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For

ComplianceControl cGARD 6.0

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- 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 - 12th May 2005
 - 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 - 4th June 2008
 - ICH E15: Terminology in Pharmacogenomics - 1st November 2007

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 - ICH M4: The Common Technical Document
 - ICH M5: Data Elements and Standards for Drug Dictionaries - 10th May 2005
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 - ICH Q1B: Stability Testing: Photostability Testing of New Drug Substances and Products - 6th November 1996
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 - 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
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- 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
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- ICH Q6B: Specifications: Test Procedures And Acceptance Criteria For Biotechnological/Biological Products - 10 March 1999
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- Q10: Pharmaceutical Quality System - June 2008
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 - 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
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 - 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: Pre-Clinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals - 16th July 1997
 - 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)

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- 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
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 - Directive 93-42-EEC:
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 - 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:
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 - Directive 2001-20-EC:
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 - Directive 2001-83-EC:
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 - Directive 2001-95-EC:
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 - Directive 2002-95-EC:
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 - Directive 2002-96-EC:
DIRECTIVE 2002/96/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 January 2003 on waste electrical and electronic equipment (WEEE)

- Directive 2002-98-EC:

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- Directive 2003-63-EC:

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- 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:

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- Directive 2005-28-EC:

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- Directive 90/219/EEC

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- Directive 2008-29-EC:

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- Eudralex Volume 4
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 - Eudralex Volume 4 Annex 1:

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- Clinical Investigation on Medicinal Products in the Treatment of Hypertension
- Clinical Medicinal Products intended for the Treatment of Neuropathic Pain
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- Clinical Trials in Small Populations
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- 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
- Clinical evaluation of medicinal products used in weight control - Addendum on weight control in children
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- Guidance on the Assessment of environmental risks of veterinary medicinal products
- Guideline on Dossier requirements for Type IA and Type IB Notifications Revision 1
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- 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
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- PART I - Summary of the dossier _ Administrative data
- Volume 6B Notice to applicants Veterinary medicinal products Presentation and contents of the dossier (March 2004)

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- Additional quality requirements for products intended for incorporation into animal feedingstuffs (medicated pre-mixes)
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- Anthelmintics for cats and dogs specific requirements
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- 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)
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- Efficacy of veterinary medicinal products for use in farmed aquatic species
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- 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
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- 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

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- 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

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- 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)

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- Functional Design Specification
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- Software Code Review
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