Document Roadmap TechDoc

This is a proposed roadmap to creating the TechDoc file. The documents are grouped by "Design Phase". To each document, a responsible person is assigned as the author. Go through the list phase by phase. You can mix up the order of documents within a phase, but I recommend to finalize documents from one phase before moving on to the next.

PHASE 1: Planning & Feasability

Document	Author	Comment
Intended Use	CEO	This is the most important document of your TechDoc. Business and Regulatory Strategy depend on it.
Medical Device Classification	QA/RA Manger	Defining the product's medical device classification acc. to MDR.
Product Roadmap	Product Manager	Not an essential document. This is for feasibility assessments and resource planning. Helps to keep track of what's to come.
Software Development and Maintenance Plan	Software Developer	Giving product-specific information on the tools, resources and methods to be used for software development. Helpful for developer teams to align regarding the development setup.
Change Evaluation List	QA/RA Manger	Listing and assessing gaps between the last and the upcoming software version. Follows criteria from MDCG 2020-3. Not needed for the very first release.
Risk Management Plan and Risk Acceptance Matrix	Risk Manager	Specifies the methods for assessing risks to be used for the product at hand. Defines probability and severity categories and acceptable ranges.
Clinical Evaluation Plan	Clinician / Scientific Person	Specifying the methodology that shall be used to assess the clinical benefits and risks of the product.

PHASE 2: Specification

Document	Author	Comment
User Needs List	Product Manager	This is a list of high-level requirements. Most of them will be implemented through Software Requirements.
User Needs Checklist	QA/RA Manager	Checking if the User Needs List makes sense.
Software Requirements List	Developer-adjacent person	Specifying how User Needs will be incorporated in the software. Describing the details of a feature.
List of Hazard-Related Use Scenarios	Risk Manager	Identifying scenarios in which users could be prone to hazards.
Risk Table	Risk Manager	Anticipating and assessing risks. Gathering input from various channels.
Software Requirements Checklist	QA/RA Manager	Checking if the Software Requirements List makes sense.
Software Test Plan	Software Developer	Defining tests for every Software Requirement and mapping them to each other.
Usability Test Plan	Product Manager / Usability Engineer	Specifying the methodologies to be used to conduct the Usability Test.

PHASE 3: Development

Document	Author	Comment
SOUP List	Software Developer	List of external libraries, frameworks and packages used in the product, incl. their assessment of criticality.
Software Architecture	Software Developer	Description/Graphic outlining the software components and their interaction.

The actual programming work takes place in this phase. It makes sense to create the SOUP list and the software architecture immediately before programming begins and to adjust them if anything changes during code creation. These documents should actually be created in advance, but due to the iterative nature of software development, it will not be possible to plan everything before the actual work begins. Therefore, it makes sense to create them in parallel with the programming.

PHASE 4: Verification and Validation

Document	Author	Comment
Software Test Results	QA Tester	Results of the Software Tests: passed or failed?
List of Known Anomalies	Software Developer / Product Manager	List of known bugs and failed software tests. Justification why the software can still be released without impacting benefit/safety and a timeline when those bugs will be fixed.
Instructions For Use	Person with the best overview	The name says it all.
Usability Test Protocol	Product Manager / Usability Engineer	Specifying the actual usability test cases: Testing User Needs, Hazard-Related Use Scenarios and Instructions for Use.
Usability Test Report	Product Manager	Summary of the results of the Usability Test.
Clinical Evaluation Report	Clinician / Scientific Person	Analysing scientific data to prove the products safety and efficacy.
Risk Management Report	Risk Manager	Summary of the Risk Management Activities

PHASE 5: Product Release

Document	Author	Comment
GSPR List	QA/RA Manager	Checking if the "General Safety and Performance Requirements" are fulfilled.
PMS (/PMCF) Plan	QA/RA Manager	Planning the product-specific activities for Post-Market Surveillance. If the clinical data is not sufficient, also plan Post-Market Clinical Follow-Up activities.
Software Release Checklist	QA/RA Manager	Checking if all the requirements are fulfilled, if the documents are complete and if the product is safe to be used.

Document	Author	Comment
Release Notes	Product Manager OR Software Developer	Description of new features in the current release.
Declaration of Conformity	QA/RA and CEO	Declaring the product's conformity with the regulations and standards.