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	Standard Operating Procedure	
	PDP Phase 3	
	Design Verification	
	SOP-XXX	Revision X
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<p>This document is intended to be used for informational purposes. The content, format, and application of this document must be appropriately modified to meet unique company and product development requirements. This document should be carefully reviewed against specific company requirements.</p>		

PURPOSE

The purpose of this procedure is to establish requirements for Phase 3 of the Product Development Program: Design Verification. Phase 3 includes documenting and building verification prototypes, writing verification protocols, testing and documenting the results in verification reports. Design Verification is intended to demonstrate that the device design meets physical, functional, and performance requirements.

SCOPE

This procedure applies to a new product or a change to an existing product under development by COMPANY XXX.

REFERENCES

SOP-XXX PDP Glossary of Terms

SOP-XXX Development and Maintenance of Protocol and Reports

SOP-XXX Laboratory Notebook Maintenance

TERMS AND DEFINITIONS

Refer to PDP Glossary of Terms, SOP-XXX.

RESPONSIBILITY

R&D/Engineering- R&D is responsible for developing design verification prototypes and testing in accordance with pre-approved protocols.

Production- Production is responsible for working with R&D to assist in the development of verification prototypes.

Project Team- The Project Team is responsible for reviewing the design verification protocols to assure they are sufficient to demonstrate that the design is able to meet physical, functional, and performance requirements established in the Design Requirements.

Project Leader- will coordinate cross-departmental functions related to design verification. The R & D Project Leader is responsible for assuring that the Design

- 8.4. A verification report is written to document results of each design verification protocol. The Project Team members shall review/approve the verification reports.

9. Completing Phase 3, Design Verification

- 9.1. The design verification phase is complete when all Design Requirements have been successfully tested or verified and the appropriate Verification Reports have been approved. At this point the design is considered frozen so that design transfer, during which drawings are released under ECO as part of the DMR, can be performed. These released documents shall be used for the manufacture of production devices intended for design validation in Phase 5.
- 9.2. Once verification testing has been completed, and confirms that all design requirements have been met, Engineering shall update the Design Requirements document to include testing documentation number.
- 9.3. Engineering shall review the Design FMEA and update it if necessary.
- 9.4. Once verification is completed successfully, Regulatory Affairs may begin the regulatory approval process, if appropriate.
- 9.5. A Phase 3 Design Review is conducted and documented per SOP-XXX.
- 9.6. Regulatory Affairs audits the DHF.
- 9.7. The Project Plan Checklist is updated by the Project Leader to reflect the completion of Phase 3 tasks and make any revisions necessary for the next phase(s). The revised project plan is reviewed/approved by the Project Team.

10. Elements of the Phase 3 Design Review

- 10.1. The Project Team shall perform and document a Phase 3 Design Review according to the Design Review Procedure, SOP-XXX.
- 10.2. The design review shall verify that all design verification has been properly documented and that the tasks specified in the project plan have been completed.
- 10.3. The Project Leader shall ensure that the outputs from Phase 3 are filed in the project DHF according to the Design History File Procedure, SOP-XXX.
- 10.4. Regulatory Affairs audits the DHF.

11. PHASE 3 Outputs:

Document	Location
Design Verification Protocols	Originals in Doc. Control; Referenced within the Design Requirements-Traceability Matrix.
Design Verification Reports	Originals in Doc. Control; Referenced

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	within the Design Requirements-Traceability Matrix.
Pre-release DMR documentation	Document Control
Updated DESIGN REQUIREMENTS (including X-ref to verification documentation)	DHF, Folder: Design Requirements
Updated FMEA (if update is necessary)	DHF, Folder: DFMEA
Memos, correspondence	DHF: Phase 3/Correspondence
Phase 3 Design Review Form and meeting minutes.	DHF: Phase 3/Design Review

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Quick Approval

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Name/Signature	Title	Date	Meaning/Reason
Sonali Shelar (SHELAR)		06 Jan 2023, 01:12:22 AM	Approved

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