Medical Device Design & Development Checklist – FDA, ISO & MDR Compliant

Design & Development Planning

- Design and development plan with responsibilities
- Milestone definitions and review points
- Regulatory pathway (510(k), CE, PMA) identified
- Alignment with ISO 13485:2016

Design Inputs & Outputs

- Product requirements, user needs gathered and includes but not limited to functional, performance, user, and regulatory requirements
- Risk management process implemented (ISO 14971)
- Design outputs documented and traceable to design inputs
- Ethical and data protection considerations, if applicable
- Labeling and packaging requirements
- User interface requirements considered
- Product specifications finalized

Verification & Validation

- Master Verification and Validation plan documented
- Complete test reports including protocols available
- Validation testing aligned with intended use (ex; Biocompatibility, electrical safety etc.)
- Software validated per IEC 62304 (if applicable)
- Verification and validation carried out, as appropriate, when changes are made to the product or the suppliers

Review & Transfer

- Design History File is freezed
- Design reviews documented (at each phase)
- Transfer criteria defined and executed
- Design transfer checklist is available for transfer to production

Documentation & Compliance

- DHF, DMR, DHR structured and maintained
- EU MDR technical documentation aligned with Annex II/III
- Evidence of conformity assessment (NB or FDA) prepared
- Unique Device Identification (UDI) strategy and registration (FDA GUDID, EUDAMED, if applicable)
- Documents, as needed for FDA eStar submission, is available