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BATCH Q: Quality		
Finalised Guidelines *(Step 4)*		
Q1A(R2)	Stability Testing of New Drug Substances and Products (Second Revision)	Feb. 2003
Q1B	Stability Testing: Photostability Testing of New Drug Substances and Products	Nov. 1996
Q1C	Stability Testing for New Dosage Forms	Nov. 1996
Q1D	Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products	Feb. 2002
Q1E	Evaluation for Stability Data	Feb. 2003
~~Q1F*~~	~~Stability Data Package for Registration Applications in Climatic Zones III and IV~~ *(Guideline withdrawn in June 2006).*	~~Feb. 2003~~
Q2(R1)	Validation of Analytical Procedures: Text and Methodology *(The Addendum dated November 1996 has been incorporated into the core guideline in November 2005).*	Oct. 1994
Q3A(R2)	Impurities in New Drug Substances	Oct. 2006
Q3B(R2)	Impurities in New Drug Products	June 2006
Q3C(R5)	Impurities: Guideline for Residual Solvents *(including the two Revised PDE for THF and NMP dated September 2002 and October 2002 incorporated in core Guideline in November 2005 and revised PDE for Cumene incorporated in core Guideline in February 2011)*	Feb. 2011
Q3D	Guideline for Elemental Impurities	Dec. 2014
Q4B	Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions	Nov. 2007
Q4B Annex 1(R1)	Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Residue on Ignition/Sulphated Ash General Chapter	Sept. 2010
Q4B Annex 2(R1)	Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Test for Extractable Volume of Parenteral Preparations General Chapter	Sept. 2010
Q4B Annex 3(R1)	Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Test for Particulate Contamination: Sub-Visible Particles General Chapter	Sept. 2010
Q4B Annex 4A(R1)	Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests General Chapter	Sept. 2010
Q4B Annex 4B(R1)	Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Microbiological Examination of Non-Sterile Products: Tests for Specified Micro-Organisms General Chapter	Sept. 2010
Q4B Annex 4C(R1)	Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Microbiological Examination of Non-Sterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use General Chapter	Sept. 2010
Q4B Annex 5(R1)	Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Disintegration Test General Chapter	Sept. 2010
Q4B Annex 6	Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on University of Dosage Units General Chapter	Nov. 2013
Q4B Annex 7(R2)	Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Dissolution Test General Chapter	Nov. 2010

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Q4B Annex 8(R1)	Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Sterility Chapter General Chapter	Sept. 2010
Q4B Annex 9(R1)	Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Tablet Friability General Chapter	Sept. 2010
Q4B Annex 10(R1)	Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Polyacrylamide Gel Electrophoresis General Chapter	Sept. 2010
Q4B Annex 11	Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Capillary Electrophoresis General Chapter	June 2010
Q4B Annex 12	Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Analytical Sieving General Chapter	June 2010
Q4B Annex 13	Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Bulk Density and Tapped Density of Powders General Chapter	June 2012
Q4B Annex 14	Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Bacterial Endotoxins Test General Chapter	Oct. 2012
Q5A(R1)	Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin	Sept. 1999
Q5B	Quality of Biotechnological Products: Analysis of the Expression Construct in Cells Used for Production of r-DNA Derived Protein Products	Nov. 1995
Q5C	Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products	Nov. 1995
Q5D	Derivation and Characterisation of Cell Substrates Used for Production of Biotechnological/ Biological Products	Jul. 1997
Q5E	Comparability of Biotechnological/Biological Products Subject to Changes in Their Manufacturing Process	Nov. 2004
Q6A	Specifications : Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products : Chemical Substances	Oct. 1999
Q6B	Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products	Mar. 1999
Q7	Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients	Nov. 2000
Q8(R1)	Pharmaceutical Development	Nov. 2008
Q9	Quality Risk Management	Nov. 2005
Q10	Pharmaceutical Quality System	June 2008
Q11	Development and Manufacture of Drug Substances (Chemical Entities and Biotechnological/Biological Entities)	May 2012

Guidelines released for consultation (*Step 2b*)

July 2013

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BATCH S: Safety

Finalised Guidelines (*Step 4*)

S1A	Guideline on the Need for Carcinogenicity Studies of Pharmaceuticals	Nov. 1995
S1B	Testing for Carcinogenicity of Pharmaceuticals	July 1997
S1C(R2)	Dose Selection for Carcinogenicity Studies of Pharmaceuticals	Mar. 2008
S2(R1)	Guidance on Genotoxicity Testing and Data Interpretation for Pharmaceuticals Intended for Human Use	Nov. 2011
S3A	Note for Guidance on Toxicokinetics: The Assessment of Systemic Exposure in Toxicity Studies	Oct. 1994
S3B	Pharmacokinetics: Guidance for Repeated Dose Tissue Distribution Studies	Oct. 1994
S4	Duration of Chronic Toxicity Testing in Animals (Rodent and Non Rodent Toxicity Testing)	Sept. 1998
S5(R2)	Detection of Toxicity to Reproduction for Medicinal Products and Toxicity to Male Fertility *(the Addendum dated November 1995 has been incorporated into the core guideline in November 2005)*	June 1993
S6(R1)	Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals	June 2011
S7A	Safety Pharmacology Studies for Human Pharmaceuticals	Nov. 2000
S7B	The Non-clinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals	May 2005
S8	Immunotoxicity Studies for Human Pharmaceuticals	Sept. 2005
S9	Nonclinical Evaluation for Anticancer Pharmaceuticals	Oct. 2009
S10	Photosafety Evaluation	Nov. 2013

Guidelines released for consultation (*Step 2b*)

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BATCH E: Efficacy

Finalised Guidelines (*Step 4*)

E1	The Extent of Population Exposure to Assess Clinical Safety for Drugs Intended for Long-Term Treatment of Non-Life-Threatening Conditions	Oct. 1994
E2A	Clinical Safety Data Management: Definitions and Standards for Expedited Reporting	Oct. 1994
E2B(R3) Implementation Guide	Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports	Nov. 2014
E2C(R2)	Periodic Benefit-Risk Evaluation Report	Nov. 2012
E2C(R2) Q&As	Periodic Benefit-Risk Evaluation Report – Questions & Answers	Mar. 2014
E2D	Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting	Nov. 2003
E2E	Pharmacovigilance Planning	Nov. 2004
E2F	Development Safety Update Report	Aug. 2010
E3	Structure and Content of Clinical Study Reports	Nov. 1995
E3 Q&As (R1)	Structure and Content of Clinical Study Reports – Questions & Answers	July 2012
E4	Dose-Response Information to Support Drug Registration	Mar. 1994
E5(R1)	Ethnic Factors in the Acceptability of Foreign Clinical Data	Mar. 1998
E6(R1)	Good Clinical Practice: Consolidated Guideline	May 1996
E7	Studies in Support of Special Populations: Geriatrics	June 1993
E7 Q&As	Studies in Support of Special Populations: Geriatrics – Questions & Answers	July 2010
E8	General Considerations for Clinical Trials	July 1997
E9	Statistical Principles for Clinical Trials	Feb. 1998
E10	Choice of Control Group and Related Issues in Clinical Trials	July 2000
E11	Clinical Investigation of Medicinal Products in the Pediatric Population	July 2000
E14	The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs	May 2005
E14 Q&As (R2)	The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs – Questions and Answers	Mar. 2014
E15	Definitions for Genomic Biomarkers, Pharmacogenomics, Pharmacogenetics, Genomic Data and Sample Coding Categories	Nov. 2007
E16	Biomarkers Related to Drug or Biotechnology Product Development: Context, Structure and Format of Qualification Submissions	Aug. 2010

Documents released for consultation (*Step 2b*)

Consensus Draft Principle

E12	Principles for Clinical Evaluation of New Antihypertensive Drugs	Mar. 2000

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BATCH M: Multidisciplinary

Finalised Guidelines (*Step 4*)

M2 ICSR (R2)	Electronic Transmission of Individual Case Safety Reports Message Specification (ICH ICSR DTD Version 2.1) companion document to E2B(R3)	Feb. 2001
M3(R2)	Guidance on Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals	June 2009
M3(R2) Q&As (R2)	Guidance on Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals Questions & Answers	Mar. 2012
M4(R3)*	Organisation of the Common Technical Document for the Registration of Pharmaceuticals for Human Use *(Edited with Numbering and Section Header Changes, September 2002)* Including the Annex : the Granularity Document (Revised November 2003).	Nov. 2000
M4Q(R1)*	The Common Technical Document for the Registration of Pharmaceuticals for Human Use : **Quality** *(Edited with Numbering and Section Header Changes, September 2002)*	Nov. 2000
M4S(R2)*	The Common Technical Document for the Registration of Pharmaceuticals for Human Use : **Safety** *(Edited with Numbering and Section Header Changes, September 2002)*	Nov. 2000
M4E(R1)*	The Common Technical Document for the Registration of Pharmaceuticals for Human Use : **Efficacy** *(Edited with Numbering and Section Header Changes, September 2002)*	Nov. 2000
M7	Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk	June 2014

Guidelines released for consultation (*Step 2b*)

* **Notice for Clarification:**
Within the ICH regions, local versions are published. The wording of the core CTD (Modules 2, 3, 4 and 5) in the local versions might be slightly different from one region to another due to specific editing that takes into consideration regional regulations. It does not affect the common understanding by the six ICH parties of the CTD published on the ICH website (http://www.ich.org).

Questions & Answers:
In order to facilitate the implementation of the CTD, the ICH Experts have developed a series of Q&As which are continuously updated and can be downloaded from the ICH website directly from the following url:
http://www.ich.org/products/ctd.html