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Documentation @ Frencken

27-01-2022

Ben Bruggink

Mechatronics

Confidential

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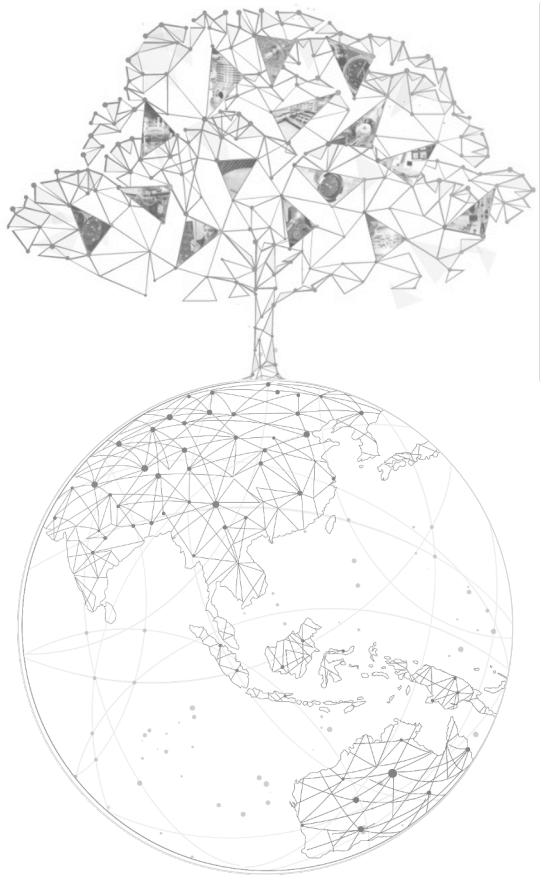
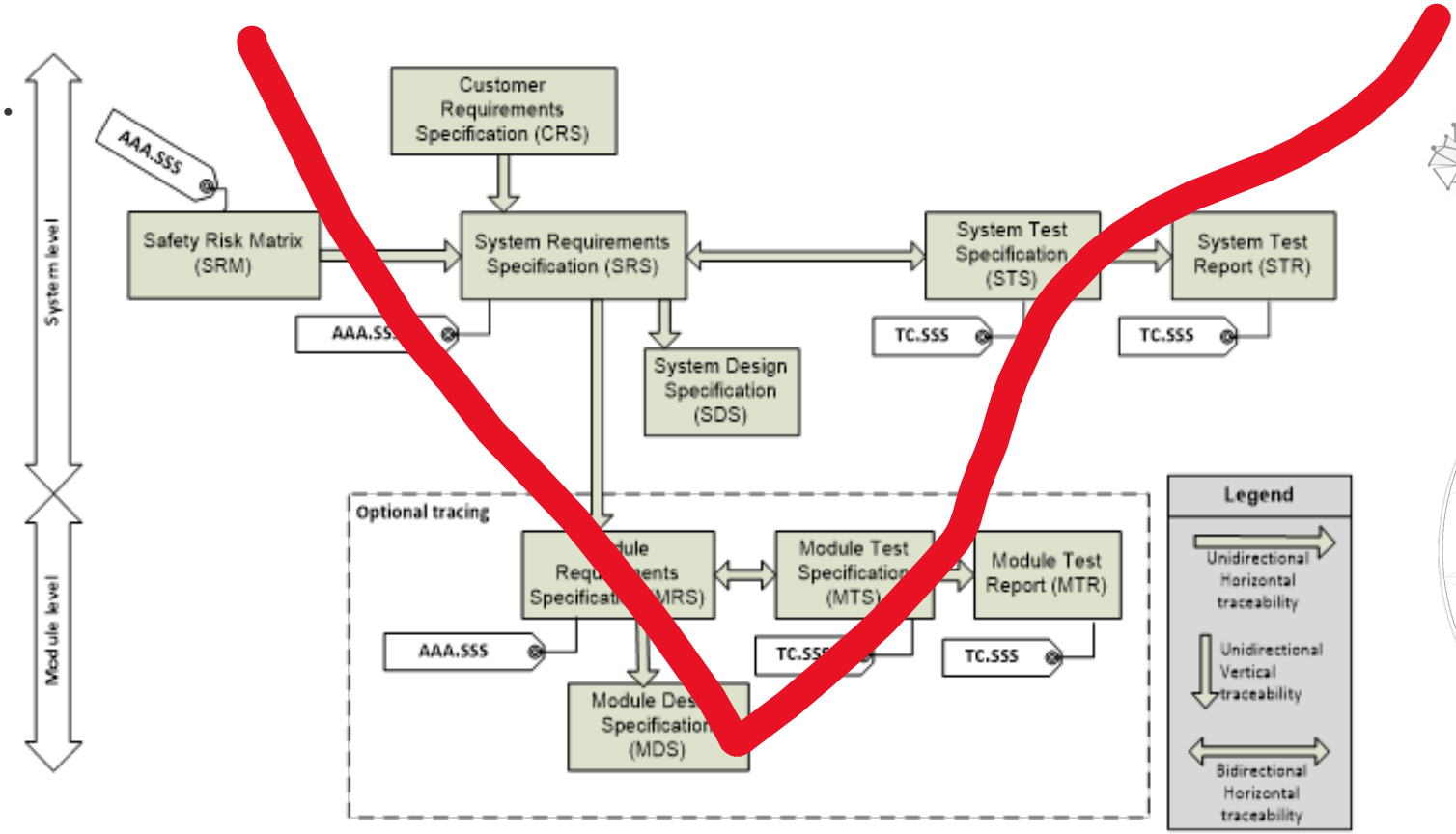
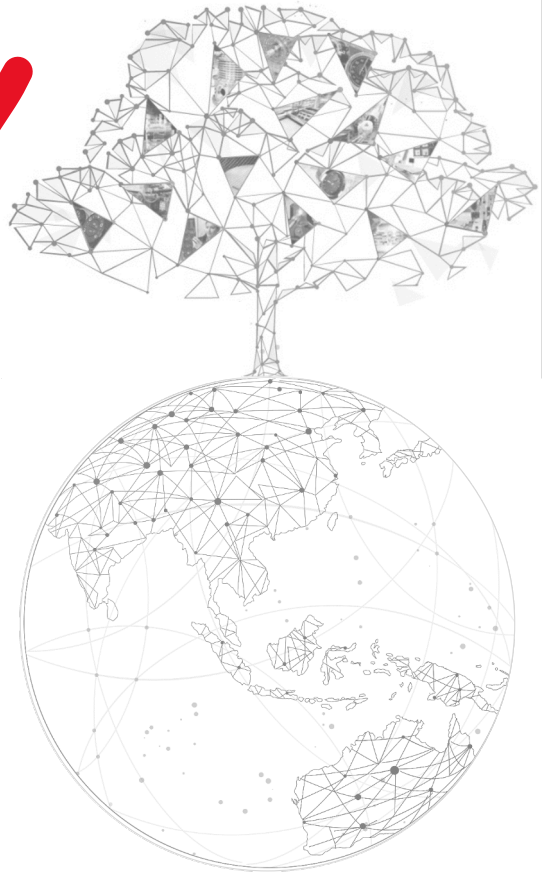


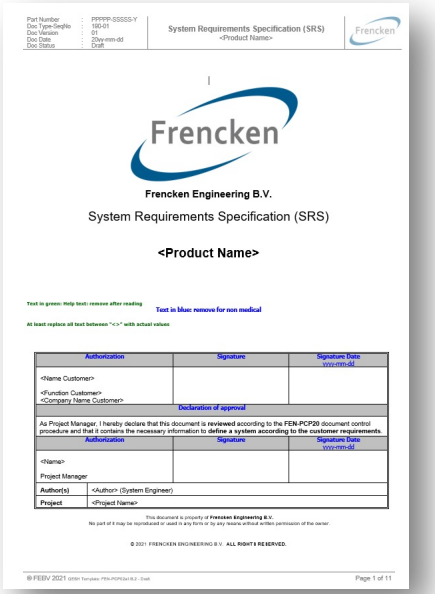
V-model





Documenten

- Documents are written as Word or Excel files and signed in PDF.
- The amount depends on the character of the project but many tens of files over the whole design and engineering process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Frencken Engineering B.V.

System Requirements Specification (SRS)

<Product Name>


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System Design Specification (SDS)

<Product Name>


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Safety Risk Matrix (SRM)

<Product Name>

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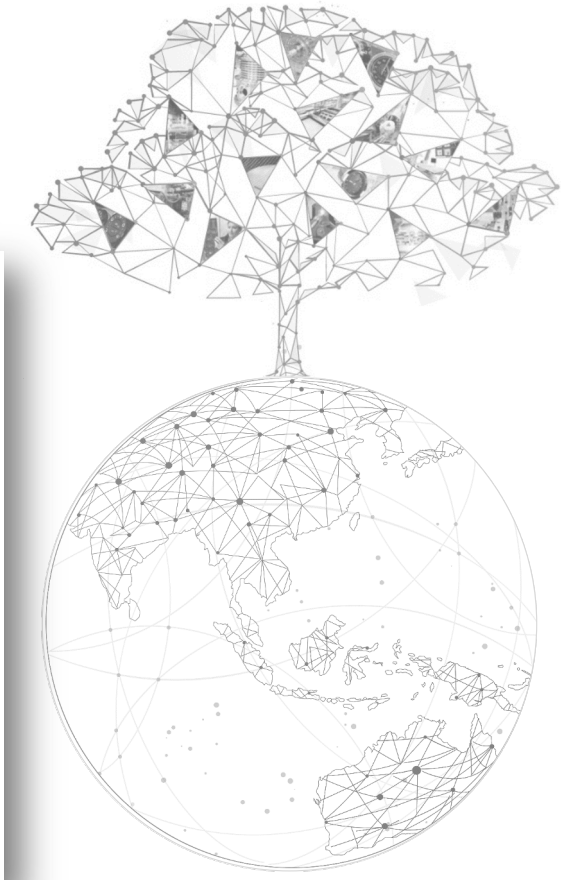

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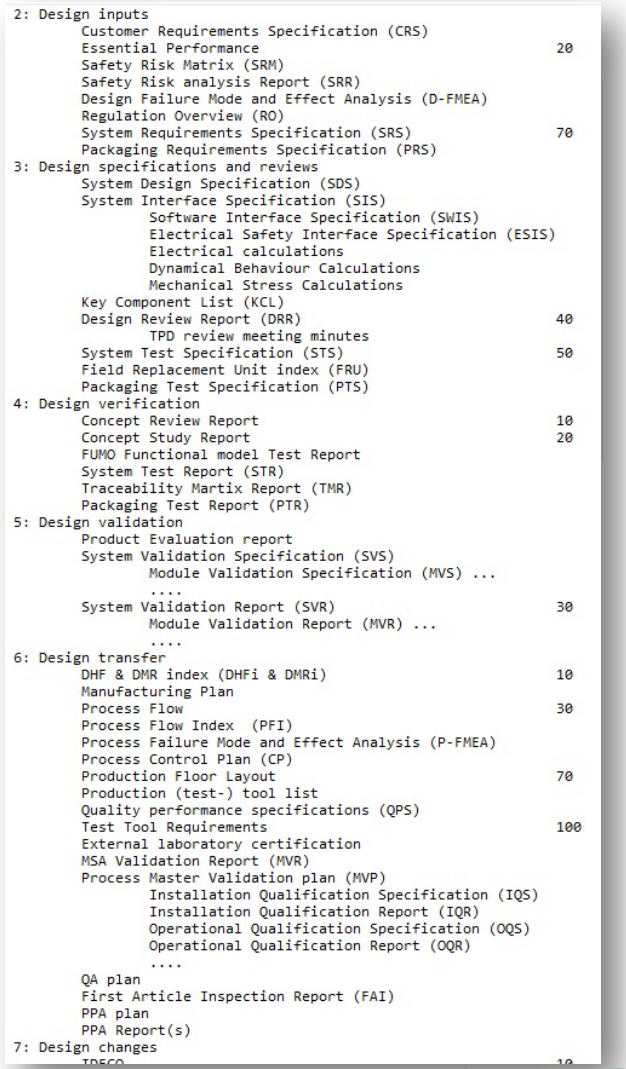
Overview of documents in PLM

- Structure according the FDA Design History File.



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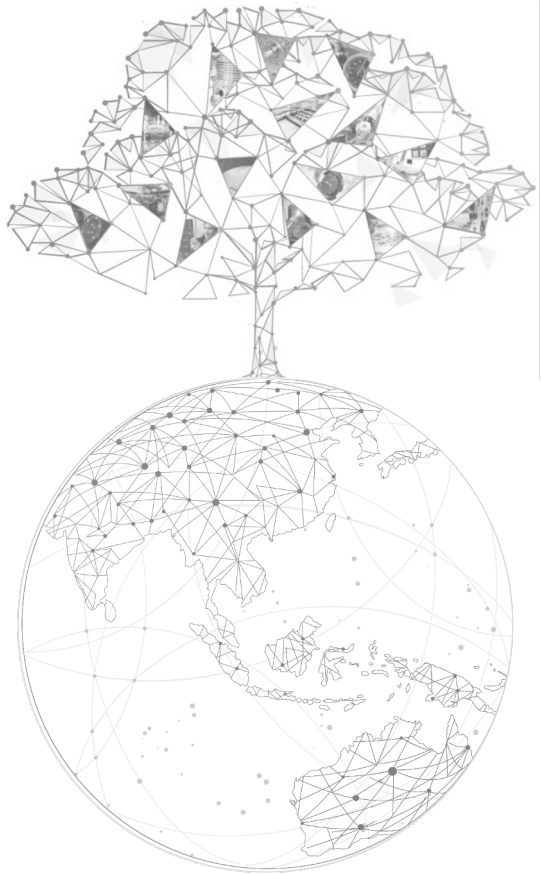
2: Design inputs
        Customer Requirements Specification (CRS)
        Essential Performance                                          20
        Safety Risk Matrix (SRM)
        Safety Risk analysis Report (SRR)
        Design Failure Mode and Effect Analysis (D-FMEA)
        Regulation Overview (RO)
        System Requirements Specification (SRS)                        70
        Packaging Requirements Specification (PRS)
3: Design specifications and reviews
        System Design Specification (SDS)
        System Interface Specification (SIS)
                Software Interface Specification (SWIS)
                Electrical Safety Interface Specification (ESIS)
                Electrical calculations
                Dynamical Behaviour Calculations
                Mechanical Stress Calculations
        Key Component List (KCL)
        Design Review Report (DRR)                                     40
                TPD review meeting minutes
        System Test Specification (STS)                                50
        Field Replacement Unit index (FRU)
        Packaging Test Specification (PTS)
4: Design verification
        Concept Review Report                                          10
        Concept Study Report                                           20
        FUMO Functional model Test Report
        System Test Report (STR)
        Traceability Martix Report (TMR)
        Packaging Test Report (PTR)
5: Design validation
        Product Evaluation report
        System Validation Specification (SVS)
                Module Validation Specification (MVS) ...
                ....
        System Validation Report (SVR)                                 30
                Module Validation Report (MVR) ...
                ....
6: Design transfer
        DHF & DMR index (DHFi & DMRi)                                  10
        Manufacturing Plan
        Process Flow                                                   30
        Process Flow Index  (PFI)
        Process Failure Mode and Effect Analysis (P-FMEA)
        Process Control Plan (CP)
        Production Floor Layout                                        70
        Production (test-) tool list
        Quality performance specifications (QPS)
        Test Tool Requirements                                         100
        External laboratory certification
        MSA Validation Report (MVR)
        Process Master Validation plan (MVP)
                Installation Qualification Specification (IQS)
                Installation Qualification Report (IQR)
                Operational Qualification Specification (OQS)
                Operational Qualification Report (OQR)
                ....
        QA plan
        First Article Inspection Report (FAI)
        PPA plan
        PPA Report(s)
7: Design changes
        IDECO                                                          10
```

All starts with the Customer

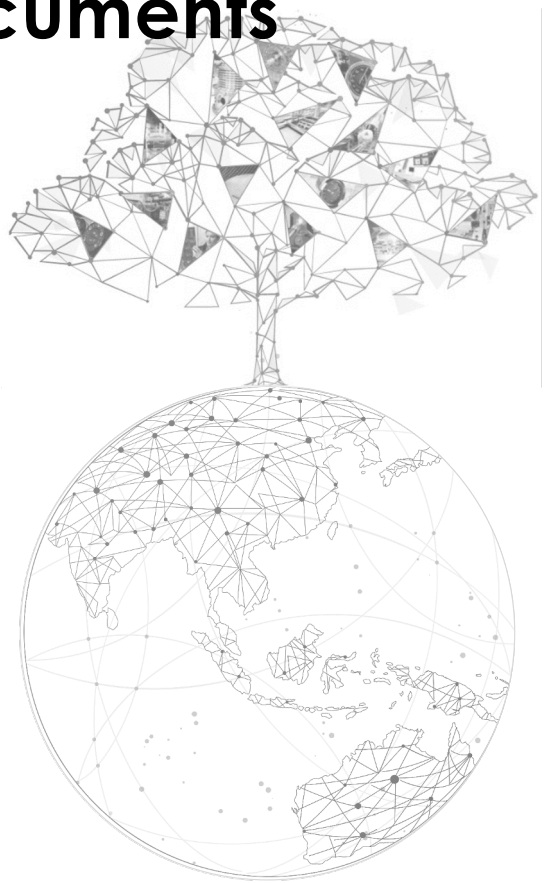
- Customer sends the requirements
- Very high level, often packed with references to ISO, IEC regulations
- Even more high level contractual requirements (like ISO certifications, GMP etc.)
- Nesting of those documents into sub and sub sub sub documents
- This makes it much more difficult to find the exact set of single level requirements
- All together we call **CRS** Customer Requirements Specification

- The complexity is why we always make our **SRS** System Requirements Specification
- This must be a list of very specific demands we need to fulfil in the construction



Complex building of inter-dependent documents

- In order to keep track of all the documents and the contents we have the Traceability Matrix
- Here we register all the tags of various specification items
- It is quite difficult to make the documentation in the first time right
- There will always be changes during the creation process
- Often this means to start again from CRS and work all these changes into all the sequential documents. Hence all documents will be re written many times over. This administration is killing for our performance and cost structure.



				SYSTEM LEVEL							MODULE LEVEL						
					[STS]			[SRS]				[MTS]			[MRS]		
Customer [CRS]-TAG	Safety [SRM]-TAG	TAG	[SRS] requirement description	[SDS] TAG	[Doc ID] TAG	[Doc ID] TAG	[Doc ID] TAG	[Doc ID] TAG	[Doc ID] TAG	[Doc ID] TAG	[MDS] TAG	[Doc ID] TAG	[Doc ID] TAG	[Doc ID] TAG	[Doc ID] TAG	[Doc ID] TAG	[Doc ID] TAG
TAG [CRS]	TAG [SRM]	TAG	Description TAG [SRS]														
		TAG	Description TAG [SRS]														
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