit of subcontractor not included)
- Compilation of Internal Audit Report

5. External Audit

- Accompany External Audit
- Resolution of CAPA issued