Design & Development Plan (DDP)
ClearView Software

ORIGINATOR:

Name	Job Title	Signature	Date
Andrew Mason	Chief Technology Officer		3/5/12

APPROVALS:

Name	Job Title	Signature	Date
Nancy Rizzo	Founder and CEO		3/5/12.
Mike Stowell	V.P of Operations		3/5/12
Brian Tompson	Software Engineer		3/5/12
Andrea Miller	Quality Assurance Manager		3/5/12

REVISION HISTORY

Revision	Revision Date	Reason for Revision/Change Request	Revised By
000	3/5/12	Initial Release	A. Mason

1.0 PURPOSE

1.1 The purpose is to define the Design & Development Plan (DDP) for the EPIC ClearView software. This DDP will provide a comprehensive view of the project to assist the design team in successful completion of each phase and activity.

1.2 This will ensure that all necessary activities are addressed including the method in which they will be conducted and all responsible parties involved therein.

2.0 SCOPE

2.1 The objective of this DDP is to outline the activities to be performed in order to develop and implement the EPIC ClearView Software, Version 1.1.1.2. Included in this document are the roles and responsibilities of individuals that are required to perform these activities.

NOTE: Significant development has occurred prior to the development of this DDP. The development is fully documented in requirements documents, specifications documents, design approval and design review minutes. Engineering study documents have also been developed which characterize the algorithm development. This DDP is being written to bring the ClearView Software Design History File (DHF) into compliance with EPIC's quality system procedural requirements.

2.2 The scope of this project is to fully document the implementation of the developed algorithm into the ClearView software. Additional user requirements and software improvements will be included in this project.

2.3 Aspects of the design process included within this DDP are planning, design, verification, validation, and design transfer. Included in the plan are all individuals, resources, and facilities involved.

3.0 REFERENCE DOCUMENTS

3.1 Regulatory Documentation:

- FDA 21 CFR 820, Quality System Regulations (QSRs)
- ISO 13485:2003 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes

4.0 PROJECT REQUIREMENTS

4.1 Software requirements have been developed and a summary of these requirements can be found in the EPIC ClearView System Product Requirements Trace Matrix (IO-001). Specific, detailed requirements are currently tracked in design development requirements documents designated as SR-XXX (there will be multiple separate documents all with individually assigned numbers for tracking within the design history file).

5.0 RESPONSIBILITIES

5.1 Chief Technology Officer – development of ClearView software.

5.2 Quality and Project Management Director – oversight of development, validation, and implementation.

5.3 Quality Assurance Manager – management of quality system requirements.

5.4 Information Technology Department – verification of performance standards.

6.0 ORGANIZATION, INTERFACES, RESPONSIBILITES, AND APPROVAL AUTHORITY

6.1 All pertinent steps and documents, such as design control documents, design review, verification, and validation, must be approved by the following departments:

- Executive Management
- Operations
- Information Technology
- Quality Assurance
- Software Engineering

6.2 All Engineering Studies must have the signature of the following departments:

- Information Technology
- Quality Assurance
- Software Engineering

7.0 MAJOR TASKS (MILESTONES) & SCHEDULE

7.1 Algorithm Development- Completed prior to DDP creation and documented in ENG-025 and ENG-026 (Jan/Feb 2012)

7.2 Design and Development Plan created. (Feb 2012)

7.3 Executive Management reviews DDP and documents on approval form. (Feb 2012)

7.4 Design requirements finalized. (Feb 2012)

7.5 Design inputs and outputs documented and approved. (March 2012)

7.6 Design developed resulting in design outputs documentation. (Feb 2012)

7.7 Finalize and approve risk analysis (March 2012)

7.8 Design verification and validation. (Feb/March 2012)

7.9 Final design review and approval. (March 2012)

7.10 Design release for use in IDE investigations. (March 2012)

7.11 Review results of IDE investigations, requirements modifications (April/May 2012)

7.12 Update requirements, DDP and initiate product changes through EPIC's Design Changes Process. (June/July 2012)

7.13 Release final version to production (Aug 2012)

8.0 DESIGN VERIFICATION & VALIDATION APPROACH

8.1 Design verification and validation will be performed by testing all software functionality to the requirements. The final results of the verification and validation testing will be formalized through design verification and validation protocols to be written prior to performance of the testing and summarized into final reports which outline the results of all verification and validation testing. The general outlines of the steps taken are as follows:

- Verification testing according to EPIC's Design Verification and Validation procedure (EG-006).
- Development of V&V test protocols.
- Execution of the V&V test protocols.
- Summary of V&V test results into final reports.
- Summary of all V&V activities into Validation Analysis.
- Review and approval of all documentation.

9.0 RISK ANALYSIS

9.1 Risk analysis draft has been developed. The project plan will include activities to update and approve the risk analysis based on the changes implemented as necessary.

10.0 PROJECT CONSTRAINTS

10.1 There are not any constraints at this time. Any additional constraints will be noted in a further revision of this plan.

11.0 DESIGN HISTORY FILE (DHF)

11.1 The DHF will be assembled and contain the following at a minimum:

- Design and Development Plan (DDP-002)
- Design Input and Outputs (IO-001, specifically the Software section)
- Verification and Validations
- Design Reviews
- Risk Management

11.2 The DHF may contain the following:

- Design Review Meeting Minutes
- Engineering Studies supporting design activities
- ClearView Architecture Design Chart
- ClearView Software Description
- ClearView Software Development Environment Description
- Revision History documentation
- Unresolved Anomalies Reports