

Content Statement

For

ComplianceControl cGARD

Regulations:

International

- ICH E
 - ICH E1: The extent of population exposure to assess clinical safety for drugs intended for long-term treatment of non-life threatening conditions - 26th October 1994
 - ICH E2A: Clinical Safety Data Management : Definitions and Standards for Expedited Reporting - 27 October 1994
 - ICH E2B Q and A(R5): E2B Implementation Working Group Questions answers (R5) - 3rd March 2005
 - ICH E2B(R3): Revision of the ICH Guideline on Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports – 31 Oct 2011
 - ICH E2C(R1): Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs - November 2005
 - ICH E2D: Post- Approval Safety Data Management: Definitions and Standards for Expedited Reporting - 12th November 2003
 - ICH E2E: Pharmacovigilance Planning - 18th November 2004
 - ICH E3: Structure and Content of Clinical Study Reports - 30th November 1995
 - ICH E4: Dose-Response Information to Support Drug Registration - 10th March 1994
 - ICH E5Qa(R1): E5 Implementation Working Group - 2nd June 2006 Questions answers (R1) - 2nd June 2006
 - ICH E5(R1): Ethnic Factors in the Acceptability of Foreign Clinical Data - 5th February 1998
 - ICH E6(R1): Good Clinical Practice: Consolidated Guidance - 10 June 1996
 - ICH E7: Studies in support of Special Populations: Geriatrics - 24th June 1993
 - ICH E8: General Considerations for Clinical Trials - 17th July 1997
 - ICH E9: Statistical Principles for Clinical Trials - 5th February 1998
 - ICH E10: Choice of Control Group and Related Issues in Clinical Trials - 20th July 2000
 - ICH E11: Clinical Investigation of Medicinal Products in the Pediatric Population - 20th July 2000
 - ICH E12: Principles for Clinical Evaluation of New Antihypertensive Drugs - 2nd March 2000
 - ICH E14: The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs - 12th May 2005
 - ICH E14: Questions & Answers – 05th Apr 2012
 - ICH E15: Terminology in Pharmacogenomics - 1st November 2007

- ICH M
 - ICH M1: MedDRA - 1st March 1999
 - ICH M2: Electronic Standards for the Transfer of Regulatory Information
 - ICH M3(R2): Maintenance of the ICH Guideline on Non-Clinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals - 11th June 2009
 - ICH M4: The Common Technical Document
 - ICH M5: Data Elements and Standards for Drug Dictionaries - 10th May 2005
- ICH Q
 - ICH Q1A(R2): Stability Testing of New Drug Substances and Products - 6th February 2003
 - ICH Q1B: Stability Testing: Photostability Testing of New Drug Substances and Products - 6th November 1996
 - ICH Q1C: Stability Testing for New Dosage Forms - 6th November 1996
 - ICH Q1D: Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products - 7th February 2002
 - ICH Q1E: Evaluation for Stability Data - 6th February 2003
 - ICH Q1F: Stability Data Package for Registration Applications in Climatic Zones III and IV - withdrawn 8th June 2006
 - ICH Q2(R1): Validation of Analytical Procedures: Text and Methodology - November 2005
 - ICH Q3A(R2): Impurities in new drug substances - 25 October 2006
 - ICH Q3B(R2): Impurities in new drugs products - 2 June 2006
 - ICH Q3C(R4): Impurities: Guideline for residual solvents - February 2009
 - ICH Q4: Pharmacopoeias - June 2006
 - ICH Q4A: Pharmacopoeias Harmonisation - June 2006
 - ICH Q4B: Evaluation and Recommendation of Pharmacopoeial Texts for Use In The ICH Regions - 1 November 2007
 - ICH Q4B Annex 1: Evaluation and Recommendation of Pharmacopoeial Texts for Use In The ICH Regions on Residue on Ignition/Sulphated Ash General Chapter - 1 November 2007
 - ICH Q4B Annex 2: Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Test for Extractable Volume of Parenteral Preparations General Chapter
 - ICH Q4B Annex 3: Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Test for Particulate Contamination: Sub-Visible Particles General Chapter
 - ICH Q4B (Annex 4A): Evaluation And Recommendation Of Pharmacopoeial Texts For Use In The ICH Regions On Microbiological Examination Of Non-Sterile Products: Microbial Enumerations Tests General Chapter
 - ICH Q4B (Annex 4B): Evaluation And Recommendation Of Pharmacopoeial Texts For Use In The ICH Regions On Microbiological Examination Of Non-Sterile Products: Test For Specified Micro-Organisms General Chapter
 - ICH Q4B (Annex 4C): Evaluation and Recommendation Of Pharmacopoeial Texts For The Use In The ICH Regions On Microbiological Examination Of Non-Sterile Products: Acceptance Criteria For Pharmaceutical Preparations And Substances For Pharmaceutical Use General Chapter
 - ICH Q4B (Annex 5): Evaluation and Recommendation Of Pharmacopoeial Texts For The Use In The ICH Regions On Disintegration Test General Chapter
 - ICH Q4B (Annex 8): Evaluation And Recommendation Of Pharmacopoeial Texts For Use In The ICH Regions On Sterility Test General Chapter
 - ICH Q5A(R1): Viral Safety Evaluation Of Biotechnology Products Derived From Cell Lines Of Human Or Animal Origin - 23 September 1999

- ICH Q5B: Quality Of Biotechnological Products: Analysis Of The Expression Construct In Cells Used For Production Of R-DNA Derived Protein Products - 30 November 1995
- ICH Q5C: Quality Of Biotechnological Products: Stability Testing Of Biotechnological/Biological Products - 30 November 1995
- ICH Q5D: Derivation And Characterisation Of Cell Substrates Used For Production Of Biotechnological/Biological Products - 16 July 1997
- ICH Q5E: Comparability Of Biotechnological/Biological Products Subject To Changes In Their Manufacturing Process - 18 November 2004
- ICH Q6A: Specifications: Test Procedures And Acceptance Criteria For New Drug Substances And New Drug Products: Chemical Substances - 6 October 1999
- ICH Q6A: Decision Trees - 6 October 1999
- ICH Q6B: Specifications: Test Procedures And Acceptance Criteria For Biotechnological/Biological Products - 10 March 1999
- ICH Q7: Good Manufacturing Practice Guide For Active Pharmaceutical Ingredients - 10 November 2000
- ICH Q8(R2): Pharmaceutical Development - August 2009
- ICH Q9: Quality Risk Management - 9 November 2005
- ICH Q8/Q9/Q10 Q&As: Quality Implementation Working Group on Q8, Q9 and Q10 Questions & Answers - 11 March 2009
- Q10: Pharmaceutical Quality System - June 2008
- ICH S1
 - ICH S1A: Guideline on the need for carcinogenicity studies of Pharmaceuticals - 29th November 1995
 - ICH S1B: Testing for carcinogenicity of Pharmaceuticals - 16th July 1997
 - ICH S1C(R2): Dose Selection for Carcinogenicity Studies of Pharmaceuticals limit Dose - March 2008
 - ICH S2A: Guidance on specific aspects of regulatory Genotoxicity Tests for Pharmaceuticals - 19th July 1995
 - ICH S2B: Genotoxicity: A Standards Battery for Genotoxicity Testing of Pharmaceuticals - 16th July 1997
 - ICH S3A: Note for Guidance on Toxicokinetics: The assessment of Systemic Exposure in Toxicity Studies - 27th October 1994
 - ICH S3B: Pharmacokinetics: Guidance for Repeated Dose Tissue Distribution Studies - 27th October 1994
 - ICH S4: Duration of Chronic Toxicity Testing in Animals (Rodent and Non-Rodent Toxicity Testing) - 2nd September 1998
 - ICH S5(R2): Detection of Toxicity to Reproduction for Medicinal Products toxicity to Male Fertility - November 2005
 - ICH S6(R1): Pre-Clinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals – 30th June 2011
 - ICH S7A: Safety Pharmacology Studies for Human Pharmaceuticals - 8th November 2000
 - ICH S7B: The Non-Clinical Evaluation of the Potential for delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals - 12th May 2005
 - ICH S8: Immunotoxicity Studies For Human Pharmaceuticals
- OECD
 - OECD ENV-MC-CHEM(98)17 - OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring Number 1 - OECD Principles on Good Laboratory Practice (as revised in 1997)

EU/EC

- Directives
 - GDP 94-C 63-03

Guidelines on Good Distribution Practice of Medicinal Products for Human Use (94/C 63/03) - 31 March 1992

- DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices
- Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market
- Eudralex Volume 1
 - Directive 78/25/EEC
Council Directive 78/25/EEC, of 12 December 1977, on the approximation of the laws of the Member States relating to the colouring matters which may be added to medicinal products
 - Directive 98-105-EEC:
COUNCIL DIRECTIVE of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems
 - Directive 93-42-EEC:
Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
 - Directive 178-2002-EC:
REGULATION (EC) No 178/2002 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
 - Directive 1935-2004-EC:
REGULATION (EC) No 1935/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC
 - Directive 1999-93-EC:
DIRECTIVE 1999/93/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 13 December 1999 on a Community framework for electronic signatures
 - Directive 2001-20-EC:
DIRECTIVE 2001/20/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use
 - Directive 2001-83-EC:
DIRECTIVE 2001/83/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 November 2001 on the Community code relating to medicinal products for human use
 - Directive 2001-95-EC:
DIRECTIVE 2001/95/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 3 December 2001 on general product safety
 - Directive 2002-95-EC:
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 - Directive 2002-96-EC:
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- Directive 2002-98-EC:
DIRECTIVE 2002/98/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 January 2003 and amending Directive 2001/83/EC
- Directive 2003-63-EC:
COMMISSION DIRECTIVE 2003/63/EC of 25 June 2003 amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use
- Directive 2003-94-EC:
Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use
- Directive 2004-23-EC:
DIRECTIVE 2004/23/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells
- Directive 2004-24-EC:
DIRECTIVE 2004/24/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 March 2004 amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use
- Directive 2004-24-EC:
DIRECTIVE 2004/27/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (Text with EEA relevance)
- Directive 2005-28-EC:
Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice regarding investigational medicinal products for human use and requirements for authorisation of manufacturing or importation of such products
- Directive 90/219/EEC
Council Directive 90/219/EEC, of 23 April 1990, on the contained use of genetically modified micro-organisms
- Directive 2008-29-EC:
Directive 2008/29/EC of the European Parliament and of the Council of 11 March 2008 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the implementing powers conferred on the Commission
- Eudralex Volume 4
 - Eudralex Volume 4 Part I:
Eudralex Volume 4 Medicinal Products for Human and Veterinary Use: Good Manufacturing Practices - Part I 'Basic Requirements for Medicinal Products' to Council Directive 2003/94/EC and 91/412/EEC - Revision February 2008
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Eudralex Volume 4 Medicinal Products for Human and Veterinary Use: Good Manufacturing Practices - Part II 'Basic Requirements for Active Substances used as Starting Materials' - 03 Feb 2010
 - Eudralex Volume 4 Annex 1:
Eudralex Volume 4 Medicinal Products for Human and Veterinary Use: Good Manufacturing Practices - Annex 1 'Manufacture of Sterile Medicinal Products' to Council Directive 2003/94/EC and 91/412/EEC - Revision November 2008

- Eudralex Volume 4 Annex 2:
Eudralex Volume 4 Medicinal Products for Human and Veterinary Use: Good Manufacturing Practices - Annex 2 'Manufacture of Biological Medicinal Products for Human Use' to Council Directive 2003/94/EC and 91/412/EEC
- Eudralex Volume 4 Annex 3:
Eudralex Volume 4 Medicinal Products for Human and Veterinary Use: Good Manufacturing Practices - Annex 3 - 'Manufacture of Radiopharmaceuticals' to Council Directive 2003/94/EC and 91/412/EEC - Revision September 2008
- Eudralex Volume 4 Annex 4:
Eudralex Volume 4 Medicinal Products for Human and Veterinary Use: Good Manufacturing Practices - Annex 4 'Manufacture of Veterinary Medicinal Products other than Immunological Veterinary Medicinal' to Council Directive 2003/94/EC and 91/412/EEC
- Eudralex Volume 4 Annex 5:
Eudralex Volume 4 Medicinal Products for Human and Veterinary Use: Good Manufacturing Practices - Annex 5 'Manufacture of Immunological Veterinary Products' to Council Directive 2003/94/EC and 91/412/EEC
- Eudralex Volume 4 Annex 6:
Eudralex Volume 4 Medicinal Products for Human and Veterinary Use: Good Manufacturing Practices - Annex 6 - 'Manufacture of medicinal gases'
- Eudralex Volume 4 Annex 7:
Eudralex Volume 4 Medicinal Products for Human and Veterinary Use: Good Manufacturing Practices - Annex 7 'Manufacture of Herbal Medicinal Products' to Council Directive 2003/94/EC and 91/412/EEC
- Eudralex Volume 4 Annex 8:
Eudralex Volume 4 Medicinal Products for Human and Veterinary Use: Good Manufacturing Practices - Annex 8 - 'Sampling of Starting and Packaging Materials' to Council Directive 2003/94/EC and 91/412/EEC
- Eudralex Volume 4 Annex 9:
Eudralex Volume 4 Medicinal Products for Human and Veterinary Use: Good Manufacturing Practices - Annex 9 - 'Manufacture of Liquids, Creams and Ointments' to Council Directive 2003/94/EC and 91/412/EEC
- Eudralex Volume 4 Annex 10:
Eudralex Volume 4 Medicinal Products for Human and Veterinary Use: Good Manufacturing Practices - Annex 10 'Manufacture of Pressurised Metered Dose Aerosol Preparations for Inhalation' to Council Directive 2003/94/EC and 91/412/EEC
- Eudralex Volume 4 Annex 11:
Eudralex Volume 4 Medicinal Products for Human and Veterinary Use: Good Manufacturing Practices - Annex 11 'Computerised Systems' to Council Directive 2003/94/EC and 91/412/EEC
- Eudralex Volume 4 Annex 12:
Eudralex Volume 4 Medicinal Products for Human and Veterinary Use: Good Manufacturing Practices - Annex 12 'Use of Ionising Radiation in the Manufacture of Medicinal Products' to Council Directive 2003/94/EC and 91/412/EEC
- Eudralex Volume 4 Annex 13:
Eudralex Volume 4 Medicinal Products for Human and Veterinary Use: Good Manufacturing Practices - Annex 13 'Investigational Medicinal Products'
- Eudralex Volume 4 Annex 14:
Eudralex Volume 4 Medicinal Products for Human and Veterinary Use: Good Manufacturing Practices - Annex 14 - 'Manufacture of medicinal products derived from human blood or plasma' to Council Directive 2003/94/EC and 91/412/EEC

- Eudralex Volume 4 Annex 15:
Eudralex Volume 4 Medicinal Products for Human and Veterinary Use: Good Manufacturing Practices - Annex 15 'Qualification and Validation' to Council Directive 2003/94/EC and 91/412/EEC - Revision July 2001
- Eudralex Volume 4 Annex 16:
Eudralex Volume 4 Medicinal Products for Human and Veterinary Use: Good Manufacturing Practices - Annex 16 - 'Certification by a Qualified Person and Batch Releases' to Council Directive 2003/94/EC and 91/412/EEC - Revision July 2001
- Eudralex Volume 4 Annex 17:
Eudralex Volume 4 Medicinal Products for Human and Veterinary Use: Good Manufacturing Practices - Annex 17 - 'Parametric Release' to Council Directive 2003/94/EC and 91/412/EEC - Revision July 2001
- Eudralex Volume 4 Annex 19:
Eudralex Volume 4 Medicinal Products for Human and Veterinary Use: Good Manufacturing Practices - Annex 19 - 'Reference and Retention Samples' to Council Directive 2003/94/EC and 91/412/EEC - Revision December 2005
- Eudralex Volume 4 Annex 20:
Eudralex Volume 4 Medicinal Products for Human and Veterinary Use: Good Manufacturing Practices - Annex 20 - Quality Risk Management - February 2008
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Commission Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products
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 - Eudralex Volume 9A:
Eudralex Volume 9A – Pharmacovigilance for Medicinal Products for Human Use (version September 2008)
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Eudralex Volume 9B – Pharmacovigilance for Medicinal Products for Veterinary Use (Volume 9 first made public June 2004) revised 31 Oct 2011.

USA

- 21 CFR Vol. 1 (Parts 1 – 99)
 - 21st Code of Federal Regulations Part 1
General Enforcement Regulations - Revised as of 23 Feb 2012
 - 21st Code of Federal Regulations Part 2
General Administrative Rulings and Decisions - Revised as of April 1, 2009
 - 21st Code of Federal Regulations Part 3
Product Jurisdiction - Revised as of April 1, 2009
 - 21st Code of Federal Regulations Part 5
Organisation - Revised as of April 1, 2009
 - 21st Code of Federal Regulations Part 7
Enforcement Policy - Revised as of 27 Jan 2012
 - 21st Code of Federal Regulations Part 10
Administrative Practices and Procedures - Revised as of April 1, 2009
 - 21st Code of Federal Regulations Part 11
Electronic Records; Electronic Signatures - Revised as of April 1, 2009
 - 21st Code of Federal Regulations Part 12
Formal Evidentiary Public Hearing - Revised as of April 1, 2009

- 21st Code of Federal Regulations Part 13
Public Hearing Before a Public Board Of Inquiry - Revised as of April 1, 2009
- 21st Code of Federal Regulations Part 14
Public Hearing Before a Public Advisory Committee - Revised as of April 1, 2009
- 21st Code of Federal Regulations Part 15
Public Hearing Before the Commissioner - Revised as of April 1, 2009
- 21st Code of Federal Regulations Part 16
Regulatory Hearing Before the Food and Drug Administration - Revised as of 24 Apr 2012
- 21st Code of Federal Regulations Part 17
Civil Money Penalties Hearings - Revised as of April 1, 2009
- 21st Code of Federal Regulations Part 19
Standards of Conduct and Conflicts of Interest - Revised as of April 1, 2009
- 21st Code of Federal Regulations Part 20
Public Information - Revised as of 17 Aug 2012
- 21st Code of Federal Regulations Part 21
Protection of Privacy - Revised as of 20 Jul 2012
- 21st Code of Federal Regulations Part 25
Environmental Impact Considerations - Revised as of April 1, 2009
- 21st Code of Federal Regulations Part 26
Mutual recognition of pharmaceutical good manufacturing practice reports, medical device quality system audit reports, and certain medical device product evaluation reports: United States and The European Community - Revised as of April 1, 2009
- 21st Code of Federal Regulations Part 50
Protection of human subjects - Revised as of April 1, 2009
- 21st Code of Federal Regulations Part 54
Financial disclosure by Clinical Investigators - Revised as of April 1, 2009
- 21st Code of Federal Regulations Part 56
Institutional Review Boards - Revised as of January 15, 2009
- 21st Code of Federal Regulations Part 58
Good laboratory practice for nonclinical laboratory studies - Revised as of April 1, 2009
- 21st Code of Federal Regulations Part 60
Patient Term Restoration - Revised as of April 1, 2009
- 21st Code of Federal Regulations Part 70
Color Additives - Revised as of April 1, 2009
- 21st Code of Federal Regulations Part 71
Color Additive Petitions - Revised as of April 1, 2009
- 21st Code of Federal Regulations Part 73
Listing of Color Additives Exempt From Certification - Revised as of January 5, 2009
- 21st Code of Federal Regulations Part 74
Listing of Color Additives Subject to Certification - Revised as of 29 Jun 2012
- 21st Code of Federal Regulations Part 80
Color Additive Certification - Revised as of April 1, 2009
- 21st Code of Federal Regulations Part 81
General Specifications and General Restrictions for Provisional Color Additives for use in Foods, Drugs, And Cosmetics - Revised as of April 1, 2009
- 21st Code of Federal Regulations Part 82
Listing of Certified Provisionally Listed Colors and Specifications - Revised as of April 1, 2009
- 21st Code of Federal Regulations Part 99
Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices - Revised as of April 1, 2009

- 21 CFR Vol. 2 (Parts 100 - 169)
 - 21st Code of Federal Regulations Part 110
Current good manufacturing practice in manufacturing, packing, or holding human food - Revised as of April 1, 2009
 - 21st Code of Federal Regulations Part 111
Current good manufacturing practice in manufacturing, packaging, labeling, or holding operations for dietary supplements - Revised as of April 1, 2009
- 21 CFR Vol. 4 (Parts 200 – 299)
 - 21st Code of Federal Regulations Part 200
Drugs General - Revised as of April 1, 2009
 - 21st Code of Federal Regulations Part 201
Labeling - Revised as of April 1, 2009
 - 21st Code of Federal Regulations Part 202
Prescription Drug Advertising - Revised as of April 1, 2009
 - 21st Code of Federal Regulations Part 203
Prescription drug marketing - Revised as of April 1, 2009
 - 21st Code of Federal Regulations Part 205
Guidelines for State licensing of wholesale prescription drug distributors - Revised as of April 1, 2009
 - 21st Code of Federal Regulations Part 206
Imprinting of solid oral dosage form drug products for human use - Revised as of April 1, 2009
 - 21st Code of Federal Regulations Part 207
Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution - Revised as of April 1, 2009
 - 21st Code of Federal Regulations Part 208
Medication Guides for prescription drug products - Revised as of April 1, 2009
 - 21st Code of Federal Regulations Part 210
Current good manufacturing practices in manufacturing, processing, packing or holding of drugs; general - Revised as of April 1, 2009
 - 21st Code of Federal Regulations Part 211
Current good manufacturing practises for finished pharmaceuticals - Revised as of 13 Mar 2012
 - 21st Code of Federal Regulations Part 216
Pharmacy compounding - Revised as of April 1, 2009
 - 21st Code of Federal Regulations Part 225
Current good manufacturing practice for medicated feeds - Revised as of April 1, 2009
 - 21st Code of Federal Regulations Part 226
Current Good Manufacturing Practice For Type A Medicated Articles - Revised as of April 1, 2009
 - 21st Code of Federal Regulations Part 250
Special Requirements for Specific Human Drugs - Revised as of April 1, 2009
 - 21st Code of Federal Regulations Part 290
Controlled Drugs - Revised as of April 1, 2009
 - 21st Code of Federal Regulations Part 299
Drugs; Official Names and Established Names - Revised as of April 1, 2009
- 21 CFR Vol. 5 (Parts 300 – 499)
 - 21st Code of Federal Regulations Part 300
General - Revised as of April 1, 2009
 - 21st Code of Federal Regulations Part 310
New Drugs - Revised as of 08 May 2012
 - 21st Code of Federal Regulations Part 312
Investigational new drug application - Revised as of 24 Apr 2012

- 21st Code of Federal Regulations Part 314
Applications for FDA approval to market a new drug - Revised as of 13 Dec 2011
- 21st Code of Federal Regulations Part 315
Diagnostic Radiopharmaceuticals - Revised as of April 1, 2009
- 21st Code of Federal Regulations Part 316
Orphan Drugs - Revised as of April 1, 2009
- 21st Code of Federal Regulations Part 320
Bioavailability and bioequivalence requirements - Revised as of April 1, 2009
- 21st Code of Federal Regulations Part 328
Over-the-counter drug products intended for oral ingestion that contain alcohol - Revised as of April 1, 2009
- 21st Code of Federal Regulations Part 330
Over-the-counter (OTC) human drugs which are generally recognized as safe and effective and not misbranded - Revised as of April 1, 2009
- 21st Code of Federal Regulations Part 331
Antacid products for over-the-counter (OTC) human use - Revised as of April 1, 2009
- 21st Code of Federal Regulations Part 332
Antiflatulent products for over-the-counter human use - Revised as of April 1, 2009
- 21st Code of Federal Regulations Part 333
Topical antimicrobial drug products for over-the-counter human use - Revised as of April 1, 2009
- 21st Code of Federal Regulations Part 335 - Antidiarrheal drug products for over-the-counter human use - Revised as of April 1, 2009
- 21st Code of Federal Regulations Part 336
Antiemetic drug products for over-the-counter human use - Revised as of April 1, 2009
- 21st Code of Federal Regulations Part 338
Nighttime sleep-aid drug products for over-the-counter human use - Revised as of April 1, 2009
- 21st Code of Federal Regulations Part 340
Stimulant drug products for over-the-counter human use - Revised as of April 1, 2009
- 21st Code of Federal Regulations Part 341
Cold, cough, allergy, bronchodilator, and antiasthmatic drug products for over-the-counter human use - Revised as of April 1, 2009
- 21st Code of Federal Regulations Part 343
Internal analgesic, antipyretic, and antirheumatic drug products for over-the-counter human use - Revised as of April 1, 2009
- 21st Code of Federal Regulations Part 344
Topical OTIC drug products for over-the-counter human use - Revised as of April 1, 2009
- 21st Code of Federal Regulations Part 346
Anorectal drug products for over-the-counter human use - Revised as of April 1, 2009
- 21st Code of Federal Regulations Part 347
Skin protectant drug products for over-the-counter human use - Revised as of April 1, 2009
- 21st Code of Federal Regulations Part 348
External analgesic drug products for over-the-counter human use - Revised as of April 1, 2009
- 21st Code of Federal Regulations Part 349
Ophthalmic drug products for over-the-counter human use - Revised as of April 1, 2009
- 21st Code of Federal Regulations Part 352
Sunscreen drug products for over-the-counter human use [stayed indefinitely] - Revised as of April 1, 2009
- 21st Code of Federal Regulations Part 355
Anticaries drug products for over-the-counter human use - Revised as of April 1, 2009

- 21st Code of Federal Regulations Part 357
Miscellaneous internal drug products for over-the-counter human use - Revised as of April 1, 2009
- 21st Code of Federal Regulations Part 358
Miscellaneous external drug products for over-the-counter human use - Revised as of April 1, 2009
- 21st Code of Federal Regulations Part 361
Prescription drugs for human use generally recognized as safe and effective and not misbranded: Drugs used in research - Revised as of April 1, 2009
- 21st Code of Federal Regulations Part 369
Interpretative statements re warnings on drugs and devices for over-the-counter sale - Revised as of April 1, 2009
- 21 CFR Vol. 7 (Parts 600 – 799)
 - 21st Code of Federal Regulations Part 600
Biological products: general - Revised as of 27 Apr 2012
 - 21st Code of Federal Regulations Part 601
Licensing - Revised as of April 1, 2009
 - 21st Code of Federal Regulations Part 606
Current good manufacturing practice for blood and blood components - Revised as of 22 Dec 2012
 - 21st Code of Federal Regulations Part 607
Establishment Registration and Product Listing for Manufacturers of Human Blood and Blood Products - Revised as of April 1, 2009
 - 21st Code of Federal Regulations Part 610
General Biological Products Standards - Revised as of 27 Apr 2012
 - 21st Code of Federal Regulations Part 630
General Requirements for Blood, Blood Components and Blood Derivatives - Revised as of April 1, 2009
 - 21st Code of Federal Regulations Part 640
Additional Standards for Human Blood and Blood Products - Revised as of 22 Dec 2012
 - 21st Code of Federal Regulations Part 660
Additional Standards for Diagnostic Substances for Laboratory Tests - Revised as of April 1, 2009
 - 21st Code of Federal Regulations Part 680
Additional Standards for Miscellaneous Products - Revised as of 27 Apr 2012
 - 21st Code of Federal Regulations Part 700
Cosmetics General - Revised as of April 1, 2009
 - 21st Code of Federal Regulations Part 701
Cosmetic Labeling - Revised as of April 1, 2009
 - 21st Code of Federal Regulations Part 710
Voluntary Registration of Cosmetic Product Establishments - Revised as of April 1, 2009
 - 21st Code of Federal Regulations Part 720
Voluntary Filing of Cosmetic Product Ingredient Composition Statements - Revised as of April 1, 2009
 - 21st Code of Federal Regulations Part 740
Cosmetic Product Warning Statements - Revised as of April 1, 2009
- 21 CFR Vol. 8 (Parts 800 – 1299)
 - 21st Code of Federal Regulations Part 800
General - Revised as of April 1, 2009
 - 21st Code of Federal Regulations Part 801
Labeling - Revised as of April 1, 2009
 - 21st Code of Federal Regulations Part 803
Medical Device Reporting - Revised as of April 1, 2009
 - 21st Code of Federal Regulations Part 806
Medical Devices; Reports of Corrections and Removals - Revised as of April 1, 2009

- 21st Code of Federal Regulations Part 807
Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices - Revised as of 27 Jul 2012
- 21st Code of Federal Regulations Part 808
Exemptions from Federal Preemption of State And Local Medical Device Requirements - Revised as of April 1, 2009
- 21st Code of Federal Regulations Part 809
In Vitro Diagnostic Products for Human Use - Revised as of April 1, 2009
- 21st Code of Federal Regulations Part 810
Medical Device Recall Authority - Revised as of April 1, 2009
- 21st Code of Federal Regulations Part 812
Investigational device exemptions - Revised as of 24 Apr 2012
- 21st Code of Federal Regulations Part 814
Premarket approval of medical devices - Revised as of April 1, 2009
- 21st Code of Federal Regulations Part 820
Quality system regulation - Revised as of April 1, 2009
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- Clinical Investigation of the Pharmacokinetics of Therapeutic Proteins
- Clinical Investigation on Medicinal Products in the Treatment of Hypertension
- Clinical Medicinal Products intended for the Treatment of Neuropathic Pain
- Clinical Requirements for Locally Applied, Locally Acting Products containing Known Constituents
- Clinical Trials in Small Populations
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- Clinical assessment of fixed combinations of herbal substances preparations
- Clinical development of products for specific immunotherapy for the treatment of allergic diseases
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- Clinical evaluation of medicinal products used in weight control - Addendum on weight control in children
- Clinical investigation of Medicinal Products for the Treatment of Obsessive Compulsive Disorder
- Clinical investigation of Medicinal Products in the Treatment of Patients with Acute Respiratory Distress Syndrome
- Clinical investigation of Medicinal Products indicated for Generalised Anxiety Disorder
- Clinical investigation of Medicinal Products indicated for Panic Disorder
- Clinical investigation of human normal immunoglobulin for intravenous administration (IVIg)
- Clinical investigation of immunosuppressants for solid organ transplantation
- Clinical investigations of medicinal products for the treatment of pulmonary arterial hypertension
- Co-ordinating Investigator Signature of Clinical Study Reports
- Core SPC for Hepatitis B for Intramuscular Use
- Core SPC for Hepatitis B for Intravenous Use
- Core SPC for Human Albumin Solution
- Core SPC for Human Anti-D Immunoglobulin for Intramuscular Use
- Core SPC for Human Anti-D Immunoglobulin for Intravenous Use
- Core SPC for Human Normal Immunoglobulin for Subcutaneous and Intramuscular use
- Core SPC for Human Plasma Coagulation Factor VII Products

- Core SPC for Human Plasma Derived and Recombinant Coagulation Factor IX Products
- Core SPC for Human Plasma Derived and Recombinant Coagulation Factor VIII Products
- Core SPC for Human Plasma Derived von Willebrand Factor
- Core SPC for Human Plasma derived Antithrombin
- Core SPC for Human Prothrombin Complex Products
- Core SPC for Human Rabies Immunoglobulin for Intramuscular Use
- Core SPC for Human Tetanus Immunoglobulin for Intramuscular Use
- Core SPC for Human Tick-Borne Encephalitis Immunoglobulin for Intramuscular Use
- Core SPC for Human Varicella Immunoglobulin for Intramuscular Use
- Core SPC for Plasma derived Fibrin Sealant Haemostatic Products
- Core SmPC for Human Fibrinogen Products
- Core SmSPC for Human Normal Immunoglobulin (IVIg) for Intravenous administration
- Data Monitoring Committee
- Development of Medicinal Products for the Treatment of Post-Traumatic Stress Disorder (PTSD)
- Development of New Medicinal Products for the Treatment of Smoking
- Development of medicinal products for the treatment of alcohol dependence
- Development of new medicinal products for the treatment of ulcerative colitis
- Evaluation of Anticancer Medicinal Products in Man
- Evaluation of Medicinal Products for Cardiovascular Disease Prevention
- Evaluation of Medicinal Products indicated for Thrombolysis in Acute Myocardial Infarction (STEMI)
- Evaluation of New Medicinal Products in the Treatment of Primary Osteoporosis
- Evaluation of medicinal products indicated for treatment of bacterial infections
- Evaluation of the Pharmacokinetics of Medicinal Products in Patients with Impaired Hepatic Function
- Evaluation of the Pharmacokinetics of Medicinal Products in Patients with Impaired Renal Function
- Excipients in the Label and Package leaflet of Medicinal Products for Human Use
- Extrapolation of results from clinical studies conducted outside europe to the eu-population
- Fixed Combination Medicinal Products
- Guideline on Clinical trials with Haematopoietic Growth Factors for the Prophylaxis of Infection
- Guideline on clinical evaluation of diagnostic agents
- Guideline on clinical investigation of medicinal products in the treatment of epileptic disorders
- Guideline on the clinical development of medicinal products for the treatment of cystic fibrosis
- ICH E 14 Questions and Answers The Clinical Evaluation of QT QTs Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic drugs
- ICH E1 Population Exposure The Extent of Population Exposure to Assess Clinical Safety
- ICH E10 Choice of Control Group in Clinical Trials
- ICH E11 Clinical Investigation of Medicinal Products in the Paediatric Population
- ICH E12 Principles for Clinical Evaluation of new Antihypertensive Drugs
- ICH E14 The Clinical Evaluation of QT QTs Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs
- ICH E2A Clinical Safety Data Management Definitions and Standards for Expedited Reporting

- ICH E3 Structure and Content of Clinical Study Reports
- ICH E4 Dose response Information to Support Drug Registration
- ICH E5 (R1) Ethnic Factors in the Acceptability of Foreign Clinical Data
- ICH E5 (R1) Questions and Answers Ethnic Factors in the Acceptability of Foreign Clinical Data
- ICH E6 (R1) Guideline for Good Clinical Practice
- ICH E7 Studies in Support of Special Populations Geriatrics
- ICH E8 General Considerations for Clinical Trials
- ICH E9 Statistical Principles for Clinical Trials
- Inclusion of Appendices to Clinical Study Reports in Marketing Authorisation Applications
- Investigation of bioequivalence
- Investigation of drug interactions
- Medicinal Products (Non-steroidal Anti-inflammatory Compounds) for the Treatment of Chronic Disorders
- Medicinal Products for the Treatment of Alzheimer's Disease and other Dementias
- Medicinal products for the treatment of insomnia
- Missing data in confirmatory clinical trials
- Modified Release Oral and Transdermal Dosage Forms
- Non-Clinical and Clinical Development of Medicinal Products for the Treatment of Nausea and Vomiting associated with Cancer Chemotherapy
- Note for guidance on the investigation of bioavailability and bioequivalence
- PMS Studies for Metered Dose Inhalers with New Propellants
- Pharmacokinetic Studies in man
- Pharmacokinetics and Pharmacodynamics in the Development of Antibacterial Medicinal Products
- Points to Consider concerning Endpoints in Clinical Studies with Haematopoietic Growth Factors for Mobilisation of Autologous Stem Cells
- Points to Consider on Adjustment for Baseline Covariates
- Points to Consider on Application with 1. Meta-analyses; 2. One Pivotal study
- Points to Consider on Clinical Investigation of Medicinal Products for the Treatment of Acute Stroke
- Points to Consider on Clinical Investigation of Medicinal Products for the Treatment of Amyotrophic Lateral Sclerosis
- Points to Consider on Clinical Investigation of Medicinal Products in the Treatment of Patients with Chronic Obstructive Pulmonary Disease (COPD)
- Points to Consider on Clinical Investigation of New Medicinal Products for the Treatment of Acute Coronary syndrome (ACS) without persistent ST-Segment Elevation
- Points to Consider on Multiplicity Issues in Clinical Trials
- Points to Consider on Pharmacokinetics and Pharmacodynamics in the Development of Antibacterial Medicinal Products
- Points to Consider on Switching between Superiority and Non-inferiority
- Points to Consider on Wording of Helicobacter Pylori Eradication Therapy in selected SPC Sections
- Points to Consider on the Clinical Investigation of Medicinal Products other than Nsaids in Rheumatoid Arthritis
- Points to Consider on the Clinical Requirements of Modified Release Products Released as a Line Extension of an Existing Marketing Authorisation

- Points to Consider on the Evaluation of Medicinal Products for the Treatment of Irritable Bowel Syndrome
- Points to Consider on the Evaluation of the Diagnostic Agents
- Points to Consider on the Requirements for Clinical Documentation for Orally Inhaled Products (OIP)
- Position Paper on the Regulatory Requirements for the Authorisation of low-Dose Modified Release ASA Formulations in the Secondary Prevention of Cardiovascular Events
- Positions on specific questions addressed to the EWP therapeutic subgroup on Pharmacokinetics
- Questions & Answers on the Bioavailability and Bioequivalence Guideline
- Questions and Answers on Guideline Clinical investigation of corticosteroids intended for use on the skin
- Questions and answers document on the clinical development of fixed combinations of drugs belonging to different therapeutic classes
- Recommendations on the Need for Revision of the Guideline on Clinical Investigation of Medicinal Products for Prophylaxis
- Reflection Paper on Methodological Issues in Confirmatory Clinical Trials planned with an adaptive design
- Reflection Paper on the Regulatory Guidance for the Use of Health-Related Quality of Life (HRQL) Measures in the Evaluation of Medicinal Products
- Reflection paper on the adaptogenic concept
- Replacement of Chlorofluorocarbons (Cfc) in Metered Dose Inhalation Products
- Reporting the Results of Population Pharmacokinetic Analyses
- Requirements for clinical documentation for orally inhaled products (OIP) including the requirements for demonstration of therapeutic equivalence
- Role of Pharmacokinetics in the Development of Medicinal Products in the Paediatric Population
- Specification Limits for Residues of Metal Catalysts
- Strategies to identify and mitigate risks for first-in-human clinical trials with investigational medicinal products
- Summary of Product Characteristics for Benzodiazepines as Anxiolytics or Hypnotics
- Summary of Product Characteristics of Angiotensin Converting Enzyme Inhibitors
- User Leaflet on Oral Contraceptives
- Warning on Transmissible Agents in SPCs and Package Leaflets for Plasma-derived Medicinal Products

Eudralex Volume 3: Multidisciplinary

- Adjuvants in Vaccines for Human Use
- Allergen Products
- Annex to Guideline on Clinical Evaluation of New Vaccines
- Annex to Guideline on Similar Biological Medicinal Products - Guidance on Similar Medicinal Products containing Recombinant Human Insulin
- Annex to Guideline on Similar Biological Medicinal Products - Guidance on Similar Medicinal Products containing Somatropin
- Annex to Guideline on Similar Biological Medicinal Products containing Biotechnology-Derived Proteins as Active Substance
- Annex to Guideline on Similar Biological Medicinal Products containing Biotechnology-Derived Proteins as Active Substance Non-Clinical and Clinical Issues
- CHMP Position Paper on Thiomersal Implementation of the Warning Statement Relating to Sensitisation
- Clinical Evaluation of New Vaccines

- Comparability of Biotechnology-Derived Medicinal Products after a change in the Manufacturing Process - Non-Clinical and Clinical Issues
- Comparability of Medicinal Products containing Biotechnology-derived Proteins as Active Substance -Quality Issues
- Comparability of Medicinal Products containing Biotechnology-derived Proteins as Drug Substance - Non Clinical and Clinical Issues
- Conduct of Pharmacovigilance for medicines used by the paediatric population
- Core SPC for Pandemic Influenza Vaccines
- Development and Manufacture of Lentiviral Vectors
- Development of Vaccinia Virus Based Vaccines against Smallpox
- Dossier Structure and Content for Pandemic Influenza Marketing Authorisation Application
- EMEA Public Statement on Thiomersal in Vaccines for Human Use - Recent Evidence Supports Safety of Thiomersal-containing Vaccines
- Excipients in the Label and Package Leaflet of Medicinal Products for Human Use
- Explanatory note on Immunomodulators for the Guideline on Adjuvants in vaccines for human use
- Follow-up of patients administered with gene therapy medicinal products
- Guideline on xenogeneic cell-based medicinal products
- Guiding principles Processing Joint FDA EMEA Voluntary Genomic Data Submissions (VGDSs) within the framework of the Confidentiality Arrangement
- Harmonisation of Requirements for Influenza Vaccines
- Human cell-based medicinal products
- ICH Considerations - Oncolytic Viruses
- ICH Topic E 15 Definitions for genomic biomarkers, pharmacogenomics, pharmacogenetics, genomic data and sample coding categories
- Immunogenicity Assessment of Biotechnology-derived Therapeutic Proteins
- Influenza vaccines prepared from viruses with the potential to cause a pandemic and intended for use outside of the core dossier context
- Investigation of Chiral Active Substances
- Investigation of bioequivalence
- Investigation of medicinal products in the term and preterm neonate
- Limits of genotoxic impurities
- M 2 Business Requirements
- Matters Relating to the Replacement of Cfc's in Medicinal Products
- Non-Clinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals
- Non-Clinical testing for Inadvertent Germline transmission of Gene Transfer Vectors
- Non-clinical and clinical development of similar medicinal products containing recombinant interferon alpha
- Non-clinical studies required before first clinical use of gene therapy medicinal products
- Note for guidance on the investigation of bioavailability and bioequivalence
- Pharmacogenetics Briefing Meeting
- Points to Consider on the Reduction, Elimination or Substitution of Thiomersal in Vaccines
- Position Paper on Terminology in PharmacoGenetics
- Potency testing of cell based immunotherapy medicinal products for the treatment of cancer

- Procedural Aspects Regarding a CHMP Scientific Opinion in the Context of Cooperation with the World Health Organization (WHO)
- Public Statement on Thiomersal containing medicinal products
- Quality, Preclinical and Clinical Aspects of Gene Transfer Medicinal Products
- Questions and answers on gene therapy
- Reflection Paper on pharmacogenomic samples, testing and data handling
- Reflection Paper on the use of Pharmacogenetics in the Pharmacokinetic Evaluation of Medicinal Products
- Reflection paper on in-vitro cultured chondrocyte containing products for cartilage repair of the knee
- Replacement of Chlorofluorocarbons (Cfc) in Metered Dose Inhalation Products
- Scientific Requirements for the Environmental Risk Assessment of Gene Therapy Medicinal Products
- Similar Biological Medicinal Product
- Similar Biological Medicinal Products Containing Biotechnology-Derived Proteins as Active Substance Quality Issues
- Similar Biological Medicinal Products containing Biotechnology-Derived Proteins as Active Substance
- Similar biological medicinal products containing low-molecular-weight-heparins
- Similar medicinal products containing recombinant Erythropoietins
- Submission of Marketing Authorisation Applications for Pandemic Influenza Vaccines through the Centralised Procedure

Eudralex Volume 3: Non-clinical

- Annex Guideline on Similar Biological Medicinal Products containing Biotechnology-Derived Proteins as Active Substance
- Assessment of genotoxicity of herbal substances
- Background to the CPMP Position Paper on possible pre-clinical studies to investigate addiction and dependence
- Background to the CPMP Position Paper on selective serotonin uptake inhibitors (SSRIs) and dependency
- CHMP SWP Conclusions and recommendations on the use of genetically modified animal models for carcinogenicity assessment
- Carcinogenic potential
- Carcinogenicity Evaluation of Medicinal Products for the Treatment of HIV Infection
- Carcinogenicity testing for carcinogenicity of pharmaceuticals (ICH S1B)
- Comparability of medicinal products containing biotechnology-derived proteins as active substance -annex on non-clinical and clinical issues
- Declaration of Herbal Substances and Herbal Preparations in Herbal Medicinal Products
- Dose selection for carcinogenicity studies of pharmaceuticals (ICH S1 C (R2))
- Dossier Structure and Content for Pandemic Influenza Vaccine Marketing Authorisation Application
- Duration of chronic toxicity testing in animals (rodent and non-rodent toxicity testing) (ICH S4A)
- Environmental Risk Assessment of Medicinal Products for Human Use
- Environmental risk assessment for human medicinal products containing or consisting of GMOs
- Evaluation of Control Samples for Non - clinical Safety Studies Checking for Contamination with the Test Substance
- Genotoxicity a standard battery for genotoxicity testing of pharmaceuticals (ICH S2B)
- Immunotoxicity studies for Human Pharmaceuticals (ICH S8)

- Impurities Residual solvents
- Impurities in new drug products (Revision)
- Impurities testing impurities in new drug substances (Revision)
- Investigation of chiral active substances
- Limitations to the use of ethylene oxide in the manufacture of medicinal products
- Limits of genotoxic impurities
- Maintenance of Note for guidance on impurities Residual solvents
- Medicinal Gases Pharmaceutical Documentation (including recommendation on non-clinical safety requirements for well established medicinal gases)
- Need for Non-Clinical Testing in Juvenile Animals on Human Pharmaceuticals for Paediatric Indications
- Need for carcinogenicity studies of pharmaceuticals (ICH S1A)
- Need for revision of the Note for Guidance on photosafety testing
- Non-Clinical Development of Fixed Combinations of Medicinal Products
- Non-Clinical Documentation for Herbal Medicinal Products in Applications for Marketing Authorization
- Non-Clinical Documentation for Mixed Marketing Authorisation Applications
- Non-Clinical Investigation of the Dependence Potential of Medicinal Products
- Non-Clinical Safety Studies For The Conduct Of Human Clinical Trials For Pharmaceuticals (ICH M3[R2]) modification
- Non-clinical local tolerance testing of medicinal products
- Nonclinical evaluation for anticancer pharmaceuticals (ICH S9)
- Pharmacokinetics Guidance for repeated dose tissue distribution studies (ICH S3B)
- Pharmacokinetics and metabolic studies in the safety evaluation of new medicinal products in animals
- Points to consider on the Need for assessment of reproduction toxicity of human insulin analogues
- Points to consider on the Non-clinical assessment of the carcinogenic potential of human insulin analogues
- Position Paper on the genotoxic and carcinogenic potential of phenolphthalein
- Position Paper on the non-clinical safety studies to support clinical trials with a single micro dose
- Pre-clinical evaluation of anti- cancer medicinal products
- Pre-clinical pharmacological and toxicological testing of vaccines
- Preclinical safety evaluation of biotechnology-derived pharmaceuticals (ICH S6)
- Reflection Paper on the assessment of the Genotoxic Potential of Antisense Oligodeoxynucleotides
- Reflection paper on ethanol content in herbal medicinal products and traditional herbal medicinal products used in children
- Repeated dose toxicity
- Replacement of animal studies by in-vitro models
- Reproductive toxicology Detection of toxicity to reproduction for medicinal products including toxicity to male fertility (ICH S5A)
- Risk Assessment of Medicinal Products on Human Reproduction and Lactation From Data to Labelling
- Safety pharmacology studies for human pharmaceuticals (ICH S7A)
- Selection of test materials for genotoxicity testing for Traditional Herbal Medicinal Products
- Specific aspects of regulatory genotoxicity tests for pharmaceuticals (ICH S2A)
- Specification Limits for Residues of Metal Catalysts

- Strategies to identify and mitigate risks for first-in-human clinical trials with investigational medicinal products
- The nonclinical Evaluation of the potential for delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals (ICH S7B)
- Toxicokinetics the assessment of systemic exposure in toxicity studies (ICH S3A)

Eudralex Volume 3: Quality

- Active Substance Master File Procedure
- Annex 1 to Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions (ICH Q4B)
- Annex 2 to Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions (ICH Q4B) on Test for Extractable Volume in Parenteral Preparations General Chapter
- Annex 3 to Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions (ICH Q4B) on Test for Particulate Contamination
- Annex 4A to Evaluation and recommendation of pharmacopoeial texts for use in the ICH regions on micrological examination of non-sterile products
- Annex 4B to Evaluation and recommendation of pharmacopoeial texts for use in the ICH regions on test for micrological examination of non-sterile products
- Annex 4C to Evaluation and recommendation of pharmacopoeial texts for use in the ICH regions on test for micrological examination of non-sterile products
- Annex 5 to Evaluation and recommendation of pharmacopoeial texts for use in the ICH regions on disintegration test general chapter
- Annex Declaration of Storage Conditions for Medicinal Products Particulars and Active Substances
- Annex II Process Validation - Non-Standard Processes
- Annex Start of Shelf-Life of the Finished Dosage Form
- Annex to Development Pharmaceuticals Decision trees for selection of sterilisation methods
- Annexes to Specifications for class 1 and class 2 residual solvents in active substances
- Bracketing and Matrixing Designs for Stability Testing of Drug Substances and Drug Products (ICH Q1D)
- Chemistry of Active Substances
- Chemistry of New Active Substances
- Control of Impurities of Pharmacopoeial Substances
- Declaration of Herbal Substances and Herbal Preparations in Herbal Medicinal Products
- Development Pharmaceuticals
- Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions (ICH Q4B)
- Evaluation of Stability Data (ICH Q1E)
- Excipients in the Dossier for Application for Marketing Authorisation of a Medicinal Product
- Excipients in the label and package leaflet of medicinal products for human use
- Good Agricultural and Collection Practice for starting materials of Herbal Origin
- ICH Topic Q8, Q9 and Q10 Quality Implementation Working Group Questions and Answers
- Impurities Residual Solvents (ICH Q3C (R3))
- Impurities Testing Impurities in New Drug Substances (ICH Q3A R2))
- Impurities in New Medicinal Products (ICH Q3B (R2))
- In-Use Stability Testing of Human Medicinal Products
- Inclusion of Antioxidants and Antimicrobial Preservatives in Medicinal Products

- Investigation of Chiral Active Substances
- Limitations to the Use of Ethylene Oxide in the Manufacture of Medicinal Products
- Limits of genotoxic impurities
- Manufacture of the Finished Dosage Form
- Markers used for quantitative and qualitative analysis of Herbal Medicinal Products and traditional Herbal Medicinal Products
- Maximum Shelf-Life for Sterile Products for Human Use after first opening or following Reconstitution
- Medicinal Gases Pharmaceutical Documentation (including recommendation on non-clinical safety requirements for well established medicinal gases)
- Parametric Release
- Pharmaceutical Development (ICH Q8 (R2))
- Pharmaceutical Quality of Inhalation and Nasal Products
- Photostability Testing of New Active Substances and Medicinal Products (ICH Q1B)
- Plastic Primary Packaging Materials
- Process Validation
- Q 4 B Annex 10 Step 4 Polyacrylamide Gel Electrophoresis
- Q 4 B Annex 7 Dissolution test general chapter
- Q 4 B Annex 8 to Note for evaluation and recommendation of pharmacopoeial texts for use in the ICH regions on sterility test general chapter
- Q 4 B Annex 9 Step 4 Tablet Friability General Chapter
- Quality of Combination Herbal Medicinal Products
- Quality of Herbal Medicinal Products
- Quality of Modified Release Products A) Oral Solid Dosage Forms B) Transdermal Dosage Forms Section I (Quality)
- Quality of Water for Pharmaceutical Use
- Radiopharmaceuticals
- Radiopharmaceuticals Based on Monoclonal Antibodies
- Reflection Paper on Water for Injection prepared by Reverse Osmosis
- Requirements to the Chemical and Pharmaceutical Quality Documentation Concerning Investigational Medicinal Products in Clinical Trials
- Specification Limits for Residues of Metal Catalysts
- Specifications Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products
- Specifications and control Tests on the Finished Product
- Stability Data Package for Registration in Climatic Zones III and IV (ICH Q1F)
- Stability Testing Requirements for New Dosage Forms (ICH Q1C)
- Stability Testing for Applications for Variations to a Marketing Authorisation
- Stability Testing of Existing Active Ingredients and Related Finished Products
- Stability Testing of New Drug Substances and Drug Products (ICH Q1A (R2))
- Summary of Requirements for Active Substances in the Quality Part of the Dossier
- Test procedures and Acceptance Criteria for Herbal Substances, Herbal Preparations and Herbal Medicinal Products

- The use of Fumigants
- The use of Ionizing Radiation in the Manufacture of Medicinal Products
- Use of Near Infrared Spectroscopy (NIRS) by the Pharmaceutical Industry and the Data Requirements for New Submissions and Variations
- Validation of Analytical Procedures Text and Methodology (ICH Q2 (R1))

Eudralex Volume 6

- Application form for renewal of a marketing authorisation and guidance for the completion of the application form
- Application form for variation to a marketing authorisation for medicinal products (human and veterinary) to be used in the mutual recognition and the centralised procedure
- Chapter 1 - Marketing Authorisations
- Chapter 2 - Mutual Recognition
- Chapter 3 - Community Referral
- Chapter 4 - Centralised Procedure
- Chapter 5 - Variations
- Chapter 6 - Community Marketing Authorisation
- Chapter 7 - General Information
- Guidance on environmental risk assessment for veterinary medicinal products consisting of or containing genetically modified organisms (GMOs) as or in products
- Guidance on the Assessment of environmental risks of veterinary medicinal products
- Guideline on Dossier requirements for Type IA and Type IB Notifications Revision 1
- Guideline on preparation of Summary of Product Characteristics SPC - Immunologicals for veterinary medicinal products
- Guideline on preparation of Summary of Product Characteristics SPC - Pharmaceuticals for veterinary medicinal products
- Guideline on the categorisation of New Applications (NA) versus Variations Applications (V)
- Guideline on the definition of a potential serious risk to human or animal health or for the environment in the context of Article 33(1) and (2) of Directive 2001_82_EC
- Guideline on the packaging information of veterinary medicinal products authorised by the Community
- Guideline on the processing of renewals in the centralised procedure
- Guideline on the processing of renewals in the mutual recognition procedure for veterinary medicinal products
- PART I - Summary of the dossier _ Administrative data
- Volume 6B Notice to applicants Veterinary medicinal products Presentation and contents of the dossier (March 2004)

Eudralex Volume 7

- Additional quality requirements for products intended for incorporation into animal feedingstuffs (medicated pre-mixes)
- Anthelmintics for bovines and ovines specific requirements
- Anthelmintics for cats and dogs specific requirements
- Anthelmintics for swine specific requirements
- Anthelmintics general requirements
- Anticoccidials used for the therapy of coccidiosis in chickens - turkeys and geese

- Antimicrobials for general veterinary use in target species (excluding intramammary preparations)
- Conduct of bioequivalence studies in animals
- Conduct of pharmacokinetic studies in animals
- Demonstration of efficacy of ectoparasiticides
- Efficacy of veterinary medicinal products for use in farmed aquatic species
- Environmental risk assessment for immunological veterinary medicinal products
- Environmental risk assessment for veterinary medicinal products other than gmo-containing and immunological products
- Environmental risk assessment which must accompany applications for marketing authorisation of veterinary medicinal products
- Equine anthelmintics specific requirements
- Evaluation of the safety of veterinary medicinal products for the target animals
- Fixed combination products
- General requirements for the production and control of inactivated mammalian bacterial and viral vaccines for veterinary use
- General requirements for the production and control of live mammalian bacterial and viral vaccines for veterinary use
- Good clinical practice for the conduct of clinical trials on veterinary medicinal products in the european union
- Guideline for an assessor preparing assessment reports for veterinary medicinal products
- Harmonisation of requirements for equine influenza vaccines specific requirements for substitution of a strain
- In use stability testing of veterinary medicinal products (excluding immunological veterinary medicinal products)
- Inclusion of antimicrobial preservatives in immunological veterinary medicinal products
- Inclusion of antioxidants and antimicrobial preservatives in medicinal products
- Index
- Introduction
- Investigation of chiral active substances
- List of abbreviations
- List of legislation
- List of quality guidelines accepted from the guidelines for human use
- Local tolerance of intramammary preparations in cows
- Manufacture of the finished dosage form
- Minimising the risk of transmitting agents causing spongiform encephalopathy via veterinary medicinal products
- Oecd principles of good laboratory practice
- Performance enhancers
- Specific requirements for the production and control of allergen products
- Specific requirements for the production and control of avian live and inactivated viral and bacterial vaccines
- Specific requirements for the production and control of bovine live and inactivated viral and bacterial vaccines
- Specific requirements for the production and control of equine live and inactivated viral and bacterial vaccines
- Specific requirements for the production and control of immunosera and colostrum substitutes

- Specific requirements for the production and control of live and inactivated vaccines intended for fish
- Specific requirements for the production and control of live and inactivated viral and bacterial vaccines for cats and dogs
- Specific requirements for the production and control of ovine and caprine live and inactivated viral and bacterial vaccines
- Specific requirements for the production and control of pig live and inactivated viral and bacterial vaccines
- Table of extraneous agents to be tested for in relation to the general and species specific guidelines on production and control of mammalian veterinary vaccines
- Variation assessment report (var) for veterinary medicinal products in the centralised and mutual recognition procedures
- Veterinary medicinal products administered via the teat duct to cows at drying off for the treatment of subclinical mastitis and the prevention of new infections
- Veterinary medicinal products administered via the teat duct to lactating cows for the treatment of clinical mastitis
- Veterinary medicinal products administered via the teat duct to lactating cows for the treatment of subclinical mastitis
- Veterinary medicinal products controlling varroa jacobsoni and acarapis woodi parasitosis in bees
- Veterinary medicinal products for fluid therapy in case of diarrhoea
- Veterinary medicinal products for zootechnical purposes

Eudralex Volume 8

- Notice to applicants and Guideline - Veterinary medicinal products - Establishment of maximum residue limits (MRLs) for residues of veterinary medicinal products in foodstuffs of animal origin

Eudralex Volume 9

- EU Pharmacovigilance Rules for Human and Veterinary Medicinal Products - (Volume 9 - version June 2004)
- GUIDELINE on monitoring of compliance with pharmacovigilance regulatory obligations and pharmacovigilance inspections for veterinary medicinal products

Guidelines

- Bar Code Label Requirements (October 2006)
- CGMP for Phase 1 Investigational Drugs (July 2008)
- Computerized Systems Used in Clinical Investigations (May 2007)
- Cytotoxic Handling
- Expiration Dating and Stability Testing of Solid Oral Dosage Form Drugs Containing Iron (June 1997)
- FDA - Compliance Policy Guides Manual (May 2002)
- Formal Dispute Resolution- Scientific and Technical Issues Related to Pharmaceutical CGMP (January 2006)
- Good Clinical Laboratory Practice (Version 3)
- Good Clinical Laboratory Practice – World Health Organisation
- Good Laboratory Practice Regulations - Questions and Answers (June 1981)
- Guideline For the Monitoring of Clinical Investigations (January 1988)
- Guideline on Validation of the Limulus Amebocyte Lysate Test (December 1987)
- Guideline on the Preparation of Investigational New Drug Products (Human and Animal) (March 1991)
- Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production (October 2006)

- Marketed Unapproved Drugs - Compliance Policy Guide (June 2006)
- Nuclear Pharmacy Guideline for Determining When to Register as a Drug Establishment (May 1984)
- PAT - A Framework for Innovative Pharmaceutical Development' Manufacturing' and Quality Assurance (September 2004)
- Part 11 - Electronic Records; Electronic Signatures - Scope and Application (August 2003)
- Possible Dioxin/PCB Contamination of Drug and Biological Products (August 2000)
- Prescription Drug Marketing Act - Donation of Prescription Drug Samples to Free Clinics (March 2006)
- Quality Systems Approach to Pharmaceutical CGMP Regulations (September 2006)
- Safe Use of Handling of Cytotoxic Drugs
- Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Practice (September 2004)
- Testing of Glycerin for Diethylene Glycol (May 2007)
- The Use of Mechanical Calibration of Dissolution Apparatus 1 and 2 - Current Good Manufacturing Practice (CGMP) (October 2007)

Templates

- Design Qualification Protocol
- Functional Design Specification
- Hardware Acceptance Test Specification
- Hardware Design Specification
- Installation Qualification Protocol
- Operational Qualification \ Performance Qualification Protocol
- Risk Assessment
- Software Code Review
- Software Design Specification
- User Requirements Specification
- Validation Plan
- Validation Report

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