

## DHF Remediation Checklist

- **DHF Structure Review** – Confirm all required sections are present, properly indexed, and referenced.
- **Design Plan & Inputs** – Validate documented design plans, user needs, and design inputs
- **Design Outputs** – Ensure outputs match inputs and are properly documented, and verifiable.
- **Verification & Validation** – Check that all required testing and validation records are complete, traceable, and documented
- **Traceability Matrix** – Link user needs → design inputs → design outputs → verification/validation results.
- **Risk Management Integration** – Confirm risk analysis (e.g., per ISO 14971) is reflected in design decisions
- **Design Changes** – Document and justify all design changes with controlled revision history and approval records.
- **Review & Approval Records** – Ensure signatures and approval dates are captured for all key documents
- **Labeling & Instructions for Use** – Verify that final labeling and IFU are included in the DHF and reflect approved content.
- **Compliance Gaps & CAPA** – List any gaps and associated corrective actions with target closure dates, for completion
- **Software Validation (if applicable)** – Include software verification and validation documentation as part of the DHF.