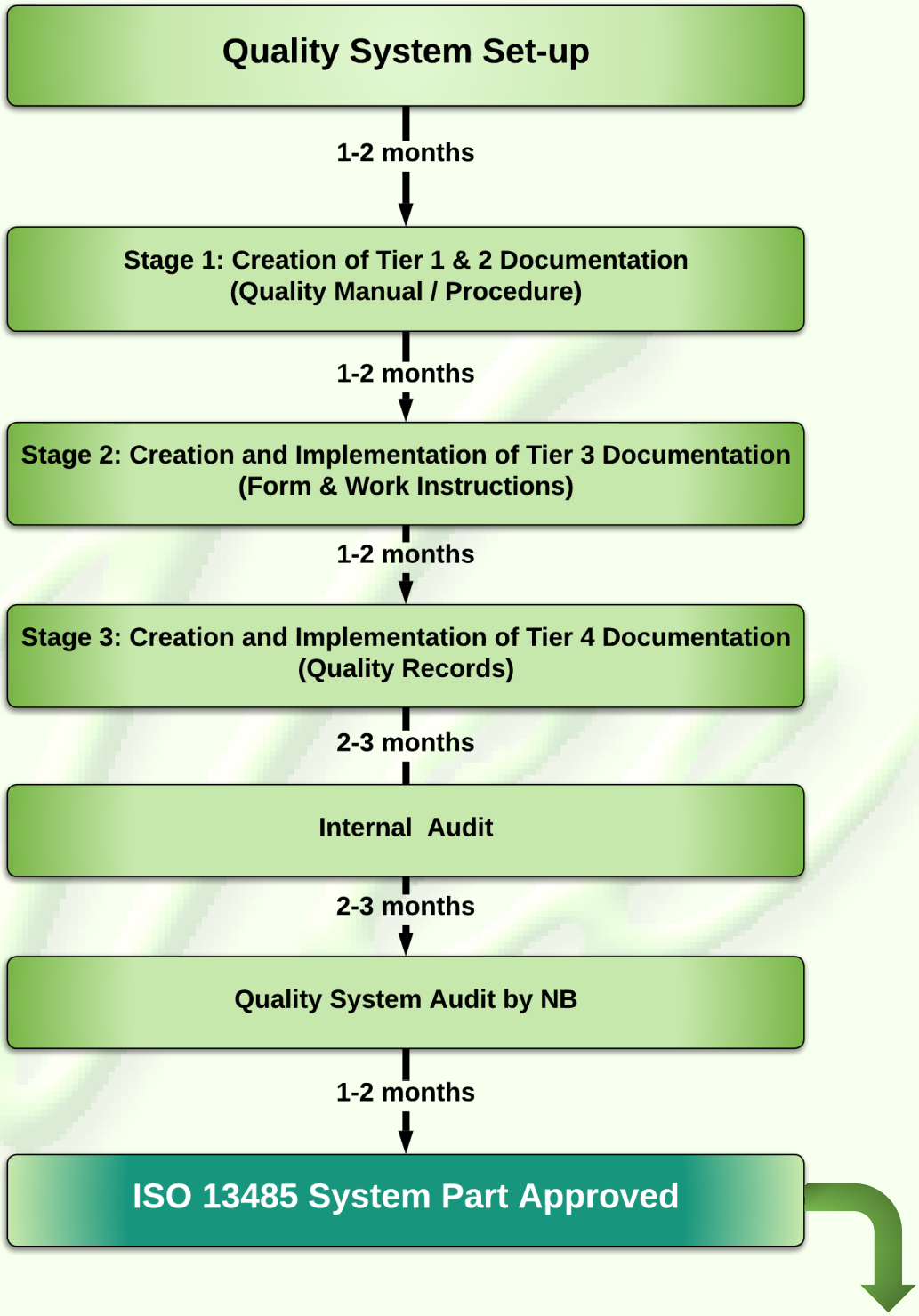
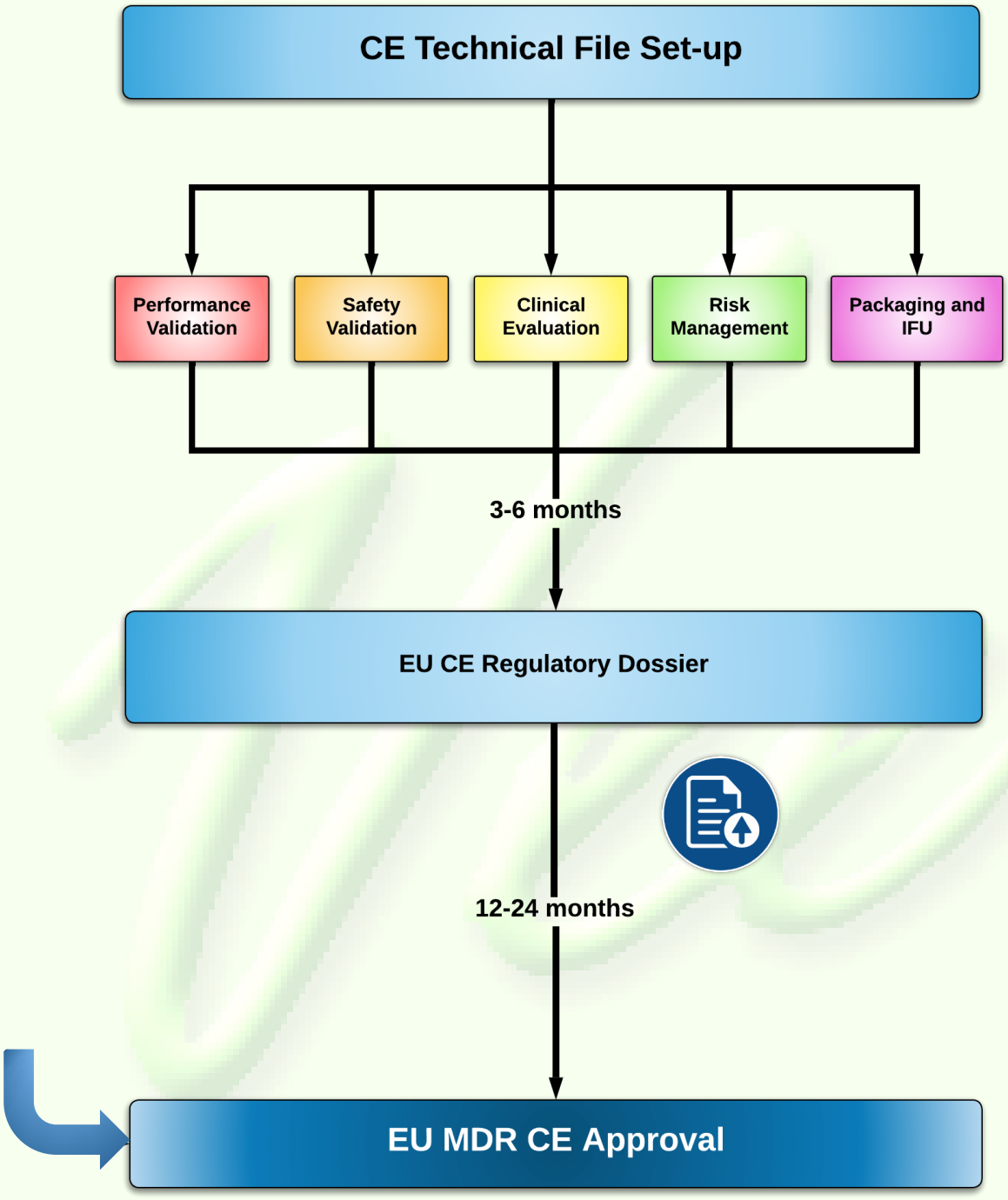
QUALITY SYSTEM REGISTRATION PROCESS



TECHNICAL FILE REGISTRATION PROCESS



MARKET ACCESS TO EU (Is, Im, IIA & IIB)

DOCUMENTS REQUIRED

- Device Descriptions and Specification
- General Safety and Performance Requirements (GSPR) Checklist
- Design and Manufacturing Information
- Benefit-Risk Analysis and Risk Management Documentation
- Product Verification & Validation Plan and Results
- Clinical Evaluation
- Information Supplied by Manufacturer
- Post Market Surveillance Plan
- Post Market Clinical Follow-up Plan