Notice to applicant.

Egyptian Drug Authority

Central Administration of Inspection on Pharmaceutical Institutions

General Administration for Factories Inspection

Administration of Inspection of Pharmaceutical Factories for Human, Herbal, Veterinary and Disinfectants

Adoption of The International Council for Harmonizations (ICH); Quality Guidelines

Code: EDREX: NP.CIP.002
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Purpose of this Notice

This Version (2/0) is issued to communicate EDA's regulatory position regarding the adoption and application of ICH Quality Guidelines (the "Q" series) as internationally harmonized technical standards that underpin modern pharmaceutical quality systems across the product lifecycle.

The ICH framework is globally recognized for setting harmonized requirements and guidance to support consistent quality expectations across regions.

This Notice is an EDA-issued regulatory communication intended for applicant awareness and implementation planning. It should be read and applied in conjunction with EDA's broader inspection and regulatory guidance ecosystem and the relevant official ICH Quality Guidelines as published by ICH and recognized by major regulatory networks.

This Notice establishes the formal adoption by the Egyptian Drug Authority of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) Quality Guidelines the full Q-series, **Q1 through Q14**, as binding technical references governing the development, manufacture, control, and lifecycle management of medicinal products in the Arab Republic of Egypt.

Regulatory and Technical Context

ICH quality guidelines are foundational to Good Manufacturing Practice expectations and are commonly referenced internationally as benchmarks for compliance and inspection readiness.

ICH Quality Guidelines address critical quality pillars such as pharmaceutical development, quality risk management, and pharmaceutical quality systems elements that are widely used by mature regulatory authorities and industry to ensure a science- and risk-based approach to manufacturing and control.

EDA maintains alignment with subsequent revisions of the ICH Quality Guidelines and with related guidance issued by WHO and stringent regulatory partners.

Scope and Applicant Expectations

This Notice applies to pharmaceutical manufacturers and Marketing Authorization Holders (MAHs) operating in Egypt or supplying the Egyptian market, and it clarifies EDA's expectations for aligning relevant parts of their pharmaceutical quality system, product dossiers, and lifecycle management practices with applicable ICH Quality Guidelines, in a manner proportionate to product type, process complexity, and patient risk. The intent is to strengthen:

- lifecycle-based quality governance and continual improvement,
- risk-based decision-making and control strategies, and
- inspection consistency and transparency through a harmonized reference framework.

Effective Date and Supersession

This Notice enters into force immediately upon its issue date (May 2026) and supersedes Version 1/0 Code: EDREX:NP.CAO.004/2025, Issue Date: 02/2025 in its entirety.

Contact information:

For further information or clarification, please contact:

General Administration for Factories Inspection -

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Links to referenced official sources

Guideline Name	Description and Scope	Link Guideline
Q1A -Q1F Stability	Q1A(R2) STABILITY TESTING OF NEW DRUG SUBSTANCES AND PRODUCTS: this Guideline provides recommendations on stability testing protocols including temperature, humidity and trial duration for Climatic Zone I and II. Furthermore, the revised document takes into account the requirements for stability testing in Climatic Zones III and IV in order to minimize the different storage conditions for submission of a global dossier. -Q1B STABILITY TESTING PHOTOSTABILITY TESTING OF NEW DRUG SUBSTANCES AND PRODUCTS: This document is an annex to the main stability Guideline and gives guidance on the basic testing protocol required to evaluate the light sensitivity and stability of new drugs and products . -Q1C STABILITY TESTING FOR NEW DOSAGE FORMS: It extends the main stability Guideline for new formulations of already approved medicines, and defines the circumstances under which reduced stability data can be accepted . -Q1D BRACKETING AND MATRIXING DESIGNS FOR STABILITY TESTING OF NEW DRUG SUBSTANCES AND PRODUCTS: This document is intended to address recommendations on the application of bracketing and matrixing to stability studies conducted in accordance with principles outlined in the main stability Guideline. -Q1E EVALUATION OF STABILITY DATA: This document extends the main stability Guideline by explaining possible situations where extrapolation of retest periods or shelf-lives beyond the real-time data may be appropriate. Furthermore, it provides examples of statistical approaches to stability data analysis	**1-Q1A(R2):** https://database.ich.org/sites/default/files/Q1A%28R2%29%20Guideline.pdf **2-Q1B:** https://database.ich.org/sites/default/files/Q1B%20Guideline.pdf **3-Q1C:** https://database.ich.org/sites/default/files/Q1C%20Guideline.pdf **4- Q1D:** https://database.ich.org/sites/default/files/Q1D%20Guideline.pdf **5- Q1E:** https://database.ich.org/sites/default/files/Q1E%20Guideline.pdf , https://database.ich.org/sites

	Q1F STABILITY DATA PACKAGE FOR REGISTRATION APPLICATIONS IN CLIMATIC ZONES III AND IV: decided to leave definition of storage conditions in Climatic Zones III and IV to the respective regions and WHO -Q1 EWG STABILITY TESTING OF DRUG SUBSTANCES AND DRUG PRODUCTS : the Q1/Q5C EWG was established to revise the current ICH Stability Guideline Series Q1A-F and Q5C by: Streamlining the series, combining the various guidelines into a single guideline focused on core stability principles; Promoting harmonised interpretation by addressing potential gaps and areas of ambiguity; Addressing additional technical issues, including relevant stability strategies and innovative tools that strengthen the application of risk management; Considering inclusion of new topics, such as stability considerations for advanced therapies	/default/files/Q1E%20Presentation.pdf **6-Q1F:** https://database.ich.org/sites/default/files/Q1F_Stability_Guideline_WHO_2018.pdf , https://database.ich.org/sites/default/files/Q1F_Explanatory_Note.pdf **7- Q1 EWG:** https://database.ich.org/sites/default/files/ICH_Q1EWG_Step2_Draft_Guideline_2025_0411.pdf
Q2 Analytical Validation :	-Q2 R2 REVISION OF Q2 (R1) ANALYTICAL VALIDATION: The scope of the revision of ICH Q2(R1) includes validation principles that cover analytical use of spectroscopic or spectrometry data (e.g., NIR, Raman, NMR or MS) some of which often require multivariate statistical analyses. The guideline continues to provide a general framework for the principles of analytical procedure validation applicable to products mostly in the scope of Q6A and Q6B. These guidelines (Q2(R2) and Q14) are intended to	**1- Q2(R2):** https://database.ich.org/sites/default/files/ICH_Q2%28R2%29_Guideline_2023_1130_ErrorCorrection_2025.pdf **2- Q2(R2)\Q14:** https://database.ich.org/sites

	complement ICH Q8 to Q12 Guidelines, as well as ICH Q13 for Continuous Manufacturing - Q2 R2\Q14 Validation of Analytical Procedures and Q14: the Q2(R2)/Q14 IWG was established to prepare and deliver training materials which will facilitate an aligned interpretation and a harmonised implementation of Q2(R2) "Validation of Analytical" Procedures and Q14 "Analytical Procedure Development" Guideline in ICH and non-ICH regions by: : Illustrating the general concepts of ICH Q2(R2) and Q14 Providing more depth to the discussion of the Annexes in ICH Q2(R2) and Q14 to address some specific implementation aspects relevant for different cases; .	**/default/files/ICH_Q2R2Q14_IWG_Final_Concept_20231030.pdf**
Q3A-Q3E Impurities	-Q3A(R2) Impurities In New Drug Substances : The Guideline addresses the chemistry and safety aspects of impurities, including the listing of impurities in specifications and defines the thresholds for reporting, identification and qualification. The revision of the Guideline has allowed clarifying some inconsistencies, to revise the decision tree, to harmonise with Q3B and to address some editorial issues -Q3B(R2) : Impurities In New Drug Products: It complements the Guideline on impurities in new drug substances and provides advice in regard to impurities in products containing new, chemically synthesized drug substances. The Guideline specifically deals with those impurities which might arise as degradation products of the drug substance, or arising from interactions between drug substance and excipients or components of primary packaging materials. The Guideline sets out a rationale for the reporting, identification and qualification of such impurities based on a scientific appraisal of likely and actual impurities observed, and of the	**1-Q3A(R2):** **https://database.ich.org/sites/default/files/Q3A%28R2%29%20Guideline.pdf** **2- Q3B(R2):** **https://database.ich.org/sites/default/files/Q3B%28R2%29%20Guideline.pdf** **3- Q3C(R9):** **https://database.ich.org/sites/default/files/ICH_Q3**

		safety implications, following the principles elaborated in the parent Guideline. Threshold values for reporting and control of impurities are proposed, based on the maximum daily dose of the drug substance administered in the product. -Q3C(R9): Guideline for residual solvents: providing recommendations on the use of less toxic solvents in the manufacture of drug substances and dosage forms, and setting pharmaceutical limits for residual solvents (organic volatile impurities) in drug products and As part of the Maintenance process, the Q3C Guideline incorporated the revision and inclusion of new Permitted Daily Exposure (PDE) levels as new toxicological data for solvents became available. -Q3C(R10): Maintenance EWG Maintenance of the guideline for residual solvents: providing recommendations on the use of less toxic solvents in the manufacture of drug substances and dosage forms, and setting pharmaceutical limits for residual solvents (organic volatile impurities) in drug products and A Maintenance process for the Q3C Guideline was setup to enable the revision and inclusion of new Permitted Daily Exposure (PDE) levels as new toxicological data for solvents become available. - Q3D(R2): Guideline for Elemental Impurities: is a quality guideline for the control of elemental impurities in new drug products (medicinal products), and it establishes Permitted Daily Exposures (PDEs) for 24 Elemental Impurities (EIs) for drug products administered by the oral, parenteral and inhalation routes of administration. In addition, guidance is provided in Q3D(R2) on how to develop an acceptable level for EIs for drug products administered by other routes of administration - Q3D(R3): Maintenance of the guideline for Elemental Impurities : It is a quality guideline for the control of elemental impurities in new drug products (medicinal	C%28R9%29_Guideline_MinorRevision_2024_2024_Approved.pdf **4- Q3C(R10):** https://database.ich.org/sites/default/files/ICH_Q3C%28R10%29_FinalConceptPaper_2024_1126_0.pdf https://database.ich.org/sites/default/files/Annex%204%20-%20Maintenance%20Procedure%20for%20Q3C%2C%20Q3D%2C%20and%20M7.pdf https://database.ich.org/sites/default/files/ICH_Q3C%28R10%29_EWG_WorkPlan_2025_0725_FINAL.pdf **5-Q3D(R2):** https://database.ich.org/sites/default/files/Q3D-

	products), and it establishes Permitted Daily Exposures (PDEs) for Elemental Impurities (EIs) for drug products administered by the oral, parenteral and inhalation routes of administration. In addition, guidance is provided in ICH Q3D on how to develop an acceptable level for EIs for drug products administered by other routes of administration -Q3D Training : Implementation of guideline for Elemental Impurities: was endorsed by the ICH Steering Committee in October 2014. Throughout the development of the Q3D Guideline, external audiences, constituents and interested parties have clearly communicated the complexity of the implementation approaches for this Guideline. The ICH Steering Committee considered that the development of a comprehensive training programme and supporting documentation sponsored by ICH was necessary to ensure the proper interpretation and effective utilisation by industry and regulators alike to enable a Harmonised and smooth implementation of Q3D on a global basis. The first training package (Modules 0-7) was endorsed by the ICH Assembly in December 2015. -Q3E EWG: Guideline for Extractables and Leachables: was established to work on the development of the Q3E Guideline on the assessment and control of extractables and leachables (E&L), and is expected would assist both applicants and regulators by providing focus on critical aspects, and improving transparency in requirements for medicinal products including drug delivery device components. .	R2_Guideline_Step4_2022_0308.pdf **6-Q3D(R3):** https://database.ich.org/sites/default/files/Annex%204%20-%20Maintenance%20Procedure%20for%20Q3C%2C%20Q3D%2C%20and%20M7_0.pdf **7- Q3D Training:** https://database.ich.org/sites/default/files/Q3D%20Training%20Concept%20Paper.pdf **8-Q3E EWG:** https://database.ich.org/sites/default/files/ICH_Q3E_EWG_Step2_DraftGuideline_2025_0704.pdf https://database.ich.org/sites/default/files/ICH_Q3E_Step2_SupportingDocumentation_Class3_Leac

		hableMonographs_2025_0704.pdf
Q4A-Q4B Pharmacopoeias	-Q4A: Pharmacopoeial Harmonisation: The pharmacopoeial authorities, working together through the Pharmacopoeial Discussion Group (PDG), have been closely involved with the work of ICH since the outset and harmonisation between the major pharmacopoeias, which started before ICH, has proceeded in parallel. -Q4B: Evaluation and Recommendation of Pharmacopeial Texts for use in the ICH Regions: This document describes a process for the evaluation and recommendation by the Q4B Expert Working Group (EWG) of selected pharmacopoeial texts to facilitate their recognition by regulatory authorities for use as interchangeable in the ICH regions. Following favourable evaluations, ICH decided to issue topic-specific annexes with information about these texts and their implementation. Implementation of the Q4B annexes is intended to avoid redundant testing by industry. Given the nature of this topic, no Concept Paper was developed for Q4B - Q4B(R1): Evaluation and Recommendation of Pharmacopeial Texts for use in the ICH Regions: This document describes a process for the evaluation and recommendation by the Q4B Expert Working Group (EWG) of selected pharmacopoeial texts to facilitate their recognition by regulatory authorities for use as interchangeable in the ICH regions. Following favourable evaluations, ICH decided to issue topic-specific annexes with information about these texts and their implementation. Implementation of the Q4B annexes is intended to avoid redundant testing by industry. Given the nature of this topic, no Concept Paper was developed for Q4B(R1). - Q4B Annex 1(R1): Residue on ignition\sulphated Ash General chapter: This annex is the result of the Q4B process for Residue on Ignition/Sulphated Ash	**1- Q4B:** https://database.ich.org/sites/default/files/Q4B%20Guideline.pdf **2-Q4B(R1):** https://database.ich.org/sites/default/files/ICH_Q4B%28R1%29_Guideline_2024_0605.pdf **3-Q4B Annex 1(R1):** https://database.ich.org/sites/default/files/Q4B%20Annex%201%28R1%29%20Guideline.pdf **4- Q4B Annex 2(R1):** https://database.ich.org/sites/default/files/Q4B%20Annex%202%28R1%29%20Guideline.pdf **5-Q4B Annex 3(R1):**

	General Chapter. This annex was revised (R1) on 27 September 2010 to include the Interchangeability Statement from Health Canada, Canada. - Q4B Annex 2(R1): TEST FOR EXTRACTABLE VOLUME OF PARENTERAL PREPARATIONS GENERAL CHAPTER : The ICH Harmonised Annex was finalised under Step 4 in June 2008. This annex is the result of the Q4B process for the Test for Extractable Volume of Parenteral Preparations General Chapter. This annex was revised (R1) on 27 September 2010 to include the Interchangeability Statement from Health Canada, Canada -Q4B Annex 3(R1): TEST FOR PARTICULATE CONTAMINATION: The ICH Harmonised Annex was finalised under Step 4 in June 2008. This annex is the result of the Q4B process for Test for Particulate Contamination: Sub-Visible Particles General Chapter. This annex was revised (R1) on 27 September 2010 to include the Interchangeability Statement from Health Canada, Canada. ..: -Q4B Annex 4A(R1): MICROBIOLOGICAL EXAMINATION OF NON-STERILE PRODUCTS: This annex is the result of the Q4B process for Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests General Chapter. This annex was revised (R1) on 27 September 2010 to include the Interchangeability Statement from Health Canada, Canada. -Q4B Annex 4B(R1): MICROBIOLOGICAL EXAMINATION OF NON-STERILE PRODUCTS: Tests for specified micro-organism general chapter: This annex is the result of the Q4B process for Microbiological Examination of Non-Sterile Products: Tests	https://database.ich.org/sites/default/files/Q4B%20Annex%203%28R1%29%20Guideline.pdf **6-Q4B Annex 4A(R1):** https://database.ich.org/sites/default/files/Q4B%20Annex4A%28R1%29%20Guideline.pdf **7-Q4B Annex 4A(R1):** https://database.ich.org/sites/default/files/Q4B%20Annex4A%28R1%29%20Guideline.pdf **8- Q4B Annex 4B(R1):** https://database.ich.org/sites/default/files/Q4B%20Annex4B%28R1%29%20Guideline.pdf **9- Q4B Annex 4C (R1):** https://database.ich.org/sites/default/files/Q4B%20Annex4C%28R1%29%20Guideline.pdf

	for Specified Micro-organisms General Chapter. This annex was revised (R1) on 27 September 2010 to include the Interchangeability Statement from Health Canada, Canada. -Q4B Annex 4C (R1): MICROBIOLOGICAL EXAMINATION OF NON-STERILE PRODUCTS: ACCEPTANCE CRITERIA FOR PHARMACEUTICAL PREPARATIONS AND SUBSTANCES FOR PHARMACEUTICAL USE : The ICH Harmonised Annex was finalised under Step 4 in November 2008. This annex is the result of the Q4B process for Microbiological Examination of Non-Sterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use General Chapter. For each regulatory region this pharmacopoeial text is non-mandatory and is provided for informational purposes only. This annex was revised (R1) on 27 September 2010 to include the Interchangeability Statement from Health Canada, Canada. -Q4B Annex 5(R1): DISINTEGRATION TEST GENERAL CHAPTER: This annex is the result of the Q4B process for Disintegration Test General Chapter. This annex was revised (R1) on 27 September 2010 to include the Interchangeability Statement from Health Canada, Canada. -Q4B Annex 6: UNIFORMITY OF DOSAGE UNITS GENERAL CHAPTER: This annex is the result of the Q4B process for Uniformity Dosage Units General Chapter. It contains the Interchangeability Statement from Health Canada, Canada. - Q4B ANNEX 7(R2): DISSOLUTION TEST GENERAL CHAPTER: This annex is the result of the Q4B process for Dissolution Test General Chapter. This annex was revised (R1) on 27 September 2010 to include the Interchangeability Statement from Health Canada, Canada. On 11 November 2010 the ICH Steering Committee approved the second revision (R2) directly under Step 4 without further public consultation.	**10- Q4B Annex 5(R1):** https://database.ich.org/sites/default/files/Q4B%20Annex%205%28R1%29%20Guideline.pdf **11-Q4B Annex 6:** https://database.ich.org/sites/default/files/Q4B%20Annex%206%20Guideline.pdf **12- Q4B ANNEX 7(R2) :** https://database.ich.org/sites/default/files/Q4B%20Annex%207%20%28R2%29%20Guideline.pdf **13- Q4B ANNEX 8(R1):** https://database.ich.org/sites/default/files/Q4B%20Annex%208%28R1%29%20Guideline.pdf **14- Q4B ANNEX 9(R1):** https://database.ich.org/sites/default/files/Q4B%20Annex%209%28R1%29%20Guideline.pdf

	- Q4B ANNEX 8(R1): STERILITY TEST GENERAL CHAPTER: This annex is the result of the Q4B process for Sterility Test General Chapter. This annex was revised (R1) on 27 September 2010 to include the Interchangeability Statement from Health Canada, Canada. - Q4B ANNEX 9(R1): TABLET FRIABILITY GENERAL CHAPTER: This annex is the result of the Q4B process for Tablet Friability General Chapter. This annex was revised (R1) on 27 September 2010 to include the Interchangeability Statement from Health Canada, Canada. -Q4B ANNEX 10(R1) : POLYACRYLAMIDE GEL ELECTROPHORESIS : This annex is the result of the Q4B process for Polyacrylamide Gel Electrophoresis General Chapter. This annex was revised (R1) on 27 September 2010 to include the Interchangeability Statement from Health Canada, Canada. Q4B ANNEX 11 :CAPILLARY ELECTROPHORESIS GENERAL CHAPTER : This annex is the result of the Q4B process for Capillary Electrophoresis General Chapter. It contains the Interchangeability Statement from Health Canada, Canada. -	**15-** Q4B ANNEX 10(R1) :**https://database.ich.org/sites/default/files/Q4B%20Annex%2010%28R1%29%20Guideline.pdf** **16-** Q4B ANNEX 11 **https://database.ich.org/sites/default/files/Q4B%20Annex%2011%20Guideline.pdf**
Q7 Good Manufacturing Practice Guide for Active	This document is intended to provide guidance regarding Good Manufacturing Practice (GMP) for the manufacturing of Active Pharmaceutical Ingredients (APIs) under an appropriate system for managing quality.	1. Q7: https://database.ich.org/sites/default/files/Q7%20Guideline.pdf

Pharmaceutical Ingredients	It is also intended to help ensure that APIs meet the requirements for quality and purity that they purport or are represented to possess. This Guideline applies to the manufacture of APIs for use in human drug (medicinal) products. It applies to the manufacture of sterile APIs only up to the point immediately prior to the APIs being rendered sterile. The sterilization and aseptic processing of sterile APIs are not covered by this guidance but should be performed in accordance with GMP guidelines for drug (medicinal) products as defined by local authorities. The ICH Harmonized Guideline was finalized under *Step 4* in November 2000.	**2.** Q7 Questions and Answers https://database.ich.org/sites/default/files/Q7%20Q%26As%20Questions%20%26%20Answers.pdf
Q8(R2) Pharmaceutical Development	This Guideline is intended to provide guidance on the contents of Section 3.2.P.2 (Pharmaceutical Development) for drug products as defined in the scope of Module 3 of the Common Technical Document (ICH topic M4). The guideline does not apply to contents of submissions for drug products during the clinical research stages of drug development. However, the principles in this guideline are important to consider during these stages. This guideline might also be appropriate for other types of products. To determine the applicability of this guideline for a particular type of product, applicants should consult with the appropriate regulatory authorities. The annex to the Harmonised ICH text was finalized under *Step 4* in November 2008 and incorporated into the core Guideline, which was then renamed Q8(R1). The annex provides further clarification of key concepts outlined in the core Guideline. In addition, this annex describes the principles of quality by design (QbD). The annex is not intended to establish new standards: however, it shows how concepts and tools (e.g., design space) outlined in the parent Q8 document could be put into	3. **Q8**(R2) https://database.ich.org/sites/default/files/Q8%28R2%29%20Guideline.pdf

	practice by the applicant for all dosage forms. Where a company chooses to apply quality by design and quality risk management (Q9: Quality Risk Management), linked to an appropriate pharmaceutical quality system, then opportunities arise to enhance science- and risk-based regulatory approaches (see Q10: Pharmaceutical Quality System). The core ICH Harmonized Guideline was finalized under *Step 4* in November 2005. Date of *Step 4*: 1 August 2009	
Q9(R1) Quality Risk Management	The ICH Q9(R1) *Quality Risk Management Guideline* is intended to provide guidance on the principles and examples of tools for quality risk management that can be applied to different aspects of pharmaceutical quality and make limited and specific adjustments to specific chapters and annexes of the current ICH Q9 Guideline on Quality Risk Management (QRM). Further to reaching *Step 4* Guideline adoption, the WG continues to work to develop specific training materials (with examples) to supplement the existing ICH briefing pack on ICH Q9, as well as to explain and facilitate the implementation and application of the proposed revisions. Further information can be found in the Q9(R1) Concept Paper and Business Plan. The ICH Q9(R1) Guideline reached *Step 4* of the ICH process on 18 January 2023.	Q9(R1): https://database.ich.org/sites/default/files/ICH_Q9%28R1%29_Guideline_Step4_2025_0115.pdf
Q10 Pharmaceutical Quality System	This Guideline applies to the systems supporting the development and manufacture of pharmaceutical drug substances and drug products, including biotechnology and biological products, throughout the product lifecycle.	Q10: https://database.ich.org/sites/default/files/Q10%20Guideline.pdf

	The elements of Q10 should be applied in a manner that is appropriate and proportionate to each of the product lifecycle stages, recognizing the differences among, and the different goals of each stage. The ICH Harmonized Guideline was finalized under *Step 4* in June 2008.	
Q8/Q9/Q10 Questions & Answers (R5)	Since reaching *Step 4* and publication within the ICH regions, experiences by all parties with the implementation of the ICH Q8(R2), Q9 and Q10 Guidelines have resulted in the need for some clarification. The Questions and Answers developed by the Quality Implementation Working Group (IWG) are intended to facilitate the implementation of the Q8(R2), Q9 and Q10 Guidelines, by clarifying key issues. The document with the first set of Q&As was finalized under *Step 4* in April 2009. Since then, new sets of questions were added three times, with the most recent version (Q8/Q9/Q10 Q&As (R4)) approved by the Steering Committee in November 2010. The ICH Quality IWG also prepared "Points to Consider" covering topics relevant to the implementation of Q8(R2), Q9 and Q10, which supplement the existing Questions & Answers and workshop training materials already produced by this group. The document with the first and second set of Points to Consider was finalized in June and November 2011, respectively. In October 2024 the Q&As were updated to Q8/Q9/Q10 Questions & Answers (R5) by removing outdated text and rephrasing the Q&As considered in view of the implementation of ICH Q8, Q9 and Q10, with minor additions to address minor content gaps in the document. Furthermore, minor edits have been made to improve the readability of the document. Date of *Step 4*:11 November 2010	Q8/Q9/Q10 Questions & Answers (R5): https://database.ich.org/sites/default/files/ICH_Q9%28R1%29_Annex_1_Q8Q9Q10_QAs%28R5%29_1030.pdf

Q11 Development and Manufacture of Drug Substances (Chemical Entities and Biotechnological/Biological Entities)	This Guideline describes approaches to developing and understanding the manufacturing process of the drug substance and also provides guidance on what information should be provided in Module 3 of the Common Technical Document (CTD) Sections 3.2.S.2.2 – 3.2.S.2.6 (ICH M4Q). It addresses aspects of development and manufacture that pertain to drug substance, including the presence of steps designed to reduce impurities. This Guideline is applicable to drug substances as defined in the Scope sections of ICH Guidelines Q6A and Q6B but might also be appropriate for other types of products following consultation with the appropriate regulatory authorities. The Guideline reached *Step 4* of the ICH process on 1 May 2012.	Q11:https://database.ich.org/sites/default/files/Q11%20Guideline.pdf Q11 Q&As: https://database.ich.org/sites/default/files/Q11_Q%26As_Q%26As.pdf
Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management	This new Guideline is proposed to provide a framework to facilitate the management of post-approval Chemistry, Manufacturing and Controls (CMC) changes in a more predictable and efficient manner across the product lifecycle. Adoption of this new ICH Guideline will promote innovation and continual improvement in the biopharmaceutical sector, and strengthen quality assurance and reliable supply of product, including proactive planning of supply chain adjustments. It will allow regulators (assessors and inspectors) to better understand the firms' Pharmaceutical Quality Systems (PQSs) for management of post-approval CMC changes. This new Guideline is intended to complement the existing ICH Q8 to Q11 Guidelines and is composed of a core Guideline and Annexes. This topic was endorsed by the ICH Steering Committee in September 2014. Date of *Step 4*: 20 November 2019	Q12: https://database.ich.org/sites/default/files/Q12_Guideline_Step4_2019_1119.pdf

Q13 Continuous Manufacturing of Drug Substances and Drug Products	The guideline: • Builds on existing ICH Quality Guidelines, provides clarification on continuous manufacturing (CM) concepts, describes scientific approaches, and presents regulatory considerations specific to CM of drug substances and drug products; • Focuses on the integrated aspects of a CM system in which two or more unit operations are directly connected; • Describes scientific and regulatory considerations for the development, implementation, operation, and lifecycle management of CM. The ICH Q13 Guideline reached *Step 4* of the ICH process on 16 November 2022.	Q13: https://database.ich.org/sites/default/files/ICH_Q13_Step4_Guideline_2022_1116.pdf
Q14 Analytical Procedure Development	The new guideline harmonizes the scientific approaches of Analytical Procedure Development and provides the principles relating to the description of Analytical Procedure Development process. This new guideline intends to improve regulatory communication between industry and regulators and facilitate more efficient, sound scientific and risk-based approval as well as post-approval change management of analytical procedures. The ICH Q14 Guideline reached Step 4 of the ICH process on 1 November 2023.	Q14: https://database.ich.org/sites/default/files/ICH_Q14_Guideline_2023_1116_1.pdf