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WHITEPAPER

Systems Engineering and Healthcare Applications:

Leveraging Innoslate for ISO 13485 Compliance

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Executive Summary

The International Organization for Standards (ISO) is an independent non-governmental organization that develops international standards covering various industries and sectors, including technology, manufacturing, healthcare, engineering, architecture, and much more. These standards provide specifications for products, services, and systems to ensure quality, safety, and efficiency. These standards are often considered the industry standard and are used by companies and organizations worldwide.

ISO 13485 is an international standard that specifies requirements for a Quality Management System (QMS) for organizations involved with medical devices and other similar products. Its purpose is to ensure that medical devices consistently meet customer and regulatory requirements.

This whitepaper demonstrates how ISO 13485 relates directly to Systems Engineering (SE) principles. Each section from the ISO document is mapped to an element of the Systems Engineering V-Model. This paper also demonstrates how the SE management tool, Innoslate, aligns in compliance with ISO 13485. Through a more detailed mapping of Innoslate's features to the ISO's sections, the paper illustrates Innoslate's ability to support effective medical device quality management through compliance with ISO 13485.

Introduction

The International Organization for Standardization (ISO) is a global organization that develops international standards to ensure quality, safety, and efficiency. ISO standards cover a wide range of fields including manufacturing, technology, healthcare, engineering, agriculture, and more. ISO standards are developed through a general consensus-based process that involves input from experts in the field, industries, governments, academia, and stakeholders. This process ensures that the standards being published are relevant and consider the diverse prospects of all involved. Companies will seek certification (from outside certification organizations) for demonstrating compliance with ISO standards to increase their credibility in their respective field [1].

A "standard" is a document that provides guidelines in the form of requirements and specifications that ensure that the service or product being provided is following the organization's goals of safety, quality, and efficiency. These standards come in a variety of different forms to ensure maximum coverage. The variation of standards includes the following:

- **Product Standards:** Can include requirements for specific products or materials such as dimensions, performance specifications, safety features, and testing methods.
- **Management System Standards:** Established frameworks to organize different aspects of a company's operations. Quality management, environmental management, information security management, and safety management are all included in the Management System Standards.
- **Process Standards:** Define best practices and procedures for carrying out tasks efficiently and effectively.
- **Service Standards:** Provides guidelines for delivering high-quality services and ensuring customer satisfaction.
- **Sector Specific Standards:** Standards to address specific needs and requirements across any industry.

ISO 13485 is an international standard that specifies requirements for a Quality Management System (QMS) for organizations involved with medical devices and other similar products. Its purpose is to ensure that medical devices consistently meet customer and regulatory requirements. The ISO was first released in 1996 but has undergone revisions to address advancements in the medical technology industry. Its most recent version was released in 2016 [2]. The key elements of the ISO standard include the following:

- **Quality Management System (QMS):** Establishes the framework for process control, documentation, and quality management that are essential for manufacturing medical devices.
- **Management Responsibility:** Outlines the responsibilities of management to ensure there is an effective implementation and maintenance of the QMS.
- **Resource Management:** Specifies the requirements for the management of resources, including human, infrastructure, and other capital needed to support the operations of the QMS.
- **Product Realization:** Describes the process for developing, producing, and delivering medical devices, ensuring the products meet customer and regulatory requirements throughout the process.
- **Measurement, Analysis, and Improvement:** Focuses on the necessary activities to monitor and analyze processes and products to then implement improvements based on the data analyzed. This will ensure compliance with customer and regulation requirements.

This whitepaper will explore how Innoslate aligns with the guidelines of ISO 13485 to support organizations in the medical device field. In addition to Innoslate's compliance, this paper will also highlight how using Innoslate can streamline processes and improve product quality to strengthen compliance with the ISO standard.

Overview of ISO 13485

ISO 13485 emphasizes the importance of establishing and maintaining a Quality Management System that's tailored to the unique needs of the medical device industry. This includes a clear documentation process, procedures, team responsibilities, and requirements to adhere to. Listed below is each major section of the ISO, along with a detailed description of the key topics highlighted within it.

Quality Management System (QMS)

The QMS is the core of this entire ISO standard, as it highlights the entire system map for maintaining quality throughout the production of the medical device. It is split into two main requirements sections that will need to be followed. Compliance with the requirements of the QMS will ensure medical devices consistently meet both customer and legal needs through effective process controls.

As detailed in the General Requirements section, organizations must document a QMS and maintain its effectiveness which consists of ensuring the QMS is capable of achieving product quality and compliance regulations. The process approach involves understanding and managing related processes as a whole system and contributes to the overall efficiency of the organization.

The Documentation Requirements section highlights the need for effective configuration management of all documents and records to ensure that no data is lost, and processes are completed as originally planned. It includes guidance on how to properly import artifacts such as the quality manual, control of documents, quality records, and even the maintenance of a medical device file for each type of device produced.

QMS is not a static requirement document. It will require continuous updating and revisiting to adapt to changes in the field, such as changes in technology, regulations, or even market conditions. Organizations are encouraged to use this framework to foster an environment for continuous improvement, which will help streamline operations and maintain the highest quality for devices.

Management Responsibility (MR)

The MR section builds off the previous section and focuses on top management implementing and maintaining the QMS. The key elements of the Management Responsibility emphasize the need for leadership's commitment to the QMS and involve active, ongoing involvement in fostering a quality-focused organization culture. Each subsection of MR is listed below:

- **Management Commitment:** Includes requirements for top management demonstrating their commitment to the development and implementation of the QMS and its continual improvement. This is shown through communication, establishing policies, setting objectives, conducting reviews, and providing the necessary resources.
- **Customer Focus:** Includes a list of requirements that will ensure that organizations are keeping the customer in mind by determining their needs/requirements and monitoring to make sure they are being met.
- **Quality Policy:** Establishes that management is responsible for implementing a quality policy that is appropriate for the organization. This policy must commit to meeting its requirements and maintain the QMS. This policy also must be communicated and understood by everyone in the organization.
- **Planning:** Planning involves setting quality objectives and the planning of the QMS itself to ensure it meets the needs of the ISO standard and the customer.
- **Responsibility and Authority:** List requirements of setting clear goals and responsibilities that must be defined and documented. This will ensure effective management of the QMS and that appropriate communication processes are established as well.
- **Management Review:** Has requirements to communicate that top management must iteratively review the QMS to ensure it continues to be aligned with the quality objectives of the ISO standard.

Resource Management (RM)

RM within the ISO standard outlines the requirements for providing and managing the resources needed to both implement and maintain the QMS. This section is also important for ensuring that the creation and delivery of medical devices meet regulations and customer needs. Listed below are the subsections of RM:

- **Provision of Resources:** This short section declares the need to implement the QMS and maintain its effectiveness.
- **Human Resources:** Personnel conducting work affecting product quality must be competent and have appropriate education, training, skills, and experience. It also specified requirements for identifying training needs so personnel will have sufficient knowledge and skills.
- **Infrastructure:** Includes requirements for establishing the appropriate infrastructure needed to achieve conformity to product requirements. This includes buildings, workspaces, utilities, and equipment (both hardware and software).
- **Work Environment:** According to the ISO standard, it is required that the work environment be controlled to ensure product safety and quality. This includes managing the work conditions and environment that could affect product quality (cleanliness, temperature, etc.).

Product Realization (PR)

PR details the processes needed for developing, manufacturing, and delivering medical devices. It ensures that products are effectively planned, executed, and controlled. The subsections for PR include:

- **Planning of Product Realization:** Details how organizations need to effectively plan the processes needed for product realization. This includes determining quality objectives, requirements for the product, documentation, and verification & validation (V&V) results.
- **Customer-Related Processes:** Involves determining customer requirements, which include the product, delivery, and post-delivery. It also includes the handling and review of customer feedback for complete customer satisfaction.

- **Design and Development:** This section covers the entire lifecycle of medical device development from concept to delivery. It also covers the inputs, controls, and outputs of the medical device to ensure the product is built to meet the specified requirements.
- **Purchasing:** List requirements that address the purchasing of external resources. This requires evaluating and selecting suppliers based on their ability and the quality of services provided.
- **Production and Service Provision:** Consists of the management and validation process for production, service provision, and sterilization (for the cleanliness of the medical devices). It emphasizes the need for traceability as it is a key part of the V&V process.
- **Control of Monitoring and Measuring Equipment:** Ensures that the equipment used to monitor and measure the product is capable, calibrated, and maintained to confirm product conformity to ISO requirements.

Measurement, Analysis, and Improvement

This final major section of the ISO ensures that an organization can demonstrate the effectiveness of its QMS and the ability to improve its processes iteratively. This includes:

- **Monitoring and Measurement:** From the list of requirements, the organizations must apply suitable conditions for monitoring and measuring the QMS and the medical device product. Monitoring and measuring include customer satisfaction feedback, internal audits, and monitoring (collecting data) of production processes. These must achieve the previously planned results.
- **Control of Nonconforming Product:** Organizations must have a way to ensure that medical devices that do not conform to product requirements are identified and pulled to prevent unintended use or delivery.
- **Analysis of Data:** This subsection states how data generated from monitoring and measurement activities must be analyzed to prove the effectiveness of the QMS. This analysis helps identify improvement areas in any of the sections mentioned previously.

- **Improvement:** This standard requires iterative improvement of the QMS in all of the previous sections of the ISO document. Specifically, the organization must take corrective actions to eliminate the cause of failed test cases. Preventive actions must also be taken to eliminate the cause of potential failures.

SE-V & ISO Compliance

The Systems Engineering V-Model (SE-V) is a structured model that goes through a systems development lifecycle from problem identification to system retirement. Each phase of the V-Model is a key step in project development, and the focus of the V-Model is system development on the left side of the V and system verification on the right side. This kind of structured approach and verification aligns closely with standards such as ISO13485 demands thorough documentation and verification at each stage of medical device development. To show how the SE-V can comply with ISO 13485, a mapping of each phase to ISO section is provided in Figure 1.

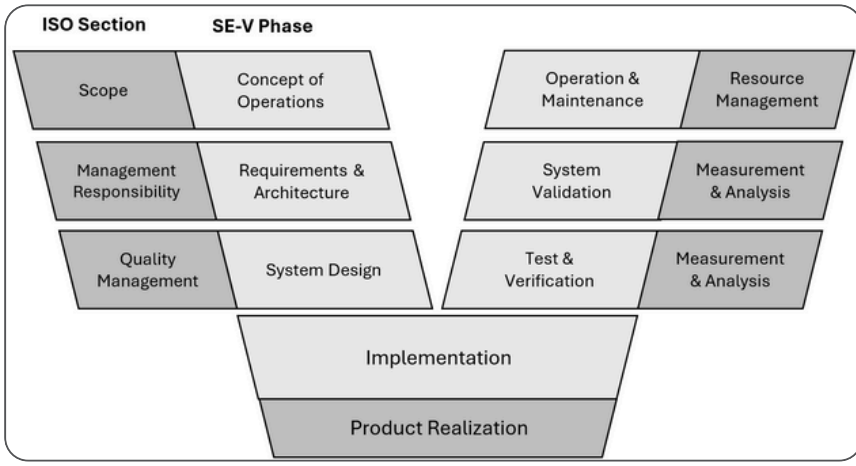

Figure 1: Systems Engineering V-Model

The inner boxes of the diagram are the phases of the V-Model. The outside boxes are the major sections of the ISO. This diagram is to show generally how the sections and phases trace to each other. A more detailed mapping can be seen in the appendix which shows the subsections of ISO 13485 traced to a subsection of the SE V-Model.

Innoslate for ISO Compliance

Innoslate offers multiple capabilities that support the compliance of the SE-V model to ISO 13485. This ISO includes many requirements to shape the standard that Innoslate can support and control the management of through its documents feature. The Documents Dashboard allows new documents to be created, and existing documents can be managed, sorted, and edited. Additionally, custom labels can also be created and added to documents to further support control management of documents.

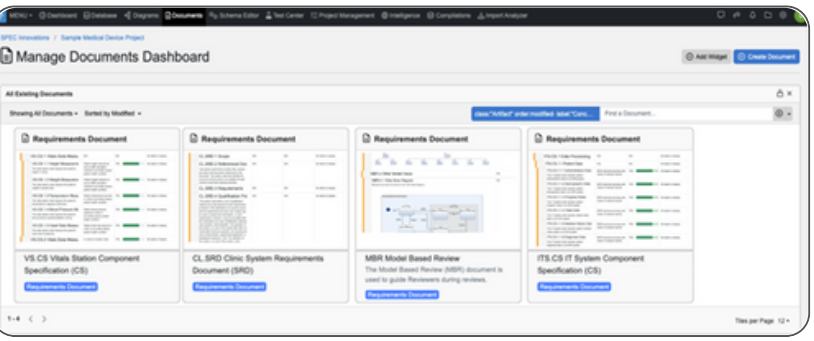

Figure 2: Documents Dashboard

Additional features are available while working on a document as well. Effective control and management of documentation is crucial for ISO 13485 and to support this, documents can be baselined, allowing for document versions and tracking of changes. Workflow can be set up where only authorized users can change a document, while others must submit change requests.

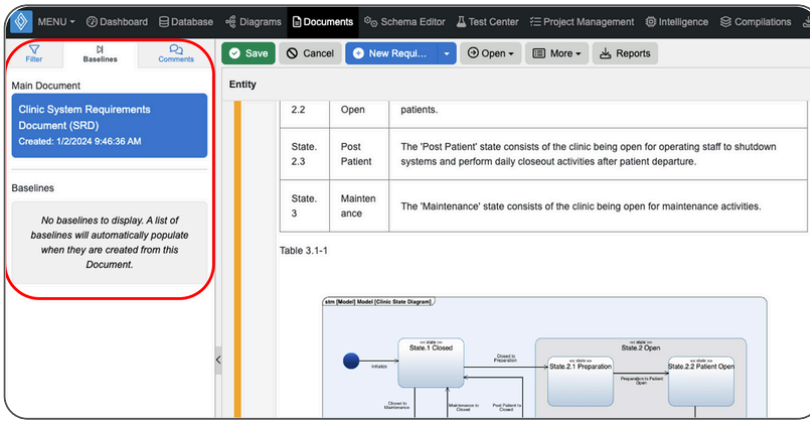

Figure 3: Change Requests

Users can also check the quality of their requirements by using Innoslate's Quality Checker feature, which analyzes a requirement and gives feedback based on the verbiage used. This ensures that requirements are clear, complete, and traceable, which further aligns with the control management aspects of ISO 13485.

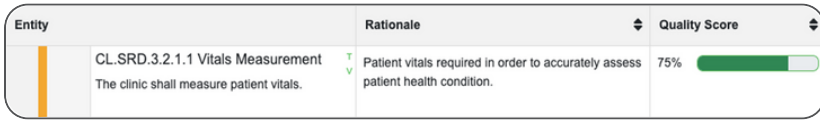

Figure 4: Quality Checking

Innoslate also supports the development of architectures and frameworks that will allow for a seamless transition to each phase of the SE-V. Easily transitioning between the development and operational phases is essential for meeting ISO 13485 standards. One of the tools that can be utilized is Innoslate's project management feature. It allows for configuration management and gives valuable project information at a glance. Users can also manage and view created Gantt charts, which are vital to understanding how far into development a medical device product is.

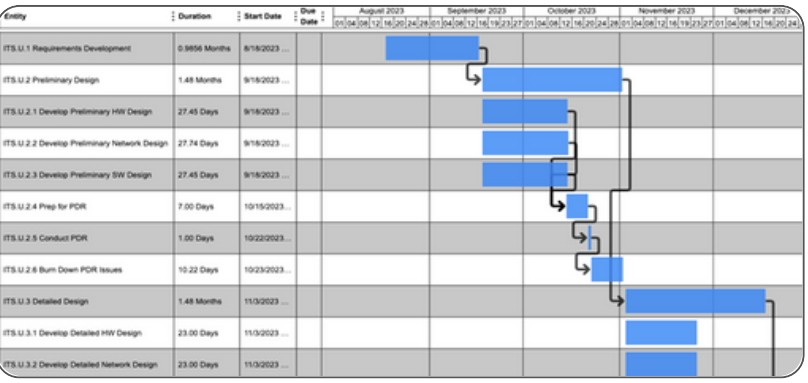

Figure 5: Gantt Charts

The use of diagrams such as the Action and State Machine diagram will also help in the execution of architectural and device product development. These diagrams give an executable model of processes that can be shared with other users and can be adjusted if any changes need to be made. These tools ensure that all steps are planned for and documented, resources are allocated appropriately, and timelines are being adhered to which continues to align with ISO 13485 requirements for planning and control.

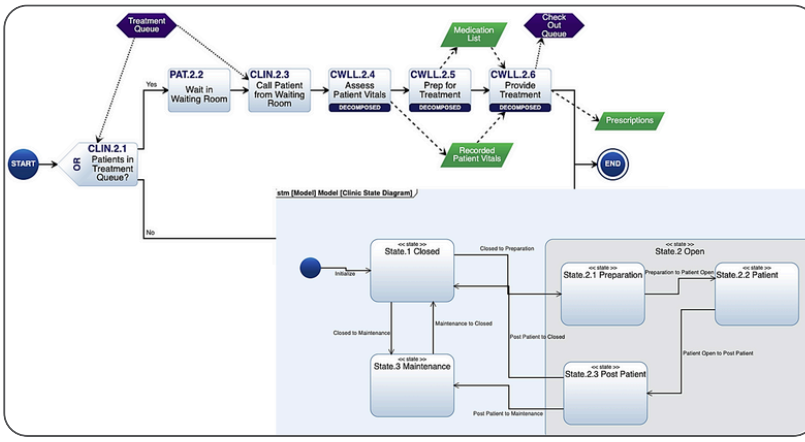

Figure 6: Actions & State Machine Diagrams

The product realization phase is the biggest section of ISO 13485; therefore, the features used to support the process must meet regulatory and customer requirements as outlined in the standard. Innoslate utilizes multiple diagrams to help visualize and manage the complex interactions within systems, showing how all components work together as intended. This is crucial for the planning and realization of medical devices.

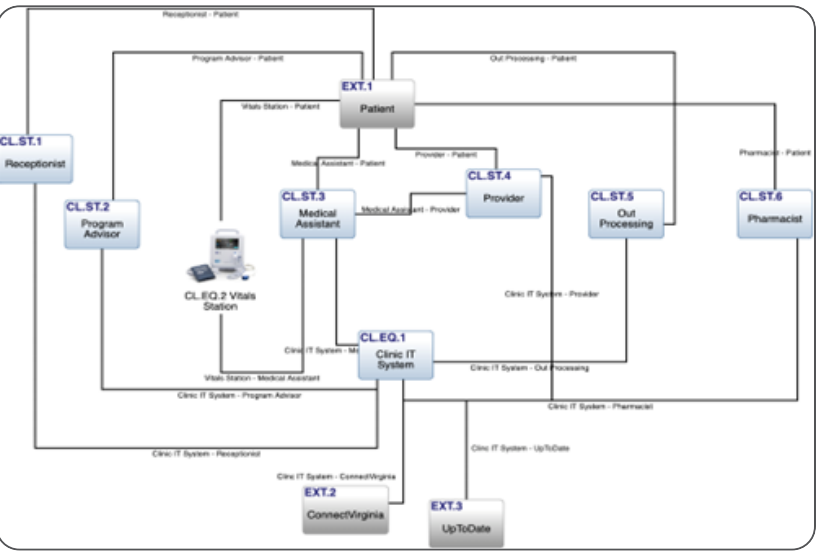

Figure 7: System Diagram

Innoslate also provides capabilities for managing risks and conducting tests. Capabilities such as risk charts, risk burndown diagrams, and test plan suites. These are needed for verifying and validating the product against design specifications and regulatory requirements.

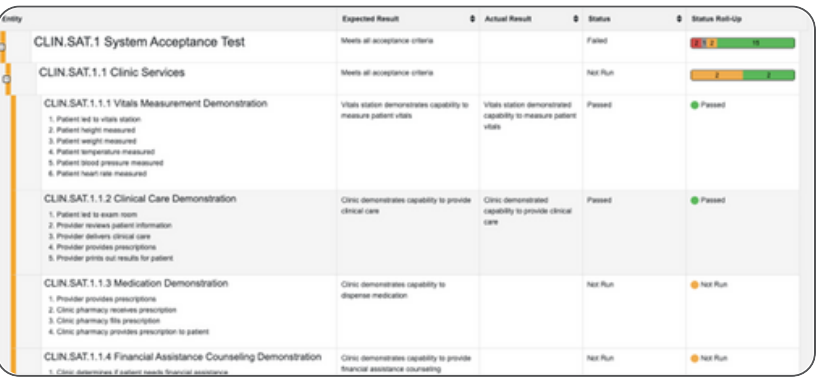

Figure 8: Test Suite

In addition to testing and monitoring, Innoslate supports iterative and continuous measurement, analysis, and improvement processes which is a key role in the ISO standard. The test suite can execute and document numerous test cycles to track changes to verification and validation over time. Only authorized users can create a new test cycle and once completed each cycle is saved to help identify areas of improvement.

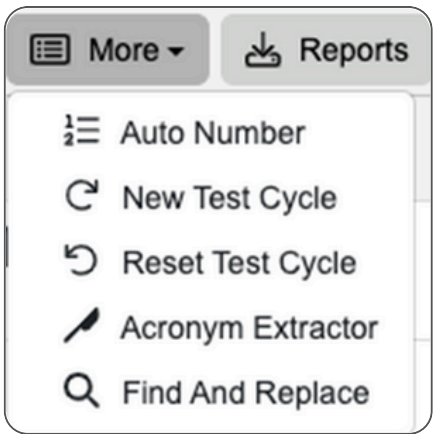

Figure 9: Test Cycles

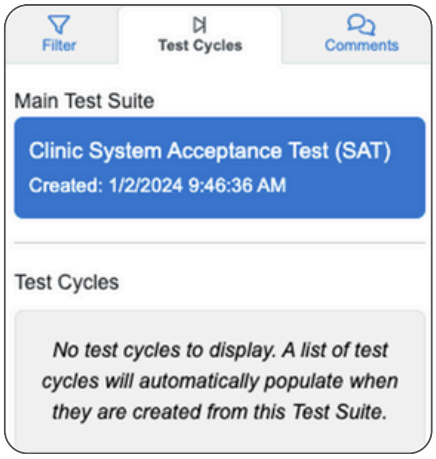

Figure 10: Test Results

All documents, test suites, and diagrams support real-time collaboration and feedback through comments, user chat, and activity dashboards. These features maximize user collaboration so that all stakeholders involved are continuously informed and engaged. All mentioned tools and features are there to ensure that all phases of the systems engineering V-model are traced and are aligned with ISO 13485 requirements. Leveraging Innoslate for this process will reduce risks, maximize productivity, and ensure that only high-quality medical devices are being delivered to patients.

Conclusion

ISO 13485 sets the global standard for quality management systems in the medical device field. Control, documentation, and continuous improvement are all needed to achieve compliance and to deliver safe high-quality medical devices. Innoslate provides a way for individuals and organizations to meet ISO 13485 requirements in a systems engineering way. Through the detailed mapping of the SE-V to ISO 13485 sections, this paper has demonstrated how Innoslate supports every phase of the medical device lifecycle from initial design to final validation. The numerous features Innoslate has, including risk analysis, testing, documentation, diagram making, and project management, not only achieve compliance with this standard but also boost operational efficiency by reducing risk, enhancing collaboration, and improving the quality of medical devices, which leads to greater customer satisfaction.

References

Developing standards. ISO. (2024a, January 31). https://www.iso.org/developing-standards.html
What we do. ISO. (2024b, January 24). https://www.iso.org/what-we-do.html

Appendix A

ISO Section			Vee Model Phase
Section Number	Name	Page Number	Model Phase
4	**Quality Management System**	**6**	**System Design**
4.1	General Requirements	6	Documentation, Requirement Diagrams, Labels
4.2	Documentation Requirements	7	Documentation, Requirement Diagrams, Labels
4.2.1	General	7	Documentation, Schema Editor
4.2.2	Quality Manual	7	Database Queries, Documentation, Quality Checker
4.2.3	Medical Device File	7	Database Queries (Organization), Documentation
4.2.4	Control of Documents	8	Project Management, Baselining, Documentation, User Workflow
4.2.5	Control of Records	8	Project Management, Baselining, Documentation, User Workflow

Table 1: Quality Management System

ISO Section			Vee Model Phase
Section Number	Name	Page Number	Model Phase
5	**Management Responsibility**	**9**	**Requirements & Architecture**
5.1	Management Commitment	9	Documentation
5.2	Customer Focus	9	Documentation, Comments Feedback
5.3	Quality Policy	9	Documentation, Labels, Schema Editor (Additional Context)
5.4	Planning	9	Documentation, Process Diagrams, Database Queries (Organization), Project Management
5.4.1	Quality Objectives	9	Document, Labeling for Database Filtering, Schema Editor (Additional Context)
5.4.2	Quality Management System Planning	9	Documentation, Labels, Quality Checker, Database w/ Saved Queries
5.5	Responsibility, Authority and Communication	10	Project Management, Access Managements, Comments for Feedback, Configuration Management (Version Control)
5.5.1	Responsibility and Authority	10	Project Management, Access Managements, Configuration Management (Version Control)
5.5.2	Management Representative	10	Project Management, Access Managements, Comments
5.5.3	Internal Communication	10	Access Managements, Comments for Feedback, User Real-Time Collaboration, User Chat Sidebar
5.6	Management Review	10	Project Management, Configuration Management (Version Control), Heuristics (e.g. Intelligence Dashboard)
5.6.1	General	10	Documentation, Labels
5.6.2	Review Input	10	Documentation, Database Labeling & Organization, Heuristics (e.g. Intelligence Dashboard), Project Management
5.6.3	Review Output	11	Documentation, Database Labeling & Organization, Heuristics (e.g. Intelligence Dashboard), Project Management

Table 2: Management Responsibility

ISO Section			Vee Model Phase
Section Number	Name	Page Number	Model Phase
6	**Resource Management**	**11**	**Operation & Maintenance**
6.1	Provision of Resources	11	Documentation, Resource Diagrams (Action Diagrams), Database Labeling & Organization, Database Queries
6.2	Human Resources	11	Documentation, Systems Architect Diagrams (e.g. Hierarchy Diagram), Database Queries
6.3	Infrastructure	12	Documentation, Systems Architect Diagrams, Database Queries, CAD Viewer, Compilations View
6.4	Work Environment and Contamination Control	12	Documentation, Compilations Documentation, System Architect & Behavior Diagrams
6.4.1	Work Environment	12	Documentation, System Architect and Behavior Diagrams
6.4.2	Contamination Control	12	Project Management

Table 3: Resource Management

ISO Section			Vee Model Phase
Section Number	Name	Page Number	Model Phase
7	**Product Realization**	**12**	**Implementation**
7.1	Planning of Product Realization	12	Documentation, Risk Diagrams (e.g. Risk Charts & Risk Burndown), Test Plan Suites
7.2	Customer-Related Process	13	Documentation, System Architect and Behavior Diagrams, Database Queries, Test Plan Suites
7.2.1	Determination of Requirements Related to Product	13	Documentation, Quality Checker
7.2.2	Review of Requirements Related to Product	13	Database Labeling & Organization, Comments, Baselining, Access Managements
7.2.3	Communication	14	Comments for Feedback, User Real-Time Collaboration, Access Managements, Platform Chat Sidebar
7.3	Design and Development	14	Documentation, System Architect and Behavior Diagrams, Database Queries
7.3.1	General	14	Documentation, Database Labeling & Organization, Database Queries & Saved Queries
7.3.2	Design and Development Planning	14	Documentation, Systems Architect Diagrams (e.g. Hierarchy Diagram), Database Queries, Database Labeling & Organization
7.3.3	Design and Development Inputs	14	Documentation, Systems Architect Diagrams, Database Queries, Intelligence Analysis Metrics
7.3.4	Design and Development Outputs	15	Documentation, Systems Architect Diagrams, Database Queries, Heuristics (e.g. Intelligence Dashboard)
7.3.5	Design and Development Review	15	Project Management, Heuristics (e.g. Intelligence Dashboard), Database Queries
7.3.6	Design and Development Verification	15	Documentation, Test Plan Cycles & Documentation, Relationships
7.3.7	Design and Development Validation	15	Documentation, Test Plan Cycles & Documentation, Relationships
7.3.8	Design and Development Transfer	16	Import Analyzer, Compilations Documents, Database Labeling & Organization
7.3.9	Control of Design and Development Changes	16	Project Management, Configuration Management, Baselining, Access Managements & Workflow
7.3.10	Design and Development Files	16	Compilations Documents, Database Queries, Entity View (Upload & Download Files)
7.4	Purchasing	17	Documentation, Project Management, Configuration Management (version control), Comments Feedback
7.4.1	Purchasing Process	17	Documentation, Comments Feedback, Risk Diagrams (e.g. Risk Charts & Risk Matrix)
7.4.2	Purchasing Information	17	Documentation, Database Labeling & Organization, Schema Editor (adding Attributes)
7.4.3	Verification of Purchased Product	17	Traceability Matrix, Database Labeling & Organization, Documentation
7.5	Production and Service Provision	18	Documentation, Systems Architect Diagrams (e.g. Action Diagram), Database Queries
7.5.1	Control of Production and Service Provision	18	Documentation, Labels, Project Management, Schema Editor (adding Attributes)
7.5.2	Cleanliness of Product	18	Documentation, System Architect and Behavior Diagrams, Database Labeling & Organization
7.5.3	Installation Activities	18	Documentation, Relationships, Diagrams View (Action Diagram)
7.5.4	Servicing Activities	19	Documentation, Database Queries (Quarries), Resource Diagrams (e.g. Action Diagram), Schema Editor
7.5.5	Particular Requirements for Sterile Medical Devices	19	Traceability Matrix, Documentation, Traceability Matrix, Database Labeling & Organization
7.5.6	Validation of Process for Production and Service Provision	19	Traceability Matrix, Labels, Documentation, Configuration Management (e.g. Change Requests), Project Management
7.5.7	Particular Requirements for Validation of Process for Sterilization and Sterile Barrier Systems	19	Documentation, Relationships, Baselining, Database Labeling & Organization
7.5.8	Identification	20	Documentation, Database Queries, Systems Architect Diagrams (e.g. Hierarchy/Asset Diagram)
7.5.9	Traceability	20	Traceability Matrix, Database Labeling & Organization, Traceability Matrix
7.5.10	Customer Property	20	Documentation, Database Queries
7.5.11	Preservation of Product	20	Documentation, Systems Architect Diagrams (e.g. Hierarchy/Asset Diagram), CAD Viewer, Test Plan Cycles & Documentation
7.6	Control of Monitoring and Measuring Equipment	21	Documentation, Baselining, Project Management, Database Labeling & Organization, Test Plan Cycles & Documentation

Table 4: Product Realization

ISO Section			Vee Model Phase
Section Number	Name	Page Number	Model Phase
8	**Measurement, Analysis**	**22**	**Integration & Test**
8.1	General	22	Test Plan Cycles & Documentation, Database Labeling & Organization, Documentation, Traceability Matrix
8.2	Monitoring and Measurement	22	Documentation, Test Plan Cycles & Documentation
8.2.1	Feedback	22	Documentation, Database Queries, Risk Diagrams (e.g. Risk Charts & Risk Burndown)
8.2.2	Complaint Handling	22	Documentation, Labels
8.2.3	Reporting to Regulatory Authorities	23	Documentation, Comments
8.2.4	Internal Audit	23	Documentation, Configuration Management (Baselining & Version Control), Project Management
8.2.5	Monitoring and Measurement of Process	23	Documentation, System Architect and Behavior Diagrams, Labels
8.2.6	Monitoring and Measurement of Product	23	Documentation, Traceability Matrix, Database Queries, traceability Matrix
8.3	Control of Nonconforming Product	24	Documentation
8.3.1	General	24	Documentation, Baselining, Access Managements
8.3.2	Actions in Response to Nonconforming Product Detected Before Delivery	24	Access Managements, User Real-Time Collaboration, Comments for Feedback
8.3.3	Actions in Response to Nonconforming Product Detected After Delivery	24	Documentation, Access Managements, Comments for Feedback
8.3.4	Rework	24	Baselining, Configuration Management (Version Control), Access Managements, Configuration Management (e.g. Change Requests)
8.4	Analysis of Data	24	Documentation, Test Plan Cycles & Documentation, Comments for Feedback, Database Labeling & Organization, User Real-Time Collaboration
8.5	Improvement	25	Documentation, Configuration Management (Version Control)
8.5.1	General	25	Database Queries, Database Labeling & Organization, Comments for Feedback, Configuration Management (Version Control)
8.5.2	Corrective Action	25	Systems Architect Diagrams (e.g. Hierarchy Diagram), Documentation, Relationships, Access Managements
8.5.3	Preventive Action	25	Documentation, Risk Diagrams (e.g. Risk Charts & Risk Burndown), Test Plan Cycles & Documentation, Traceability Matrix

Table 5: Measurement & Analysis

Appendix B

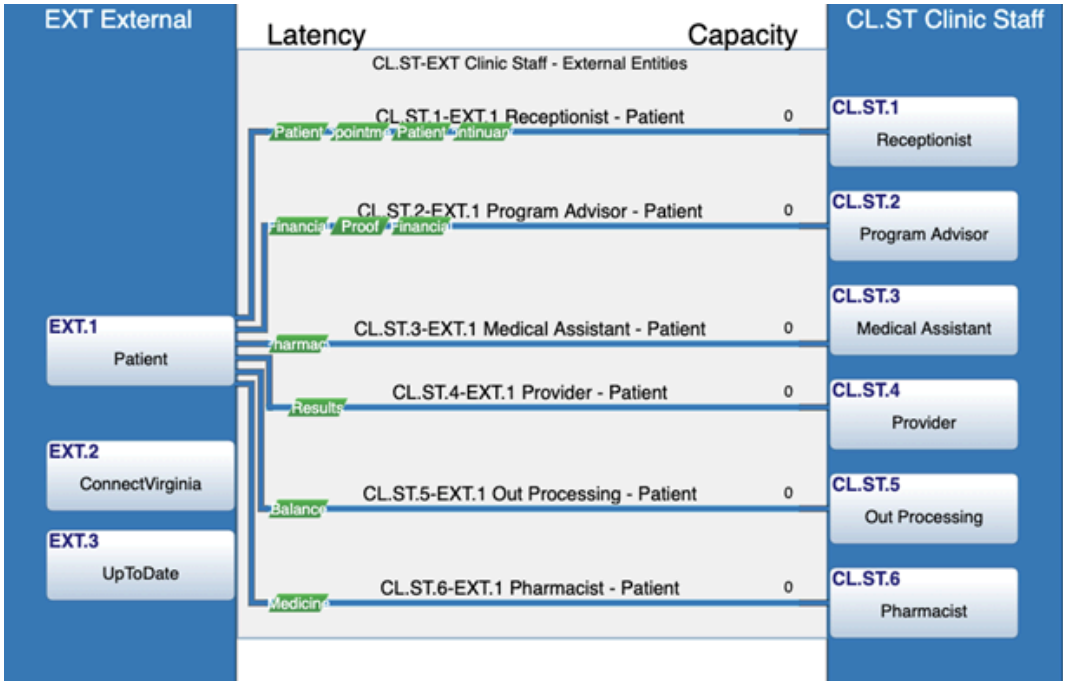

Figure 11: External Data Testing

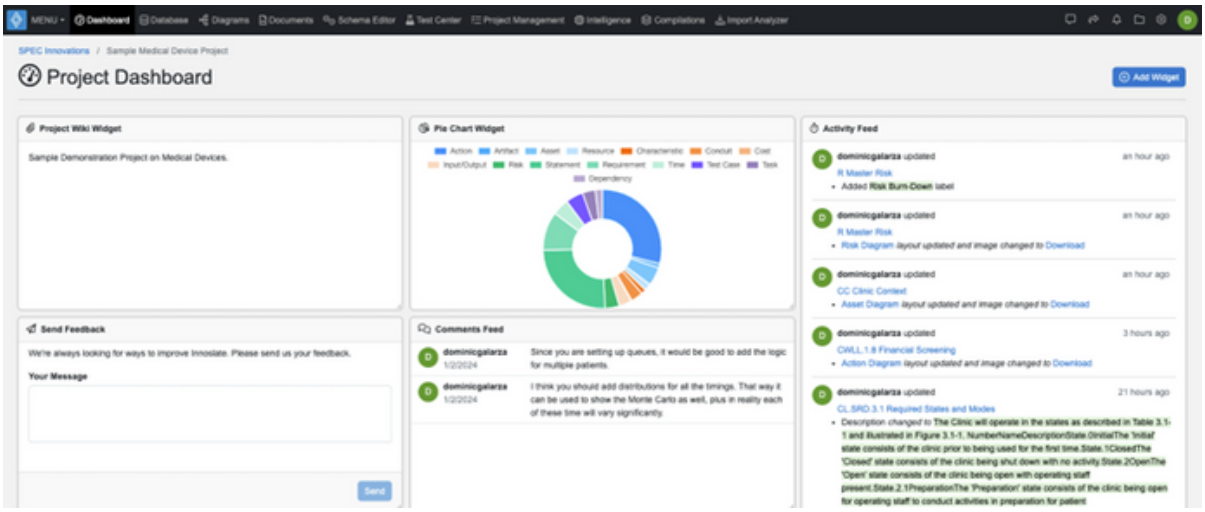

Figure 12: Project Dashboard