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Mapping R1 versus R2

The purpose of this document is to assist in understanding the M4Q(R2) structure and is not intended to provide a complete guide on what to include in each section. The mapping between M4Q(R1) and M4Q(R2) is done as per M4Q(R2) step 2 version of the guideline and is primarily conceptual and not intended to cover all possible complex scenarios or use-cases. Therefore, not all M4Q(R2) sections have a reference in this mapping table.

While M4Q(R1) has been applied across various product types, it may not fully address the specific regulatory and technical needs of newer modalities. Therefore, mapping from M4Q(R1) to M4Q(R2) may have limitations in such cases. Also, the mapping reflects the M4Q(R2) Guideline issued for Public Consultation (Step 3). It may be revised before reaching Step 4 based on the outcome of the Public Consultation.

As per M4Q (R1) guideline, Module 2.3 is a summary of Module 3 content and should not include information, data or justification that was not already included in Module 3 or in other parts of CTD. M4Q(R2) represents a fundamental shift from the M4Q(R1) approach, where Module 2.3 primarily summarized Module 3 content. Information considered critical to ensure product quality will be located in 2.3.3 Core Quality Information, Development summary and justification will be located in 2.3.4 Development Summary and Justification, and Module 3 will be the location of supportive data and information. Content across these sections is designed to be complementary rather than duplicative. This eliminates the need for the ICH M4Q(R1) Quality Overall Summary, as there is no longer an expectation to summarize Module 3 content in Module 2.3.

The mapping to M4Q(R2) headers and sub headers does not necessarily indicate that all M4Q(R2) sections must be populated; for example, sections such as SI and PI may or may not be provided based on each case specificity. A detailed explanation about the relation and the expected level of information under each section is provided by the M4Q(R2) guideline language.

Given that Module 2.3 now serves as the primary basis for regulatory review, some content previously located in Module 3 under M4Q(R1) has been relocated exclusively to the revised Module 2.3 under M4Q(R2), while the revised Module 3.2 focuses now on supporting data and information. M4Q(R2) perceived increased granularity does not indicate an expectation for additional content; instead, it is a result of:

- *Ensuring that the document reflects current regulatory science and harmonized approaches as delineated by recent ICH quality guidelines (Q8-Q13).*
- *Providing a more modular and precise framework with specific locations for each type of information, which accommodates with the expanding range of medicinal product types and modalities with greater flexibility, while clearly separating information by material type and addressing previous organizational changes (for example, section 3.2.S.2.3 previously covered starting materials and raw materials, which are now separated for better clarity).*
- *Introducing dedicated sections for information that spans beyond traditional Drug Substance or Drug Product, and address content that was previously scattered throughout different locations of the submission (e.g. Overall Control Strategy, Pharmaceutical Product, Packaged Medicinal Product, Medical Device or Integrated justification sections).*
- *This additional granularity does not lead to duplication of information but is expected to rather reduce it by facilitating cross-references and enabling content re-use (e.g. an analytical method used across DS & DP can be documented only one time in the AP section and cross-referred from DS & DP, as needed).*

M4Q(R1) MODULES	***M4Q (R2) MODULES***		
3.2 BODY OF DATA *(summarized in 2.3 QUALITY OVERALL SUMMARY (QOS))*	***2.3.3 CORE QUALITY INFORMATION***	***2.3.4 DEVELOPMENT SUMMARY AND JUSTIFICATION***	***3.2 BODY OF DATA***
2.3.S Drug Substance *3.2.S Drug Substance*			
2.3.S.1 General Information *3.2.S.1 General Information*			
3.2.S.1.1 Nomenclature	*2.3.3.DS.D.1 Nomenclature*		
3.2.S.1.2 Structure	*2.3.3.DS.D.2 Structural characteristics*		
3.2.S.1.3 General Properties	*2.3.3.DS.D.3 General properties*		
2.3.S.2 Manufacture *3.2.S.2 Manufacture*			
3.2.S.2.1 Manufacturer(s)	*2.3.3.FA Facilities*		
3.2.S.2.2 Description of Manufacturing Process and Process Controls	*2.3.3.DS.M.1 Description of the manufacturing process*		*3.2.DS.M.1 Description of manufacturing process*
	2.3.3.DS.M.2 Process controls		
3.2.S.2.3 Control of Materials	*2.3.3.SM Starting/Source Materials*	*2.3.4.SM Starting/Source Materials*	*3.2.SM Starting/Source Materials*
	2.3.3.RM Raw Materials		*3.2.RM Raw Materials*
	2.3.3.SI Substance Intermediates, if applicable		*3.2.SI Substance Intermediates, if applicable*
3.2.S.2.4 Controls of Critical Steps and Intermediates	*2.3.3.DS.M.2 Process controls*		
	2.3.3.SI Substance Intermediates, if applicable		*3.2.SI Substance Intermediates, if applicable*
3.2.S.2.5 Process Validation and/or Evaluation		*2.3.4.DS.M.4 Summary of process validation or evaluation studies*	*3.2.DS.M.7 Process validation or evaluation studies*
3.2.S.2.6 Manufacturing Process Development		*2.3.4.DS.M.1 Development of manufacturing process and process controls*	*3.2.DS.M.2 Development of manufacturing process and process controls*
		2.3.4.DS.M.2 Changes during manufacturing process development	*3.2.DS.M.5 Changes during development*
		2.3.4.DS.M.3 Comparability for multiple manufacturing sites	*3.2.DS.M.6 Comparability for multiple manufacturing sites*
			3.2.DS.M.3 Extractable and leachable studies
2.3.S.3 Characterisation *3.2.S.3 Characterisation*			

M4Q(R1) MODULES	***M4Q (R2) MODULES***		
3.2 BODY OF DATA *(summarized in 2.3 QUALITY OVERALL SUMMARY (QOS))*	***2.3.3 CORE QUALITY INFORMATION***	***2.3.4 DEVELOPMENT SUMMARY AND JUSTIFICATION***	***3.2 BODY OF DATA***
3.2.S.3.1 Elucidation of Structure and other Characteristics		*2.3.4.DS.D Description*	*3.2.DS.D Description*
3.2.S.3.2 Impurities		*2.3.4.DS.C.1 Control of impurities*	*3.2.IM.D Description*
2.3.S.4 Control of the Drug Substance *3.2.S.4 Control of the Drug Substance*			
3.2.S.4.1 Specification	*2.3.3.DS.C Control*		
3.2.S.4.2 Analytical Procedures	*2.3.3.AP Analytical Procedures*		*3.2.AP.1 Analytical Procedure Description*
3.2.S.4.3 Validation of Analytical Procedures		*2.3.4.AP.2 Analytical Procedure Validation/Qualification*	*3.2.AP.2 Analytical Procedure Validation/Qualification*
3.2.S.4.4 Batch Analyses		*2.3.4.DS.C.2 Batch analysis*	*3.2.DS.C.1 Batch analysis*
3.2.S.4.5 Justification of Specification		*2.3.4.DS.C.3 Justification of specifications*	*3.2.DS.C.2 Justification of specifications*
2.3.S.5 Reference Standards or Materials *3.2.S.5 Reference Standards or Materials*	*2.3.3.RS Reference Standards and/or Materials*	*2.3.4.RS Reference Standards and/or Materials*	
2.3.S.6 Container Closure System *3.2.S.6 Container Closure System*	*2.3.3.DS.S.1 Container Closure System*	*2.3.4.DS.S.1 Container Closure System* *2.3.4.IN.2.1 Integrated justifications of extractables and leachables*	*3.2.DS.S.1 Container closure system*
2.3.S.7 Stability *3.2.S.7 Stability*			
3.2.S.7.1 Stability Summary and Conclusions	*2.3.3.DS.S.2 Stability, storage conditions, and retest period/shelf life*	*2.3.4.DS.S.2 Stability, storage conditions, and retest period/shelf life*	
3.2.S.7.2 Post approval stability protocol and stability commitment	*2.3.3.DS.S.2 Stability, storage conditions, and retest period/shelf life*		
	OTHER MODULE 2 SECTION: 2.3.5.2.2 Post-approval Quality Commitments, if Applicable		
3.2.S.7.3 Stability Data			*3.2.DS.S.2 Stability, storage conditions, and retest period/shelf life*
2.3.P Drug Product *3.2.P Drug Product*			
2.3.P.1 Description and Composition of the Drug Product *3.2.P.1 Description and Composition of the Drug Product*	*2.3.3.DP.D Description* *2.3.3.PH.D Description, if Applicable* *2.3.3.PM.D Description, if Applicable* *2.3.3.MD.D Description, if Applicable*		
2.3.P.2 Pharmaceutical Development			

M4Q(R1) MODULES	***M4Q (R2) MODULES***		
3.2 BODY OF DATA *(summarized in 2.3 QUALITY OVERALL SUMMARY (QOS))*	***2.3.3 CORE QUALITY INFORMATION***	***2.3.4 DEVELOPMENT SUMMARY AND JUSTIFICATION***	***3.2 BODY OF DATA***
3.2.P.2 Pharmaceutical Development			
3.2.P.2 Introduction			
3.2.P.2.1 Components of the Drug Product *3.2.P.2.1.1 Drug Substance* *3.2.P.2.1.2 Excipients*		*2.3.4.DP.D.1 Components of the drug product*	*3.2.DP.D.1 Components of the drug product*
3.2.P.2.2 Drug Product *3.2.P.2.2.1 Formulation Development* *3.2.P.2.2.2 Overages*		*2.3.4.DP.D.2 Formulation development*	*3.2.DP.D.2 Formulation development*
		2.3.4.DP.D.3 Comparability during formulation and product development	*3.2.DP.D.3 Comparability during formulation and product development*
3.2.P.2.2.3 Physicochemical and Biological Properties		*2.3.4.DP.D.4 Physicochemical and biological properties of drug product*	*3.2.DP.D.4 Physicochemical and biological properties of drug product*
3.2.P.2.3 Manufacturing Process Development		*2.3.4.DP.M.1 Development of manufacturing process and process controls*	*3.2.DP.M.2 Development of manufacturing process and process controls*
		2.3.4.DP.M.2 Changes during manufacturing process development	*3.2.DP.M.4 Changes during manufacturing process development*
		2.3.4.DP.M.3 Comparability for multiple manufacturing sites	*3.2.DP.M.5 Comparability for multiple manufacturing sites*
3.2.P.2.4 Container Closure System		*2.3.4.DP.S.1 Container Closure System*	
		2.3.4.MD.D Description, if Applicable	
		2.3.4.PM.S.1 Container closure system, if applicable	
		2.3.4.IN.2.1 Integrated justifications of extractables and leachables	
3.2.P.2.5 Microbiological Attributes		*2.3.4.DP.S.1 Container Closure System*	
		2.3.4.DP.D.5 Microbiological attributes	*3.2.DP.D.5 Microbiological Attributes*
3.2.P.2.6 Compatibility		*2.3.4.DP.S.1 Container Closure System*	
		2.3.4.PH.D Description, if applicable	*3.2.PH.D Description, if applicable*
		2.3.4.PM.D Description, if applicable	*3.2.PM.D Description, if applicable*
2.3.P.3 Manufacture *3.2.P.3 Manufacture*			
3.2.P.3.1 Manufacturer(s)	*2.3.3.FA Facilities*		

M4Q(R1) MODULES	***M4Q (R2) MODULES***		
3.2 BODY OF DATA *(summarized in 2.3 QUALITY OVERALL SUMMARY (QOS))*	***2.3.3 CORE QUALITY INFORMATION***	***2.3.4 DEVELOPMENT SUMMARY AND JUSTIFICATION***	***3.2 BODY OF DATA***
3.2.P.3.2 Batch formula	*2.3.3.DP.M.1 Batch formula*		
3.2.P.3.3 Description of Manufacturing Process and Process Controls	*2.3.3.DP.M.2 Description of the manufacturing process*		*3.2.DP.M.1 Description of manufacturing process*
	2.3.3.PI.M Manufacture, if applicable		*3.2.PI.M Manufacture, if applicable*
	2.3.3.PM.M Manufacture, if applicable		*3.2.PM.M Manufacture, if applicable*
			3.2.DP.M.3 Extractable and leachable studies
3.2.P.3.4 Controls of Critical Steps and Intermediates	*2.3.3.DP.M.3 Process controls*	*2.3.4.DP.M.1 Development of manufacturing process and process controls*	*3.2.DP.M.2 Development of manufacturing process and process controls*
		2.3.4.DP.M.4 Summary of process validation or evaluation studies	
	2.3.3.PI Product Intermediates, if applicable		*3.2.PI Product Intermediates, if applicable*
3.2.P.3.5 Process Validation and/or Evaluation		*2.3.4.DP.M.4 Summary of process validation or evaluation studies*	*3.2.DP.M.6 Process validation or evaluation studies*
2.3.P.4 Control of Excipients *3.2.P.4 Control of Excipients*			
3.2.P.4.1 Specifications	*2.3.3.EX.C Control*		
3.2.P.4.2 Analytical Procedures	*2.3.3.AP Analytical Procedures*		*3.2.AP.1 Analytical Procedure Description*
3.2.P.4.3 Validation of Analytical Procedures		*2.3.4.AP.2 Analytical Procedure Validation/Qualification*	*3.2.AP.2 Analytical Procedure Validation/Qualification*
3.2.P.4.4 Justification of Specifications		*2.3.4.AP.1 Analytical Procedure Justification*	
			3.2.EX.C Control
3.2.P.4.5 Excipients of Human or Animal origin	*2.3.3.EX Excipients*	*2.3.4.IN.2.2 Integrated justifications of control of adventitious agents*	*3.2.EX Excipients*
3.2.P.4.6 Novel Excipients	*2.3.3.EX Excipients*		*3.2.EX Excipients*
2.3.P.5 Control of Drug Product *3.2.P.5 Control of Drug Product*			
3.2.P.5.1 Specification(s)	*2.3.3.DP.C Control*		

M4Q(R1) MODULES	***M4Q (R2) MODULES***		
3.2 BODY OF DATA *(summarized in 2.3 QUALITY OVERALL SUMMARY (QOS))*	***2.3.3 CORE QUALITY INFORMATION***	***2.3.4 DEVELOPMENT SUMMARY AND JUSTIFICATION***	***3.2 BODY OF DATA***
3.2.P.5.2 Analytical Procedures	*2.3.3.AP Analytical Procedures*		*3.2.AP.1 Analytical Procedure Description*
3.2.P.5.3 Validation of Analytical Procedures		*2.3.4.AP.2 Analytical Procedure Validation/Qualification*	*3.2.AP.2 Analytical Procedure Validation/Qualification*
3.2.P.5.4 Batch Analyses		*2.3.4.DP.C.2 Batch analysis*	*3.2.DP.C.1 Batch analysis*
3.2.P.5.5 Characterisation of Impurities		*2.3.4.DP.C.1 Control of impurities*	*3.2.IM.D Description*
3.2.P.5.6 Justification of Specifications		*2.3.4.DP.C.3 Justification of specifications*	*3.2.DP.C.2 Justification of specifications*
2.3.P.6 Reference Standards or Materials *3.2.P.6 Reference Standards or Materials*	*2.3.3.RS Reference Standards and/or Materials*	*2.3.4.RS Reference Standards and/or Materials*	*3.2.RS Reference Standards and/or Materials*
2.3.P.7 Container Closure System *3.2.P.7 Container Closure System*	*2.3.3.DP.S.1 Container Closure system*		*3.2.DP.S.1 Container Closure system*
	2.3.3.PM.D Description, if applicable		
	2.3.3.PM.S.1 Container closure system, if applicable		*3.2.PM.S.1 Container closure system, if applicable*
2.3.P.8 Stability *3.2.P.8 Stability*			
3.2.P.8.1 Stability Summary and Conclusion	*2.3.3.DP.S.2 Stability, storage conditions, and shelf life*	*2.3.4.DP.S.2 Stability, storage conditions, and shelf life*	
	2.3.3.PM.S.2 Stability, storage conditions, and shelf life, if applicable	*2.3.4.PM.S.2. Stability, storage conditions, and shelf life, if applicable*	
	2.3.3.PH.S.1 Stability, storage conditions, and shelf life, if applicable	*2.3.4.PH.S.1 Stability, storage conditions, and shelf life, if applicable*	
3.2.P.8.2 Post approval stability protocol and stability commitment	*2.3.3.DP.S.2 Stability, storage conditions, and shelf life*		
	2.3.3.PM.S2 stability, storage condition and shelf life, if applicable		
	2.3.3.PH.S Storage, if applicable		
	OTHER MODULE 2 SECTION: 2.3.5.2.2 Post-approval Quality Commitments, if Applicable		
3.2.P.8.3 Stability Data			*3.2.DP.S.2 Storage Stability, storage conditions, and shelf life*
			3.2.PM.S.2 Stability, storage conditions and shelf life, if applicable

M4Q(R1) MODULES	***M4Q (R2) MODULES***		
3.2 BODY OF DATA *(summarized in 2.3 QUALITY OVERALL SUMMARY (QOS))*	***2.3.3 CORE QUALITY INFORMATION***	***2.3.4 DEVELOPMENT SUMMARY AND JUSTIFICATION***	***3.2 BODY OF DATA***
			3.2.PH.S.1 Stability, storage conditions and shelf life, if applicable
2.3.A Appendices *3.2.A Appendices*			
2.3.A.1 Facilities and Equipment *3.2.A.1 Facilities and Equipment*			*3.2.FA Facilities*
2.3.A.2 Adventitious Agents Safety Evaluation *3.2.A.2 Adventitious Agents Safety Evaluation*		*2.3.4.IN.2.2 Integrated justifications of control of adventitious agents*	*3.2.DS.M.4 Viral clearance studies*
			3.2.SM.C Control
			3.2.RM.C Control
			3.2.EX.C Control
2.3.A.3 Excipients *3.2.A.3 Excipients*	*2.3.3.EX Excipients*		*3.2.EX Excipients*
2.3.R Regional Information *3.2.R Regional Information*	*Not existing anymore: relevant regional information to be included in most relevant sections of 2.3.3, 2.3.4 or 3.2 as addendum to the core section using a regional keyword.*		