國際醫藥法規協合組織(ICH)規範採認清單

2017年12月4日

一、為協助業者於藥品研發製造時能有所依循及參考，並建構與國際協和之藥品審查標準，爰參考「國際醫藥法規協合組織(International Conference on Harmonization, ICH)規範」，訂定「國際醫藥法規協合組織(ICH)規範採認清單」，說明ICH規範重點、適用範圍及我國目前相對應參考資料，以作為業者準備技術性資料之參考。

二、業者申請新藥查驗登記或臨床試驗時，應依循我國相關法規要求備齊資料。若法規無規定或特殊情況無法檢送資料者，得依據本採認清單相關ICH規範，提出科學證據，向中央主管機關提出個案討論。另外，本署亦保留額外要求技術性資料之權利。

編號	採認ICH規範			發佈年份		我國目前相對應參考資料
Quality						
1	**Q1 Stability**	Q1A(R2)	Stability Testing of New Drug Substances and Products	2003		「藥品安定性試驗基準」 (衛署藥字第87041838號) (衛署藥字第0940310335號)
2		Q1B	Stability Testing: Photostability Testing of New Drug Substances and Products	1996		
3		Q1C	Stability Testing for New Dosage Forms	1996		
4		Q1D	Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products	2002		
5		Q1E	Evaluation of Stability Data	2003		
6	**Q2 Analytical Validation**	Q2(R1)	Validation of Analytical Procedures: Text and Methodology	2005		「分析確效作業指導手冊」 (行政院衛生署 中華民國89年6月)
7	**Q3 Impurities**	Q3A(R2)	Impurities in New Drug Substances	2006		_
8		Q3B(R2)	Impurities in New Drug Products	2006		_
9		Q3C(R5)	Impurities: Residual Solvents	2011		_
10		**Q3C(R6)**	**Impurities: Guideline for residual solvents**	**2016**	**Step 4 version dated 20 Oct., 2016**	_
11		**Q3D**	**Guideline for elemental impurities**	**2014**	**Step 4 version dated 16 Dec., 2014**	_
12	**Q4 Pharmacopoeias**	Q4	Pharmacopoeias	_		「中華藥典」
13		Q4A	Pharmacopoeial Harmonization			

編號	採認ICH規範		發佈年份		我國目前相對應參考資料
14	Q4B	Evaluation and Recommendation of Pharmacopoeial Texts for Use in the International Conference on Harmonisation Regions			
15	Q4B ANNEX 1(R1)	Evaluation and Recommendation of Residue on Ignition/Sulphated Ash General Chapter			
16	Q4B ANNEX 2(R1)	Evaluation and Recommendation of Test for Extractable Volume of Parenteral Preparations General Chapter			
17	Q4B ANNEX 3(R1)	Evaluation and Recommendation of Test for Particulate Contamination: Sub-Visible Particles General Chapter			
18	Q4B ANNEX 4A(R1)	Evaluation and Recommendation of Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests General Chapter			
19	Q4B ANNEX 4B(R1)	Evaluation and Recommendation of Microbiological Examination of Non-Sterile Products: Tests for Specified Micro-organisms General Chapter			
20	Q4B ANNEX 4C(R1)	Evaluation and Recommendation of Microbiological Examination of Non-Sterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use General			
21	Q4B ANNEX 5(R1)	Evaluation and Recommendation of Disintegration Test General Chapter			
22	Q4B ANNEX 6	Evaluation and Recommendation of Uniformity Dosage Units General Chapter			

編號	採認ICH規範			發佈年份		我國目前相對應參考資料
23		Q4B ANNEX 7(R2)	Evaluation and Recommendation of Dissolution Test General Chapter			
24		Q4B ANNEX 8(R1)	Evaluation and Recommendation of Sterility Test General Chapter			
25		Q4B ANNEX 9(R1)	Evaluation and Recommendation of Tablet Friability General Chapter			
26		Q4B ANNEX 10(R1)	Evaluation and Recommendation of Polyacrylamide Gel Electrophoresis General Chapter			
27		Q4B ANNEX 11	Evaluation and Recommendation of Capillary Electrophoresis General Chapter			
28		Q4B ANNEX 12	Evaluation and Recommendation of Capillary Electrophoresis General Chapter			
29		Q4B ANNEX 13	Evaluation and Recommendation of Bulk Density and Tapped Density of Powders General			
30		Q4B ANNEX 14	Evaluation and Recommendation of Bacterial Endotoxins Test General Chapter			
31	**Q5 Quality of Biotechnological Products**	Q5A(R1)	Viral Safety Evaluation of Biotechnology Products Derived From Cell Lines of Human or Animal Origin	1999		「**生物藥品檢驗基準**」I/II 行政院衛生署食品藥物管理局 100年11月出版
32		Q5B	Quality of Biotechnological Products:Analysis of the Expression Construct in Cells Used for Production of r-DNA Derived Protein Products	1995		_
33		Q5C	Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products	1995		「**藥品安定性試驗基準**」：生物技術/生物性藥品之安定性

編號	採認ICH規範			發佈年份		我國目前相對應參考資料
34		Q5D	Quality of Biotechnological/Biological Products: Derivation and Characterization of Cell Substrates Used for Production of	1997		_
35		Q5E	Comparability of Biotechnological/Biological Products Subject to Changes in Their Manufacturing Process	2004		_
36	**Q6 Specifications**	Q6A	Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances	1999		_
37		Q6B	Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products	1999		「藥品查驗登記審查準則－基因工程藥品之查驗登記」 (衛署藥字第0910012589號)
38	**Q7 Good Manufacturing Practices**	Q7A	Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients	2000		1.「西藥藥品優良製造規範」第二部（原料藥）」 (署授食字第1021101127號) 2.「生物藥品查驗登記應符合原料藥優良製造規範」 (衛署藥字第0970332993號)
39	**Q7 Q&As Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients**	**Q7 Q&As**	**Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients**	**2015**	**Step 4 version dated June 10, 2015**	
40	**Q8 Pharmaceutical Development**	Q8(R2)	Pharmaceutical Development	2009		_
41	**Q9 Quality Risk Management**	Q9	Quality Risk Management	2005		_
42	**Q10 Pharmaceutical Quality System**	Q10	Pharmaceutical Quality System	2008		_

編號	採認ICH規範			發佈年份		我國目前相對應參考資料
43	**Q11 Development and Manufacture of Drug Substances**	Q11	Development and Manufacture of Drug Substances (Chemical Entities and Biotechnological/Biologicl Entities)	2012		_
44		Q11 Q&As	Questions & Answers: Selection and Justification of Starting Materials for the Manufacture of Drug Substances	2017	23 Aug. 2017	_
Safety						
45	**S1 Rodent Carcinogenicity Studies for Human Pharmaceuticals**	S1A	Need for Carcinogenicity Studies of Pharmaceuticals	1995		「藥品非臨床試驗安全性規範」 (FDA藥字第1031402844號)
46		S1B	Testing for Carcinogenicity of Pharmaceuticals	1997		
47		S1C(R2)	Dose Selection for Carcinogenicity Studies of Pharmaceuticals	2008		
48	**S2(R1) Guidance on Genotoxicity Testing and Data Interpretation for Pharmaceuticals Intended for Human Use**	S2A	Guidance on Specific Aspects of Regulatory Genotoxicity Tests for Pharmaceuticals	2011		
49		S2B	Genotoxicity: A Standard Battery for Genotoxicity Testing for Pharmaceuticals	2011		
50	**S3 Toxicokinetics and Pharmacokinetics**	S3A	Note for Guidance on Toxicokinetics: The Assessment of Systemic Exposure in Toxicity Studies	1994		
51		S3B	Pharmacokinetics: Guidance for Repeated Dose Tissue Distribution Studies	1994		
52	**S4 Toxicity Testing**	S4	Toxicity Testing	1998		
53	**S5 Reproductive Toxocity**	S5(R2)	Detection of Toxicity to Reproduction for Medicinal Products & Toxicity to Male Fertility	2005		

編號	採認ICH規範			發佈年份		我國目前相對應參考資料
54	**S6(R1) Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals**	S6(R1)	Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals	2011		
55	**S7 Pharmacology Studies**	S7A	Safety Pharmacology Studies for Human Pharmaceuticals	2000		
56		S7B	The Non-Clinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals	2005		
57	**S8 Immunotoxicity Studies for Human Pharmaceuticals**	S8	Immunotoxicity Studies for Human Pharmaceuticals	2005		
58	**S9 Nonclinical Evaluation for Anticancer Pharmaceuticals**	S9	Nonclinical Evaluation for Anticancer Pharmaceuticals	2009		
59	**S10 Photosafety Evaluation of Pharmaceuticals**	S10	Photosafety Evaluation of Pharmaceuticals	2013		
60	S11 Nonclinical safety testing	S11	Nonclinical safety testing in support of development of paediatric medicines	This topic was endorsed by the ICH Steering Committee in November		
Efficacy						

編號	採認ICH規範			發佈年份		我國目前相對應參考資料
61	**E1 - E2F** **Clinical Safety**	E1	The Extent of Population Exposure to Assess Clinical Safety for Drugs Intended for Long-Term Treatment of Non-Life Threatening Conditions	1994		**「新成分新藥查驗登記療效及安全性之考量重點」** (FDA藥字第1011400092號函)
62		E2A	Clinical Safety Data Management: Definitions and Standards for Expedited Reporting	1994		**「藥品優良臨床試驗準則」** (署授食字第0991407858號)
63		E2B(R3)	Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports	2005		**「藥品不良反應通報表」** (部授食字第1031405027號)
64		E2B(R3) IWG	Implementation: Electronic transmission of individual case safety reports	Nov. 2014		–
65		E2C(R2)	Periodic Benefit-Risk Evaluation Report	2012		1.**「藥物安全監視管理辦法」** (衛署藥字第0930327734號) (部授食字第1021453231號) 2.**「藥品優良安全監視規範」** (衛署藥字第0970329838號)
66		E2D	Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting	2003		1.**「藥物安全監視管理辦法」** (衛署藥字第0930327734號) (部授食字第1021453231號) 2.**「藥品優良安全監視規範」** (衛署藥字第0970329838號)
67		E2E	Pharmacovigilance Planning	2004		1.**「藥物安全監視管理辦法」** (衛署藥字第0930327734號) (部授食字第1021453231號) 2.**「藥品優良安全監視規範」** (衛署藥字第0970329838號)
68		E2F	Development Safety Update Report	2010		–
69	**E3** **Clinical Study Reports**	E3	Structure and Content of Clinical Study Reports	1995		**「臨床試驗報告之格式及內容基準」** (衛署藥字第0920318552號)

編號	採認ICH規範			發佈年份		我國目前相對應參考資料
70		E3 Q&As R1	Questions & Answers: Structure and contents of clinical study reports	6 Jul. 2012		–
71	**E4 Dose-Response Studies**	E4	Dose-Response Information to Support Drug Registration	1994		「新成分新藥查驗登記療效及安全性之考量重點」 (FDA藥字第1011400092號函)
72	**E5 Ethnic Factors**	E5(R1)	Ethnic Factors in the Acceptability of Foreign Clinical Data	1998		「銜接性試驗基準－接受國外臨床資料之族群因素考量」 (衛署藥字第0980325016號公告)
73	**E6 Good Clinical Practice**	E6(R1)	Good Clinical Practice	1996		「藥品優良臨床試驗準則」 (署授食字第0991407858號)
74		**E6(R2)**	**Good Clinical Practice**	**2016**	**Step 4 version dated 9 Nov., 2016**	–
75	**E7- E11 Clinical Trials**	E7	Studies in Support of Special Populations: Geriatrics	1993		「年老病患的藥品臨床試驗基準(Guidance for Studies of Drugs in Support of Special Populations: Geriatrics)」 (衛署藥字第0900054879號公告)
76		E7 Q&As	Questions & Answers: Studies in support of special populations: Geriatrics	6 Jul. 2010		–
77		E8	General Considerations for Clinical Trials	1997		「新成分新藥查驗登記療效及安全性之考量重點」 (FDA藥字第1011400092號函)
78		E9	Statistical Principles for Clinical Trials	1998		「新成分新藥查驗登記療效及安全性之考量重點」 (FDA藥字第1011400092號函)
79		E10	Choice of Control Group and Related Issues in Clinical Trials	2000		「新成分新藥查驗登記療效及安全性之考量重點」 (FDA藥字第1011400092號函)
80		E11	Clinical Investigation of Medicinal Products in the Pediatric Population	2000		「小兒族群的藥動學試驗基準(Guidance for Pediatric Pharmacokinetic Studies)」 (衛署藥字第0910043475號公告)

編號	採認ICH規範			發佈年份		我國目前相對應參考資料
81		**E11(R1)**	**Addendum to ICH E11: Clinical Investigation of Medical Products in the Pediatric Population**	**2017**	**Step 4 version dated 20 July, 2017**	_
82	**E12 Clinical Evaluation by Therapeutic Category**	E12	Principles for Clinical Evaluation of New Antihypertensive Drugs	2000		**「心血管治療藥品臨床試驗基準(Guidance for the Clinical Trials of Drugs Acting on Cardiovascular System)」** (衛署藥字第88057215號公告)
83	**E14 Clinical Evaluation**	E14	Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs	2005		_
84		E14 Q&As(R3)	Q&As: Clinical Evaluation of QT/QTc interval prolongation and proarrhythmic potential for non-antiarrhythmic drugs	2015	10 Dec.2015	_
85	**E15 - E16 Pharmacogenomics**	E15	Definitions for Genomic Biomarkers, Pharmacogenomics, Pharmacogenetics, Genomic Data and Sample Coding Categories	2007		**「人體生物資料庫管理條例」** (華總一義字第09900022481號) (衛署醫字第1000061677號) (華總一義字第10100177991號)
86		E16	Biomarkers Related to Drug or Biotechnology Product Development: Context, Structure, and Format of Qualification Submissions	2010		_
87		**E18 Genomic sampling**	**Genomic sampling and management of genomic data**	**2017**	**Step 4 version dated 3 Aug. 2017**	_
Multidisciplinary						

編號	採認ICH規範			發佈年份		我國目前相對應參考資料
88	**M1 Medical Dictionary for Regulatory Activities**	M1	MedDRA Terminology	–		–
89	**M2 Electronic Standards**	M2	Electronic Standards for the Transfer of Regulatory Information, ESTRI	–		–
90	**M3 Nonclinical Safety Studies**	M3(R2)	Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals	2009		**「藥品非臨床試驗安全性規範」** (衛署藥字第87040788號) (FDA藥字第1031402844號)
91		M3(R2) Q&As R2	Questions & Answers: Guidance on Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals	2012	dated 5 Mar.2012	–
92	**M4 Common Technical Document**	M4(R3)	Organisation Including the Granularity document that provides guidance on document location and paginations.	2000		**1.「通用技術文件（Common Technical Document, CTD）格式，新成分新藥查驗登記申請自102年11月1日起實施」** (署授食字第1011405725號) **2.「原料藥查驗登記審查技術資料查檢表」** (部授食字第1021400426號) (署授食字第1021401257號) 3.**「公告新成分以外之新藥查驗登記申請自103年7月1日起依通用技術文件(Common Technical Document，CTD)格式辦理」** (部授食字第1021453148號) 4.**「公告學名藥查驗登記申請自103年7月1日起依通用技術文件Common Technical Document，CTD) 格式辦理」** (部授食字第1021452529號)
93		**M4(R4) Organisation**	**Organisation Including the Granularity document that provides guidance on document location and paginations**	**2016**	**Step 4 version dated 15 June 2016**	
94		M4Q(R1)	The Common Technical Document for the Registration of Pharmaceuticals for Human Use: Quality	2000		
95		M4S(R2)	The Common Technical Document for the Registration of Pharmaceuticals for Human Use: Safety	2000		

編號	採認ICH規範			發佈年份		我國目前相對應參考資料
96		M4S Q&As (R2)		11 Nov. 2003		
97		M4E(R1)	The Common Technical Document for the Registration of Pharmaceuticals for Human Use: Efficacy	2000		
98		**M4E(R2) Efficacy**	**Guideline on enhancing the format and structure of benefit-risk information in ICH**	**2016**	**Step 4 version dated 15 June 2016**	_
99		M4E Q&As (R1)		10 June. 2004		_
100	**M5 Data Elements and Standards for Drug Dictionaries**	M5	Data Elements and Standards for Drug Dictionaries	_		_
101	**M6 Gene Therapy**	M6	Virus and Gene Therapy Vector Shedding and Transmission (draft)	_		「基因治療臨床試驗（草案）」 (FDA藥字第1001400546號)
102	**M7 Genotoxic Impurities**	M7	Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk			_
103		**M7(R1) Genotoxic impurities**	**Assessment and control of DNA reactive (mutagenic) impurities in pharmaceuticals to limit potential carcinogenic risk**	**2017**	**Step 4 version dated 31 Mar 2017**	_

編號	採認ICH規範			發佈年份		我國目前相對應參考資料
104	**M8 Electronic Common Technical Document (eCTD)**	M8	Electronic Common Technical Document			1.「**通用技術文件（Common Technical Document, CTD）格式**」 (署授食字第1011405725號) 2.「**公告實施藥品查驗登記申請得以電子送件(e-submission)**」 (署授食字第1011408090號) 3.**原料藥查驗登記審查技術資料查檢表** (署授食字第1021400426號)