FRESENIUS MEDICAL CARE

Standard Operating Procedure for CQMS Documentation Library

CQMS-SOP-000172 Rev. 2

Design Input

Translated Document Name:	-/-
Previous Reference:	-/-
Responsible Area:	GRD EMEA & AP
Area of Application:	GRD EMEA & AP
Description:	The purpose of this document is to define the process for the preparation, review and approval of Design Inputs for new or changed medical devices.
QMS Applicable:	CQMS
Other References:	CQMS-DCC-000307
QMS Roles:	Design Quality Assurance; R&D Engineering; Project Manager; Regulatory; Program System Architect; Program Application Manager

Electronic Signatures

Intention	User Name	Decision	Timestamp
Sign as Owner	Matthias Schoen	Approve	2021-05-02 14:51 GMT+02
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Sign as QA Approver	Joe Winslow	Approve (Release with CN)	2021-05-18 15:49 GMT+02

Electronic Signatures of Change

Intention	User Name	Decision	Release Target	Timestamp
Release Change Approved	Joe Winslow	Approve	Effective	2021-06-15 22:56 GMT+02

1. PURPOSE

The purpose of this document is to document the process for establishing **Design Inputs** for new products and product changes to medical devices.

2. SCOPE

This procedure applies to all product development projects of medical devices within FME.

3. RESPONSIBILITIES

Department/Title/Role	Responsibility
Design Quality Assurance	• Review the Input Requirements, to ensure that they comply this SOP as the design and development evolve. This review may be conducted in conjunction with or as part of a Design Review or Phase Exit Review.
R&D Engineering	• Shall follow the process defined in this procedure for the development of all Fresenius products. • Shall be responsible for providing input into CQMS-FORM-001055, User Input Document (UID) (User Requirements Document) and CQMS-FORM-001056 Engineering Input Document (EID) (Product Requirements Document and Component Requirements Document). • Ensure that Design Inputs fulfill the project scope outlined in the product design and development plan. • Ensure that Design Inputs are achievable, consistent, verifiable, and clearly stated. • Ensure the use of Risk / Hazard Analysis in developing Design Input items related to product safety.
Project Manager	• Shall oversee development and maintenance of all Design Inputs in accordance with this Standard Operating Procedure (SOP). • Shall assure compliance to requirements traceability.
Regulatory	• Assures applicable regulatory requirements and standards are included.
Program System Architect	• Assure Interface and Connectivity requirements are included.

Department/Title/Role	Responsibility
Program Application Manager	• Assure Usability Engineering requirements are included.
Marketing	• Assure the voice of business and the voice of the customer are translated and included.
Risk Management	• Assure safety requirements are included
Manufacturing Responsible GMQS	• Assure the product manufacturability and assemblability

4. PROCEDURE

4.1 INTRODUCTION

4.1.1 **User Inputs** are qualitative in nature and are captured in CQMS-FORM-001055, User Input Document (UID) (User Requirements). The intended use of the device, including the needs of the user, the needs of the patient, the user environment, safety (from Risk Management), and compliance requirements, shall be established and documented in the UID. The UID contains the requirements with which the design is validated.

4.1.2 Qualitative information from the UID, (User Input, Compliance Requirements, and Safety Requirements) is used as the basis for the development of quantifiable engineering inputs (Product Requirements, Component Requirements). The engineering inputs are the requirements that the Design Outputs are verified against.

4.1.3 **Design Inputs** shall be documented so that each requirement satisfies a number of properties. They must be:

4.1.3.1 Clear, Concise and Unambiguous: All requirements shall be precisely stated, eliminating room for more than one interpretation.

4.1.3.2 Non-Conflicting: All requirements, or any subset thereof, shall not make contradictory statements.

4.1.3.3 Measurable: Design Inputs must be capable of being verified and/or validated. All Inputs shall be verifiable or validate-able in an unambiguous manner that determines if the corresponding Design Outputs satisfy the Design Inputs. Tests can be either qualitative or quantitative.

4.1.3.4 Complete: Requirements must be developed to a sufficient extent to describe the physical and performance characteristics.

4.1.4 Design Inputs will be revised and updated to reflect continued inputs from complimentary design activities, e.g. changes to Design Inputs due to ongoing risk management activities.

4.1.5 The requirements development process may be iterative and continue through the completion of the Design Outputs prior to verification. Design Input documents shall be reviewed, approved, and revision controlled.

4.1.6 Requirements documents may be revised and updated as needed.

4.2 SOURCES FOR DESIGN INPUTS

4.2.1 Source materials for Design Inputs might include:

- → Marketing studies including user profiles, use scenarios, use environment, and distribution areas (e.g. Market & Customer Needs Document).
- → Business Requirements
- → Initial Risk Analysis (Preliminary Hazard Analysis).
- → Complaints, Medical Device Reporting, and adverse events
- → User considerations for example, clinical workflow.
- → Regulatory statutes
- → Technical considerations
- → External consensus standards
- → Current or previous product Design Inputs

4.2.2 Generally, user inputs (User Requirements) are "external" inputs since they are based on customer needs, external standards and control measures from Risk Management.

4.2.3 Engineering inputs (Product Requirements, Component Requirements) are "internal" inputs since they are based on the internal decisions of the project team on how to meet the user inputs and on how to address standards and control measures from Risk Management.

NOTE: Platform development projects refer to the development and the verification of components, modules used across different target systems. Inputs to the platform development projects can be external and internal: they include relevant inputs addressing all the target components and modules. The inputs can be collected in a dedicated document (e.g. Platform Stakeholdes Needs) or may be segregated into separate documents.

4.3 UID PROCESS (USER REQUIREMENT)

4.3.1 The process of developing Design Inputs shall start with a review of the following documents and activities:

- → Prior to Design Control activities, Marketing typically leads an effort to understand user needs associated with a new product or feature to be developed. These typically would be documented in customer needs document and then translated into requirements in the User Inputs Document (UID)
- → Regulatory will inform engineering of currently applicable regulations and consensus standards that the product must comply with. Information from the standard shall be documented as compliance requirements in the UID

→ A Preliminary Hazard Analysis or Risk Analysis shall be completed prior to the approval of Design Inputs. See CQMS-SOP-000189, Process of R&D Risk Management. This information shall be used as input to the safety requirements in the UID.

4.3.2 The design output will be validated against the User Inputs (User Requirements).

4.3.3 User inputs shall include but are not limited to:

4.3.3.1 Intended use of the product.

4.3.3.2 The use environment and target user group (e.g. environmental conditions for storage and operations, usage like clinic, acute or home, expected shelf life, expected numbers of use of the product).

4.3.3.3 Human Factors, Usability Engineering process interface characteristics.

4.3.3.4 Safety requirements derived from the control measures in the Preliminary Hazard Analysis / Risk Analysis. Qualitative risk control measure required to reduce an otherwise unacceptable risk, shall be identified as a User Input for the purposes of mitigating the identified risk.

4.3.3.5 Quality compliance requirements: i.e. Applicable Standards, Country Specific Regulations.

4.3.4 Additional User Input might include:

4.3.4.1 Top-Level characteristics such as weight, color, portability, etc.

4.3.4.2 Compatibility, Interface and Interchangeability requirements

4.3.4.3 Geographic distribution and language requirements.

4.3.4.4 Labeling claims.

4.3.4.5 User Regulatory Requirements (UL, HIPPA).

4.3.4.6 Legal Requirements.

4.3.4.7 Performance characteristics.

4.3.4.8 Functional characteristics.

4.3.4.9 Planned user training requirements.

4.3.4.10 Service Requirements.

4.3.5 A review shall be conducted to ensure user inputs are clear, complete, unambiguous, non-conflicting, and validable. Issues when identified shall be resolved.

4.4 EID (PRODUCT REQUIREMENTS, COMPONENT REQUIREMENTS) PROCESS

4.4.1 Based on the User Input Document prepare quantifiable Engineering Inputs with the appropriate amount of engineering detail to guide a successful design effort. Additionally, these engineering inputs shall be unambiguous to facilitate clear design verification testing. These Engineering Inputs shall be documented in the EID.

NOTE: Business requirements as well as external standards and control measures from Risk Management (if quantitative), can be addressed directly to the CQMS-FORM-001056, Engineering Input Document (EID).

4.4.2 Engineering requirements shall include but are not limited to

4.4.2.1 Performance requirements.

4.4.2.2 Mechanical requirements (including hydraulics, packaging/shipping and connections/interfaces).

4.4.2.3 Electrical requirements (including connections/interfaces).

4.4.2.4 Software requirements.

4.4.2.5 Material requirements (including structural, dimensional and biocompatibility).

4.4.2.6 Product life and reliability.

4.4.2.7 Safety requirements resulting from the Risk Management Process.

4.4.2.8 Labeling requirements.

4.4.2.9 Regulatory requirements (including product and industry standards).

4.4.3 Additional Engineering Input might include:

4.4.3.1 Manufacturability.

4.4.3.2 Interface requirements

NOTE: Interface requirements may include:
- interfaces between Medical Devices
- interfaces between Medical Devices and Non Medical Device
- interfaces between components within the same Medical Device

A member from each team should be represented.

4.4.3.3 Chemical requirements.

4.4.3.4 Sterilization requirements.

4.4.3.5 Environmental requirements (including storage, operating, disposal).

4.4.3.6 Formal user training, certification and/or re-certification programs based upon human factors evaluations and Hazard Analysis.

NOTE: Engineering requirements can be produced at all levels (System, Product, or component level). For complex products or Programmable Electrical Medical Systems (PEMS) it is recommended to produce Product Requirements and then further detail the structure of a product into components by preparing a Product Architectural Design. In this case, once the components have been identified, in addition to Product Requirement prepare quantifiable Component Requirements.

4.4.4 Engineering requirements may be contained in one document or may be segregated into separate documents such Software Requirements Specification, Mechanical Design Input, per the categories given above.

4.4.5 Each user input as documented in the UID shall trace to at least one engineering input in the EID.

4.4.6 Engineering inputs shall trace up to at least one user input where appropriate. For example, a software specific Design Input (such as operating system choice) may not necessarily trace directly to a user input in the UID, but rather will be derived from a sub-system or system level engineering requirement.

4.4.7 In addition, Engineering Inputs might be directly traced to quantitative safety requirements coming from the risk analysis and to quantitative requirements coming from the applicable standards.

4.4.8 Use the CQMS-FORM-0001056, Engineering Input Document to document the engineering requirements.

4.4.9 Engineering Inputs for software should be based on the Software Life Cycle Process (CQMS-SOP-000174).

4.4.10 Engineering requirements shall include but are not limited to the user interface, mechanical interface, electrical interface, performance requirements, alarm messages, connectivity requirements, safety requirements derived from risk control measures in the Hazard Analysis, and planned user training.

4.4.11 A review shall be conducted to ensure design inputs are clear, complete, unambiguous, non-conflicting, and verifiable. Issues when identified shall be resolved.

4.5 REQUIREMENTS TAG NUMBERING

4.5.1 A requirement tagging system will be used to establish traceability. Each input, weather User Input (User Requirement) or Engineering Input (Product Requirement, Component Requirement), must have a unique tag number assigned to them.

4.5.2 For projects using paper-based traceability, it is recommended that User Inputs begin with the letter "U" or "UR" in each tag. In addition, it is recommended that Engineering Inputs begin with the letter "E" or "PR" (referring to a Product requirement) or "CR" (referring to a Component Requirement) in each tag prior to the sequential numbering.

Example: U123 -> E123.1, E123.2, etc.

4.6 APPROVAL

4.6.1 The UID and the EID shall be approved according to CQMS-SUP-000144, Design Control Document Approval Matrix.

References

Document ID / Previous ID	Document Title / Document Translated Title
CQMS-SOP-000165 / C-PP-04-25	*Human Factors Engineering/Usability Engineering / -/-*
CQMS-SOP-000174 / -/-	*Software Life Cycle Process / -/-*
CQMS-SOP-000189 / -/-	*Process of R&D Risk Management / -/-*

References (Uses)

Document ID / Previous ID	Document Title / Document Translated Title
CQMS-FORM-001055	*User Input Document*
CQMS-FORM-001056	*Engineering Input Document*

Revision History Table

Revision	Date	Revision History	Document Owner
Rev 1	2018-10-01 (E)	This is the initial revision of the document.	Eric Renno
Rev 2	2021-06-17 (E)	Alignment of responsibilities and harmonization with North America	Christian Barth

Related Change(s)

Revision	Change ID	Change Title
Rev A	CQMS-DCC-000307	Design Input & Design Requirement Traceability
Rev A	CQMS-DCC-000396	CQMS Document Owner Clean-up
Rev A	CQMS-DCC-000457	CQMS Administrative Changes

Document Periodic Review History for this Revision

No.	Date Performed	Outcome	Performer
1	2023-05-19 07:29 GMT+02	Currently no update in CQMS needed. Next Update will be performed within GMS	Christian Barth

Regulation References

Regulation	Chapter/Section
CFR 21 Part 820 (US)	820.030 Design controls
ISO 13485:2016	7.3.3 Design and development inputs