Technical Documentation

Background

There are different approaches to set-up the Technical Documentation (TD) for Medical devices.

- GHTF Summary Technical Documentation (STED): This guidance was set-up 2008 aiming to harmonize the documentation of evidence of conformity to the essential principles of safety and performance [1].
- (EU) 2017/745 MDR Annex II and III, 2017 [2]: The European Union took into account the STED principles within the revised Medical Device Regulation to promote the global convergence of regulations.
- IMDRF Non-In Vitro Diagnostic Device Market Authorization Table of Contents (nlVDMAToC), 2014 and 2019 [3]: The guidance describes a comprehensive harmonized structure for premarket medical device submissions enabling electronic product submissions. Canada is the first country requesting nlVDMAToC [4] as of April 2019 and will discontinue accepting STED format. IMDRF released further guidance how to assemble the files including naming conventions and templates [5].

Medical device manufacturers acting globally should decide carefully about the structure of their technical documentation. Setting up the right format will prevent redundant documentation and non-value adding expenses.

References

[1] GHTF/SG1/N011:2008
[2] (EU) 2017/745 MDR Annex II and III
[3] IMDRF/RPS WG/N9 (Edition 3) FINAL: 2019
[4] Health Canada Notice: File number: 18-106132-568
[5] IMDRF/RPS WG/N27 FINAL: 2019

Comparison

The following table gives a generic overview of the above listed three formats. It can be seen, that all three approaches are equivalent. For sure, differences can be found when diving deeper into details and requirements.

Technical Documentation

GHTF STED 2008 (GHTF/SG1/N011:2008)	(EU) 2017/745 MDR Annex II and III	IMDRF ToC 2019 (imdrf-tech-190321-nivd-dma-toc-n9)
6.0 Device Description and Product Specification, including variants and accessories 6.1 Device Description 6.2 Product Specification 6.3 Reference to similar and previous generations of the device	1. Device description and specification, incl. variants and accessories 1.1 Device description and specification 1.2. Reference to previous and similar generations of the device	 2.04 Device Description 2.05 Indications for Use 2.06 Global Market History
7.0 Labelling	2. Information to be supplied by the manufacturer	5 Labeling
8.0 Design and Manufacturing Information 8.1 Device Design 8.2 Manufacturing Processes 8.3 Design and Manufacturing Sites	3. DESIGN AND MANUFACTURING INFORMATION a) Design stages b) Manufacturing information c) sites, suppliers and sub-contractors	6B QMS Device specific information 6B07 design and development Information 6B09 Production and Service control information 6B08 Purchasing information
9.0 Essential Principles (EP) Checklist a-b) Essential principles c) methods to demonstrate conformity d) references, e.g. list of standards e) identity of controlled documents	4. GENERAL SAFETY AND PERFORMANCE REQUIREMENTS a) general safety and performance requirements b) methods to demonstrate conformity c) harmonised standards, CS, … d) identity of controlled documents	3.03 Essential Principles (EP) Checklist 3.04 Standards
10.0 Risk Analysis and Control Summary	5. BENEFIT-RISK ANALYSIS AND RISK MANAGEMENT	3.02 Risk Management
11.0 Product Verification and Validation 11.1 General 11.2 Biocompatibility 11.3 Medicinal Substances 11.4 Biological Safety 11.5 Sterilisation 11.6 Software Verification and Validation 11.7 Animal Studies 11.8 Clinical Evidence	6. PRODUCT VERIFICATION AND VALIDATION 6.1 Pre-clinical and clinical data 6.2. Additional information required in specific cases	 3.05 Non-clinical studies 3.06 Non clinical Bibliography 3.07 Expiration Period and package Validation 3.08 other non clinical evidence 4 Clinical evidence
	Annex III, 1.1 PMS Plan Annex III, 1.2 PMS Report / PSUR	
		6A Quality management system procedures