Notice to applicant.

Egyptian Drug Authority
Central Administration of Operation

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

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Guideline Name	Description and Scope	Link Guideline
Q7 **Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients**	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. 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.	1. Q7: https://database.ich.org/sites/default/files/Q7%20Guideline.pdf **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.	3. **Q8(**R2**)** https://database.ich.org/sites/default/files/Q8%28R2%29%20Guideline.pdf

	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 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.	Q9(R1): https://database.ich.org/sites/default/files/ICH_Q9%28R1%29_Guideline_Step4_2025_0115.pdf

	The ICH Q9(R1) Guideline reached *Step 4* of the ICH process on 18 January 2023.	
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. 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.	Q10: https://database.ich.org/sites/default/files/Q10%20Guideline.pdf
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	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

	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	
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.	Q12: https://database.ich.org/sites/default/files/Q12_Guideline_Step4_2019_1119.pdf

	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	
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

❖ **Contact information:**

For further information or clarification, please contact:

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