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White Paper

A Change to the Common Technical Document Format for CMC/Quality Information

Control Strategy Information for Gene and Cell Therapy Products

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European organisations involved with the development of gene and cell therapy products, referred to as advanced therapy medicinal products (ATMPs) in the European Union (EU), may not be aware of the intended changes to the common technical document (CTD) format required for the submission of quality (chemistry, manufacturing and controls, CMC) information as part of EU marketing authorisation applications (MAAs). This includes details required in relation to the development and implementation of the quality control strategy, such as the quality target product profile (QTPP) and critical quality attributes (CQAs) used to define the control strategy.

This paper outlines the current situation, planned changes and proposed solutions to challenges related to the transition from the current CTD dossier format referred to as ICH M4Q(R1) to the proposed format, M4Q(R2). The current ICH work plan indicates June 2027 for adoption of the final guideline (Step 4). (1) At Step 5 of the ICH process, the guideline will be implemented by ICH Regulatory Members (2), including in Europe. Therefore, there is an urgent need to gain an understanding and familiarity with the CMC structure and content requirements, without which ATMP development may be inefficient and MAA approval delayed.

1. Introduction

A significant change will occur in Europe (and other ICH regions) in the following years regarding the format in which regulatory dossiers should be structured for marketing authorisation applications (MAAs). This includes advanced therapy medicinal products (gene therapy and cell therapy products). As outlined, a common format was adopted by Europe and has been in operation for more than 20 years. This has provided a degree of certainty as to how information should be provided in an MAA.

However, with increased progress, knowledge and experience, a change is proposed to try to further facilitate timely initial review and subsequent maintenance of the MAA. This includes a prompt for specific details regarding rational product development and control. The paper outlines the current situation and the direction of travel with a view to highlighting expectations and outputs from product development. Currently June 2027 is planned for ICH adoption of the final version of the guideline (1) and the likely implementation date for the European Union is unclear. The M4Q(R1) guideline was adopted by ICH on 12 September 2002 and implemented in Europe on 1 July 2003 so implementation of M4Q (R2) may be as rapid. (3)

2. Current Situation

2.1. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) brings together regulatory authorities and industry to discuss scientific and technical aspects of medicinal product registration.

ICH's mission is to achieve greater harmonisation worldwide to ensure that medicines are developed and registered in the most resource-efficient manner. Harmonisation is achieved through the development of ICH Guidelines via a process of scientific consensus with regulatory and industry experts. (4) ICH members include Member States of the European Union (EU) and the European Economic Area (EEA). (5)

2.2. The Common Technical Document (ICH-CTD)

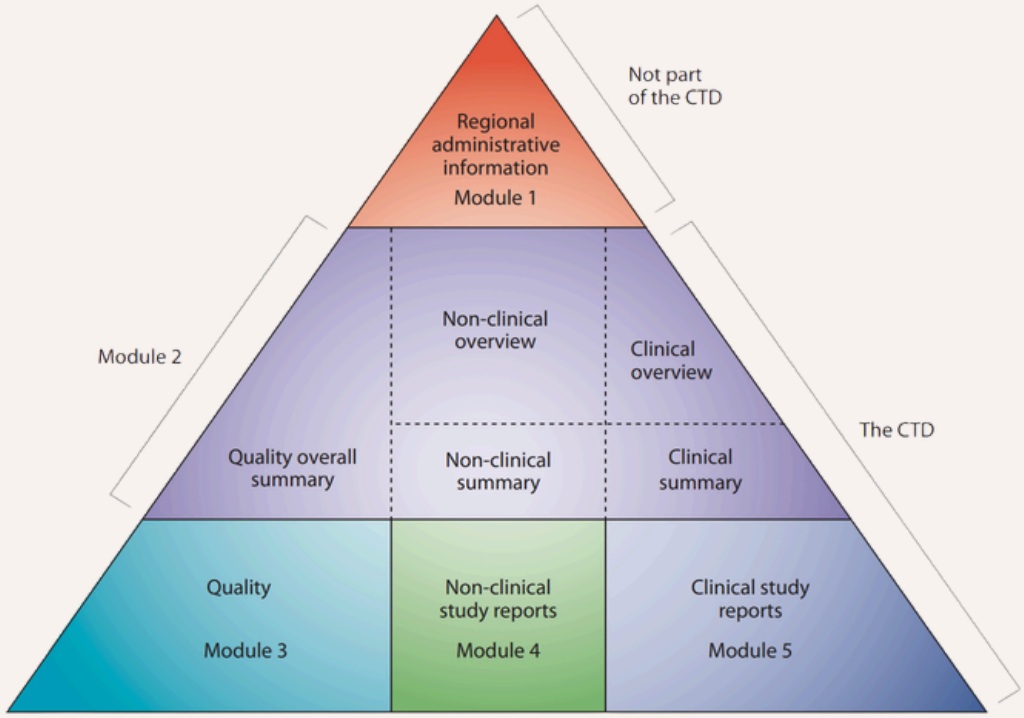
For marketing applications submitted to regulatory agencies of ICH members, the information is organised into five modules (see *Figure 1*). Module 1 is region specific and Modules 2, 3, 4 and 5 are intended to be common for all regions. (6) The CTD is the mandatory format for new drug (medicinal product) applications in the EU, including ATMPs.

The Electronic Common Technical Document (eCTD) allows for the electronic submission of the CTD from applicant to regulator. (7)

2.3. Quality Overall Summary: Module 2.3 and Quality: Module 3 (ICH M4Q(R1))

The structures for Module 2.3 and Module 3 are outlined in Appendix 1 and Appendix 2 respectively. (8) The Quality section of the Common Technical Document (M4Q) provides a harmonised structure and format for presenting CMC (Chemistry, Manufacturing and Controls) information in a registration dossier. (3) The Quality Overall Summary (QOS) is a summary that follows the scope and the outline of the information in Module 3 with sufficient information from each section to provide the Quality reviewer with an overview of Module 3. (8)

CTD Triangle



The CTD triangle. The Common Technical Document is organized into five modules. Module 1 is region specific and modules 2, 3, 4 and 5 are intended to be common for all regions.

Figure 1. *Common Technical Document Format*

2.4 Quality by Design and Control Strategy

ATMP (and other medicine) development activities should result in an appropriate control strategy, elements of which are considered to be "established conditions for manufacturing and control". This involves defining which elements are considered necessary to assure product quality and therefore should require a regulatory submission if changed after approval of an MAA. (9) Currently there are no specific locations defined for control strategy summaries in Module 3, so the placement of overall control strategy summaries is at the applicant's discretion. (10) However, detailed information related to the control strategy must be included throughout Module 3 and summarised in Module 2.3.

As outlined in ICH guidance, "quality by design" (QbD) is defined as a systematic approach to development that begins with predefined objectives and emphasizes product and process understanding and process control, based on sound science and quality risk management. (11) One of the goals of quality by design is to ensure that all sources of variability affecting a process are identified, explained and managed by appropriate measures. This enables the finished medicine to consistently meet its predefined characteristics from the start - so that it is 'right first time'. (12)

Also from ICH guidance, a "quality target product profile" (QTPP) is defined as a prospective summary of the quality characteristics of a drug product that ideally will be achieved to ensure the desired quality, taking into account safety and efficacy of the drug product. (11)

And, "process analytical technology" (PAT) is described as a system for designing, analyzing, and controlling manufacturing through timely measurements (i.e., during processing) of critical quality and performance attributes of raw and in-process materials and processes with the goal of ensuring final product quality. (11)

The "control strategy" is summarised as a planned set of controls, derived from current product and process understanding, that assures process performance and product quality. The controls can include parameters and attributes related to drug substance and drug product materials and components, facility and equipment operating conditions, in-process controls, finished product specifications, and the associated methods and frequency of monitoring and control. (13) A control strategy is designed to ensure that a product of required quality will be produced consistently. These controls should be based on product, formulation and process understanding and should include, at a minimum, control of the critical process parameters and material attributes. (11)

A more systematic approach to development (also defined as QbD) can include, for example, incorporation of prior knowledge, results of studies using design of experiments, use of quality risk management, and use of knowledge management throughout the lifecycle of the product. Such a systematic approach can enhance achieving the desired quality of the product and help the regulators to better understand a company's strategy. A greater understanding of the product and its manufacturing process can create a basis for more flexible regulatory approaches. The degree of regulatory flexibility is predicated on the level of relevant scientific knowledge provided in the registration application. It is the knowledge gained and submitted to the authorities, that forms the basis for science- and risk-based submissions and regulatory evaluations. Appropriate data demonstrating that this knowledge is based on sound scientific principles should be presented with each application. (11)

For marketing authorisation applications defined by the applicant as QbD applications, the European Medicines Agency (EMA) expectation is that applicants will provide the quality target profile, QTPP, which describes prospectively the quality characteristics of a drug product that should be achieved to ensure the desired quality, taking into account safety and efficacy of the drug product. (14) The EMA also expects that applicants will provide a list of CQAs for drug substance, finished product, and excipients when relevant. The basis of the control strategy should be to ensure that the drug substance and finished product CQAs are consistently within the specified limits. (14) An MAA QbD application would contain proposed "design space". Movement out of the design space is considered to be a change and would normally initiate a regulatory post approval change process, whilst working within the design space is not considered as a change. (11) Design space is the multidimensional combination and interaction of input variables and process parameters that have been demonstrated to provide assurance of quality. The ability to accurately assess the significance and effect of the variability of material attributes and process parameters on CQAs, and hence the limits of a design space, depends on the extent of process and product understanding. (15) The challenge of defining a design space will increase as complexity increases (such as for ATMPs). However, even if design spaces are not proposed in ATMP MAAs, the principles of QbD can be used for ATMP development.

Many ATMPs are developed to treat an unmet medical need and/or serious condition and regulatory mechanisms to expedite patient access to medicines, such a EMA's PRIority Medicines scheme (PRIME), are commonly used for eligible ATMPs. (16) It is recognised that expedited development programs have a number of challenges related to control strategy: e.g., limited manufacturing and clinical experience, difficulties in assessing if the process is consistent due to a limited number of manufactured batches, process and method validation studies not finalised, and an understanding of criticality and interactions which is not fully developed. Despite this, these products are still expected to be safe and efficacious with a positive benefit-risk balance. Flexibility in what quality information is required for marketing approval will depend on factors such as product and process knowledge, analytical capability and the quality system. (17)

2.5. Incorporating Control Strategy Development Information into ICH M4Q(R1)

More than twenty years ago an EMA guidance document suggested sections of Module 2.3 and Module 3 where PAT-related information could be included. (18) In 2009 ICH Q8(R2) provided guidance on the submission of pharmaceutical development and related information in CTD format including quality risk management and product and process development, design space, control strategy. (11) The EMA guidance document: "Questions and answers: Improving the understanding of NORs, PARs, DSp and normal variability of process parameters" (2017) indicated Module 3 sections to include details for proven acceptable ranges (S.2.2 or P.3.3 with development information in S.2.6/P.2.3) and design space (S.2.6 or P.2.3). (19)

An illustrative example of control strategy development for an ATMP is outlined in *Figure 2* and *Table 1*. It also shows how the resulting control strategy can be incorporated into Module 3 sections. As mentioned, manufacturing process development sections 3.2.S.2.6 and/or 3.2.P.2.3 can currently be used to summarize control strategy development and indicate the elements of proposed control strategy for commercial production.

3. The Future Situation

3.1 Revision of CTD Quality Sections: ICH M4Q(R2) Guideline

ICH 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.

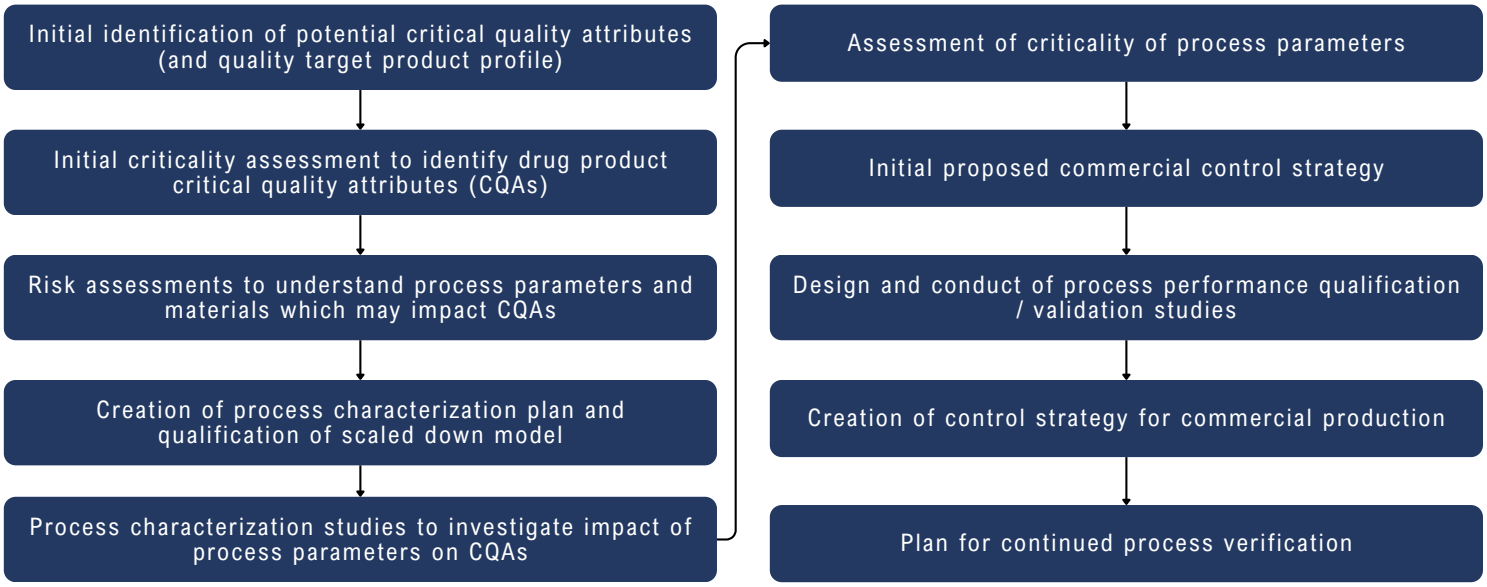


***Figure 2**. Overview of Control Strategy Development of an Advanced Therapy Medicinal Product*

***Table 1**. Example of Drug Substance and Drug Product Control Strategy – Location in Module 3 Sections (ICH M4Q(R1)*

Description	Module 3 Section (3.2.)
Control of quality of materials used for manufacture	S.2.3 Control of Materials_Raw Materials S.2.3 Control of Materials_Starting Material S.2.6 Manufacturing Process Development_Control Strategy Development P.4 Specifications A.2 Adventitious Agents Safety Evaluation
Control of manufacturing process parameters and in-process testing	S.2.2 Description of the Manufacturing Process and Process Controls S.2.4 Critical Steps and Intermediates P.3.3 Description of the Manufacturing Process and Process Controls P.3.4 Critical Steps and Intermediates
Control of intermediates	S.2.4 Critical Steps and Intermediates P.3.4 Critical Steps and Intermediates
Use of manufacturing processes concluded as under control (validated)	S.2.5 Process Validation and/or Evaluation P.3.5 Process Validation and/or Evaluation
Drug substance/product batches released in accordance with batch release specification	S.4.1 Specification P.5.1 Specifications
Use of drug product batches within defined shelf-life	P.8.1 Stability Summary and Conclusions.
Manufacture, testing and storage facilities operating to Good Manufacturing Practices	S.2.1 Manufacturers P.3.1 Manufacturers
Facility and equipment controls	A.1 Facilities and Equipment
Transportation of intermediate batches at defined storage conditions and as qualified	S.2.4 Critical Steps and Intermediates S.2.5 Process Validation and/or Evaluation
Transportation of drug product batches at defined storage conditions and as qualified	P.8.1 Stability Summary and Conclusions P.3.5 Process Validation and/or Evaluation
Sterility assurance/microbial contamination strategy	P.2.5 Microbiological Attributes A.1 Facilities and Equipment A.2 Adventitious Agents Safety Evaluation
Traceability: chain of custody and chain of identity (as applicable)	P.3.3 Description of the Manufacturing Process and Process Controls P.3.5 Process Validation and/or Evaluation

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. (20) The mapping between M4Q(R1) and M4Q(R2) is shown in Appendix 3. (20)

The quality information is organised within corresponding sections across Module 2.3 and Module 3.2.

These sections are aligned with the roles of these components, including Drug Substances (DS), Substance Intermediates (SI), Raw Materials (RM), Starting Materials (SM), Reference Standards/Materials (RS), Excipients (EX), Impurities (IM), Drug Products (DP), Product Intermediates (PI), Packaged Medicinal Products (PM), Pharmaceutical Products (PH), and Medical Devices (MD).

These sections are further organised using the structure - Description, Manufacture, Control, and Storage (21):

- **Description**: Identifies the material and its key characteristics;
- **Manufacture**: Outlines the production process and process controls;
- **Control**: Describes quality control measures such as specifications;
- **Storage**: provides container closure system, stability, storage condition, and shelf life.

Figure 3 to *Figure 5* and *Table 2* provide an overview and further details for the structure and content indicated for ICH M4Q(R2). (22), (23)

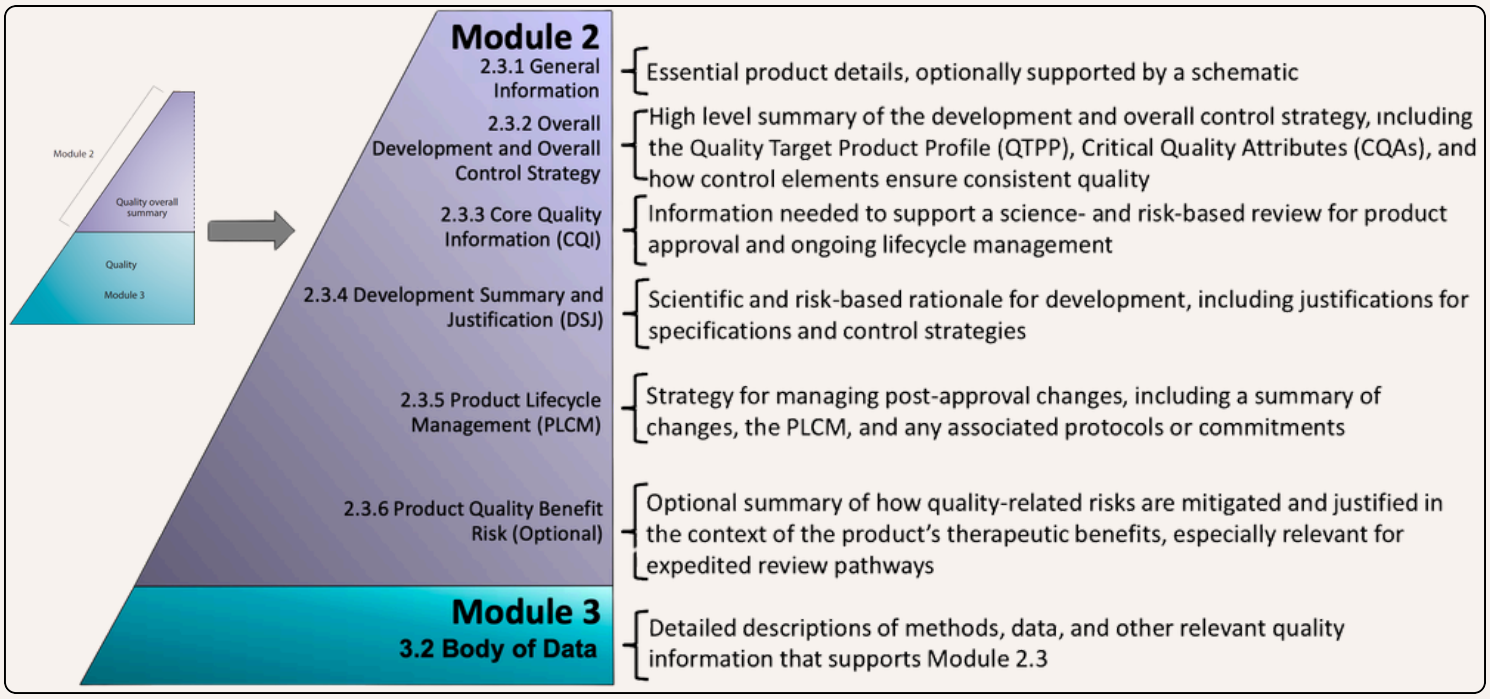


Figure 3. *ICH M4Q(R2) Structure Overview*

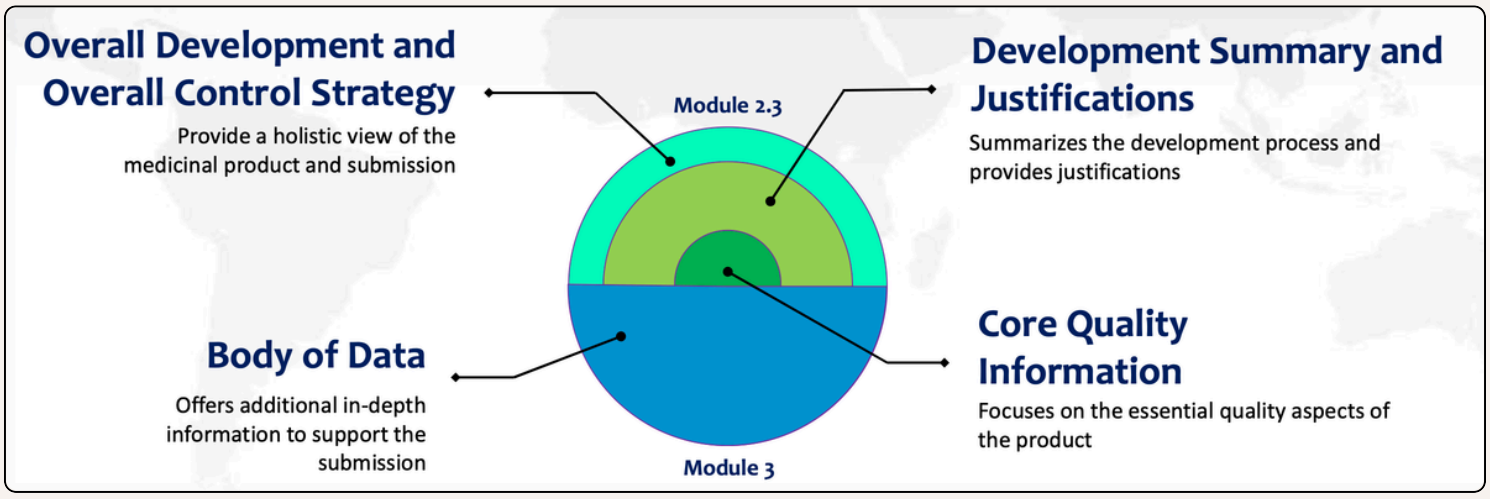


Figure 4. *ICH M4Q(R2) Structure and Division of Content Type*

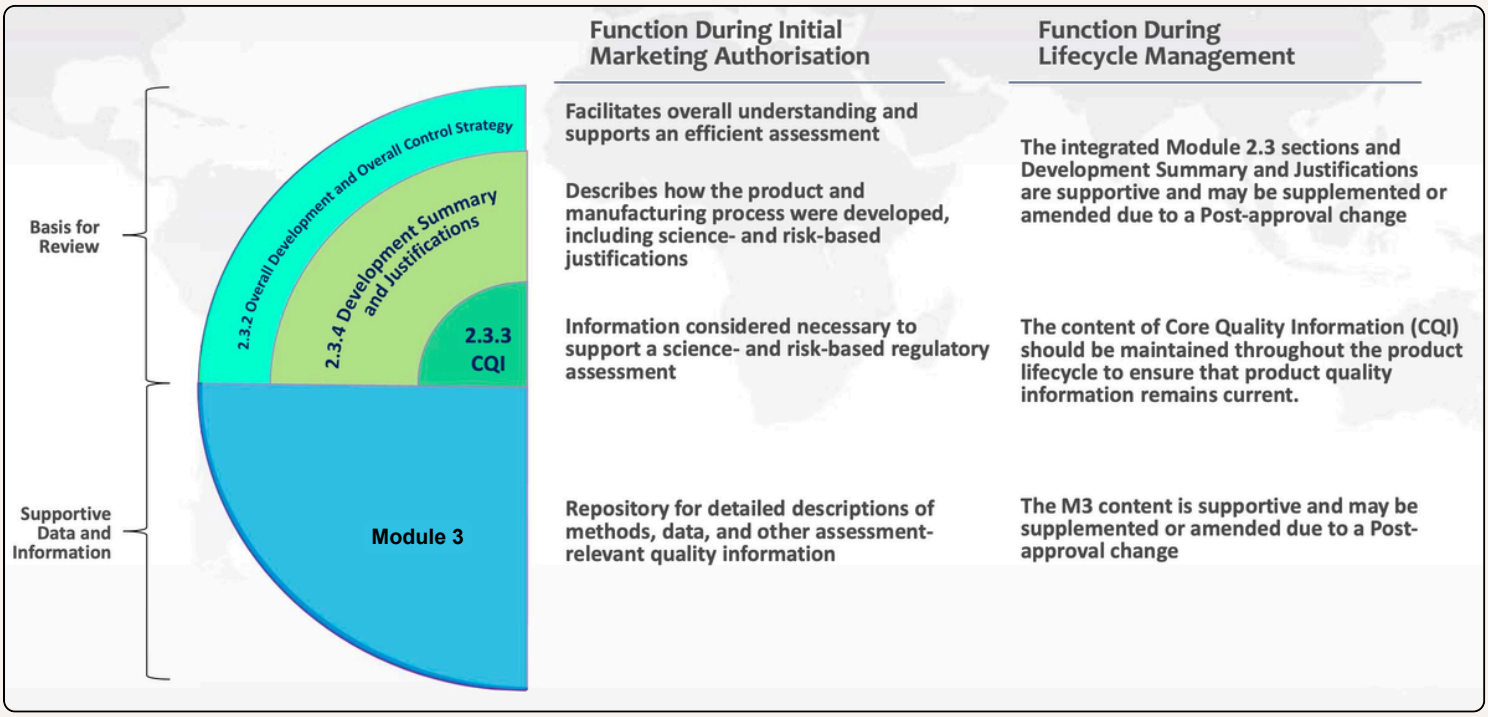


Figure 5. *ICH M4Q(R2) Structure and Use – Initial Submission and Lifecycle Management*

Table 2. *ICH M4Q(R2) Structure – Sections 2.3.3, 2.3.4 and 3.2*

	2.3.3 Core Quality Information	2.3.4 Development Summary and Justification	3.2 Body of Data
	Information related to what the material is and its key characteristics, which is considered necessary to enable marketing authorization and facilitate lifecycle management.	*Scientific and risk-based development summary and justifications related to what the material is and its key characteristics.*	*Supportive information including reports and data related to what the material is and its key characteristics.*
Description	Nomenclature, structure, composition, key characteristics.	Characterization summary, formulation development and justification.	Characterization data, formulation development and justification data.
Manufacture	Manufacturing process description, IPCs, critical process parameters.	Process development and validation/evaluation summary.	Process development and validation/evaluation data.
Control	Specifications.	Overview of batch analysis, justification of specifications.	Batch analysis and justification data.
Storage	Container closure system description, storage conditions, and retest period/ shelf life.	Overview of stability studies, justification of proposed container closure system.	Container closure selection and stability data.

3.2. Incorporating Control Strategy Development Information into M4Q(R2)

ICH M4Q(R2) guidance prompts for the inclusion of specific detail that may be considered a QbD approach to medicines development and therefore the expectations for product and process understanding are clear and have progressed since ICH M4Q(R1). Terminology previously associated with "quality by design" is used but the term itself is not included in the current version of the M4Q(R2) guidance. (21)

Section 2.3.2 includes the "overall development and overall control strategy". It provides:

… a high-level overview of the medicinal product's development and control strategy, aiming to facilitate understanding and supporting an efficient assessment. The Overall Control Strategy (OCS) is built upon the concepts defined in ICH Q8 considering the patient's needs and reflects the Core Quality Information.

This section includes:

- Quality Target Product Profile (QTPP)
- Critical Quality Attributes (CQAs)
- Overall product development strategy
- Representation of how the individual control strategies contribute to the overall control strategy.

Section 2.3.2.3 contains the "overall control strategy representation". It is described as:

… a holistic and integrated approach encompassing considerations from the CQAs to the end-to-end controls, describing how the individual control strategies interact to ensure product quality (ICH Q6A/Q6B, Q8, Q9, Q10, and Q11). (21)

The section should:

- include a representation, such as a table, diagram, or flowchart of the proposed overall control strategy.
- address the manufacturing process from the introduction of starting/source materials to the final drug product, including packaging.

And may also address the pharmaceutical product after transformation and any device to be used with the drug product, where relevant to ensure product quality or performance. (21)

As indicated in *Table 2*, Section 2.3.3 contains the "core quality information". A mockup of this (*Figure 6)* and other sections is available for a mock chemical entity (small molecule) drug, SakuraBloom R2, to illustrate the information to provide. (24).

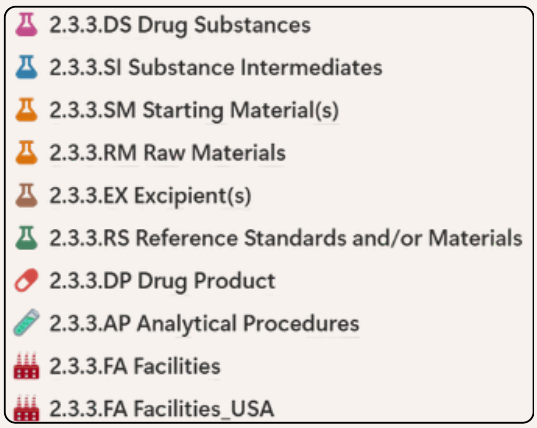


Figure 6. *Section 2.3.3 Core Quality Information from ICH M4Q(R2) Final Mock-ups*

In *Table 3,* the overall control strategy summary from the illustrative example provided in Table 1 has been converted using core quality information sections in accordance with ICH M4Q(R2).

3.3. Potential Implications for a Change from ICH M4Q(R1) to ICH M4Q(R2)

Potentially disruptive implications for a change from M4Q(R1) to EU implementation of M4Q(R2) include, but are not limited to:

- Moving from the provision of quality (CMC) information for an ATMP investigation medicinal product dossier (IMPD-Q) using a Module 3 (like) structure or similar (25) in clinical development to creating the CMC content of an EU marketing authorisation application consistent with M4Q(R2).

Unlike an EU MAA, IMPD-Qs are not required in eCTD format. The European Medicines Agency's guideline for the CMC content of an IMPD recommends the use of Module 3 headings.
Therefore, if a developer has built a comprehensive IMPD-Q over the period of clinical development, the content could be transferred to the corresponding individual MAA sections to facilitate efficient Module 3 creation.

However, with the implementation of M4Q(R2) for EU MAAs (only), the authoring process is likely to be lengthier if information from disparate parts of the IMPD-Q are required for initial drafting in M4Q(R2) format. The M4Q(R2) guideline establishes the location and structure of quality information for registration applications of medicinal products for human use. (21) It is not currently clear whether the EMA guidelines for investigational medicinal products will eventually be updated to provide some alignment.

- Resources required to create different CMC dossiers for an EU MAA and marketing applications for other ICH regions that are slower to implement M4Q(R2) or vice versa.

If implementation of M4Q(R2) is not coordinated across ICH countries, then significant time may be spent creating dossiers in both M4Q(R1) and M4Q(R2) formats. This concern was voiced by organizations such as BioPhorum and EFPIA. (26)

- Retrospectively applying a QbD approach to product development where it has not previously been applied, including the QTPP.

For speed of IMPD-Q creation, developers may not have included information not explicitly stated as required in EMA guidance. This may also mean that QTPP and associated tools have not been used to focus product development. Therefore, for MAA authoring, there may be gaps in the information available to describe control strategy development and to substantiate the final control strategy. The chosen approach to control strategy development, such as the example shown in Figure 2, can still be applied but defining the control strategy in the regulatory dossier will need to change.

- Understanding how the control strategy will be clearly defined, described, registered (core quality information) and lifecycled.

The European Medicines Agency (EMA) currently states that they "welcome" applications that include quality by design. (12) However, elements of this approach are already essential for products such as ATMPs and other biological medicinal products.

For example, demonstration of comparability through a suitable exercise is a fundamental part of the evolving manufacturing process to ensure that the safety and/or efficacy data gathered as well as the benefit/risk balance of a product is valid throughout development, for marketing authorisation and beyond. (27)

Table 3. *Example of Drug Substance and Drug Product Control Strategy: Location in Core Quality Information M4Q(R2)*

Description	Module 3 Section (3.2.)
(Overall control strategy)	2.3.2.3 Overall Control Strategy Representation
Analytical procedures	2.3.3.AP Analytical Procedures
Control of quality of materials used for manufacture	2.3.3.RM Raw Materials 2.3.3.SM Starting/Source Materials 2.3.3.EX.C Control
Control of manufacturing process parameters and in-process testing	2.3.3.DS.M.1 Description of the manufacturing process 2.3.3.DS.M.2 Process controls 2.3.3.SI Substance Intermediates 2.3.3.DP.M.2 Description of the manufacturing process 2.3.3.PI.M Manufacture, if applicable 2.3.3.DP.M.3 Process controls 2.3.3.PI Product Intermediates, if applicable
Control of intermediates	2.3.3.DS.M.2 Process controls 2.3.3.SI Substance Intermediates, if applicable 2.3.3.DP.M.3 Process controls 2.3.3.PI Product Intermediates, if applicable
Use of manufacturing processes concluded as under control (validated)	/
Drug substance/product batches released in accordance with batch release specification	2.3.3.DS.C Control 2.3.3.DP.C Control
Use of drug product batches within defined shelf-life	2.3.3.DP.S.2 Stability, storage conditions, and shelf life 2.3.3.PH.S.1 Stability, storage conditions, and shelf life
Manufacture, testing and storage facilities operating to Good Manufacturing Practices	2.3.3.FA Facilities
Facility and equipment controls	/
Transportation of intermediate batches at defined storage conditions and as qualified	2.3.3.SI Substance Intermediates
Transportation of drug product batches at defined storage conditions and as qualified	2.3.3.DP.S.2 Stability, storage conditions, and shelf life
Sterility assurance/microbial contamination strategy	/
Traceability: chain of custody and chain of identity (as applicable)	2.3.3.DP.S.2 Stability, storage conditions, and shelf life

To perform a comparability exercise requires an understanding of critical quality attributes to assess the potential impact of proposed changes on the quality of the resulting drug product and to design suitable comparability studies to demonstrate that pre- and post-change product are comparable – with respect to CQAs.

However, ICH M4Q(R2) will formally require information such as the QTPP which is not required for M4Q(R1).

Currently Module 3 content for an EU MAA can vary significantly across organisations, both qualitatively and quantitatively. Some of the variability may relate to differences in the strategies adopted, related to speed of initial approval and "compliance burden" post-approval. However, it also relates to experience gained over time with Module 3 (and Module 2.3) expectations. With a change in CMC dossier structure, MAA submissions after initial M4Q(R2) implementation are likely to be on a steep learning curve regarding the specific requirements of structure and content.

4. Proposed Solution

Early in product development, ATMP developers and associated stakeholders are strongly encouraged to adopt a suitable framework that can facilitate an evidence-based approach and culminate in sufficient product and process knowledge and experience for a robust control strategy.

Ideally this will include well-designed templates and procedures including, but not limited to the quality target product profile, quality attributes criticality assessments, interrelationship analyses for CQAs with process parameters and materials, critical process parameter confirmation, CQA impact assessments, material risk assessments, failure mode and effects analysis (FMEAs) and overview of the control strategy.

For practical challenges regarding the creation and maintenance of marketing applications, it will be important to monitor the status of ICH M4Q(R2) and implementation in ICH member states. ATMP developers are advised to use detailed and comprehensive authoring plans to facilitate efficient CMC dossier production, mindful of available and relevant resources.

Advocacy can help to raise awareness of difficulties related to CMC dossier structure divergence across regions/ countries and the importance of coordination. Stakeholders are encouraged to use available mechanisms for this advocacy.

5. Conclusion

ICH guidelines have provided some invaluable certainty regarding the expectations of ICH region regulatory agencies. ICH M4Q(R1) was fundamental in reducing the work required to structure marketing applications to the requirements of each country. M4Q(R2) has been designed with the intention of progressing regulatory dossiers with progress in medicines development. And, providing a logical structure to facilitate a more state-of-the-art approach. It is coming and it is important to acknowledge its approach.

Without a clear understanding of the structural and content requirements of the EU MAA, the risk of delays to development, registration and patient access is high. It is crucial that ATMP developers and associated stakeholders familiarise themselves with M4(R2) and plan for the changes ahead. This should include adoption of a scientific- and evidence-based approach that incorporates a QTPP, CQAs and CPPs and leads to the overall control strategy.

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7. Appendices

Appendix 1. The Quality Overall Summary (Module 2.3) – ICH M4Q(R1)

2.3: QUALITY OVERALL SUMMARY (QOS)

INTRODUCTION .....

2.3.S DRUG SUBSTANCE (NAME, MANUFACTURER).

2.3.S.1 General Information (name, manufacturer)
2.3.S.2 Manufacture (name, manufacturer)
2.3.S.3 Characterisation (name, manufacturer)
2.3.S.4 Control of Drug Substance (name, manufacturer)
2.3.S.5 Reference Standards or Materials (name, manufacturer)
2.3.S.6 Container Closure System (name, manufacturer)
2.3.S.7 Stability (name, manufacturer)

2.3.P DRUG PRODUCT (NAME, DOSAGE FORM)

2.3.P.1 Description and Composition of the Drug Product (name, dosage form)
2.3.P.2 Pharmaceutical Development (name, dosage form)
2.3.P.3 Manufacture (name, dosage form)
2.3.P.4 Control of Excipients (name, dosage form)
2.3.P.5 Control of Drug Product (name, dosage form)
2.3.P.6 Reference Standards or Materials (name, dosage form)
2.3.P.7 Container Closure System (name, dosage form)
2.3.P.8 Stability (name, dosage form)

2.3.A APPENDICES

2.3.A.1 Facilities and Equipment (name, manufacturer)
2.3.A.2 Adventitious Agents Safety Evaluation (name, dosage form, manufacturer)
2.3.A.3 Excipients.

2.3.R REGIONAL INFORMATION

Appendix 2. Module 3 Quality – ICH M4Q(R1)

3.1. TABLE OF CONTENTS OF MODULE 3
3.2. BODY OF DATA
3.2.S DRUG SUBSTANCE
3.2.S.1 General Information
3.2.S.1.1 Nomenclature
3.2.S.1.2 Structure
3.2.S.1.3 General Properties
3.2.S.2 Manufacture
3.2.S.2.1 Manufacturer(s)
3.2.S.2.2 Description of Manufacturing Process and Process Controls
3.2.S.2.3 Control of Materials
3.2.S.2.4 Controls of Critical Steps and Intermediates
3.2.S.2.5 Process Validation and/or Evaluation
3.2.S.2.6 Manufacturing Process Development
3.2.S.3 Characterisation
3.2.S.3.1 Elucidation of Structure and other Characteristics
3.2.S.3.2 Impurities
3.2.S.4 Control of Drug Substance
3.2.S.4.1 Specification
3.2.S.4.2 Analytical Procedures
3.2.S.4.3 Validation of Analytical Procedures
3.2.S.4.4 Batch Analyses
3.2.S.4.5 Justification of Specification
3.2.S.5 Reference Standards or Materials
3.2.S.6 Container Closure System
3.2.S.7 Stability
3.2.S.7.1 Stability Summary and Conclusions
3.2.S.7.2 Post-approval Stability Protocol and Stability Commitment
3.2.S.7.3 Stability Data
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3.2.P.1 Description and Composition of the Drug Product
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3.2.P.2.2 Drug Product
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3.2.P.2.2.2 Overages
3.2.P.2.2.3 Physicochemical and Biological Properties
3.2.P.2.3 Manufacturing Process Development
3.2.P.2.4 Container Closure System
3.2.P.2.5 Microbiological Attributes
3.2.P.2.6 Compatibility
3.2.P.3 Manufacture
3.2.P.3.1 Manufacturer(s)
3.2.P.3.2 Batch Formula
3.2.P.3.3 Description of Manufacturing Process and Process Controls
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3.2.P.4 Control of Excipients
3.2.P.4.1 Specifications
3.2.P.4.2 Analytical Procedures
3.2.P.4.3 Validation of Analytical Procedures
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3.2.P.5.5 Characterisation of Impurities
3.2.P.5.6 Justification of Specification(s)
3.2.P.6 Reference Standards or Materials
3.2.P.7 Container Closure System
3.2.P.8 Stability
3.2.P.8.1 Stability Summary and Conclusion
3.2.P.8.2 Post-approval Stability Protocol and Stability Commitment
3.2.P.8.3 Stability Data
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3.2.A.1 Facilities and Equipment
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3.2.R REGIONAL INFORMATION
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Appendix 3. Mapping ICH M4Q(R1) versus M4Q(R2)

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			
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	3.2.DS.S.1 Container closure system
		2.3.4.IN.2.1 Integrated justifications of extractables and leachables	
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.S.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) 3.2.P.3.2 Batch formula	2.3.3.FA Facilities 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
			3.2.PH.S.1 Stability, storage conditions and shelf life, if applicable
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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
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			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.		

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