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Dr Phillip Smith

Assistant Director of R&D

The Ipswich Hospital NHS Trust

National R&D Forum

13 April 2006

Bristol

Parallel Session I 12:45-1:00 pm

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Family Welfare Association (Great Britain)

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Guide to EU and UK Pharmaceutical Regulatory Law Pieter Erasmus,Sally Shorthose,2025-10-30 In the European Union EU its Member States and the United Kingdom UK post Brexit as elsewhere the marketing of pharmaceuticals is subject to an ever more complex web of legislation and regulation resulting from the intense scrutiny necessary to ensure such essential products are not only efficacious but also safe This useful book lays out this system with extraordinary clarity and logic Adopting a Europe wide perspective on the law governing pharmaceuticals expert contributors from the law firm Bird stages and standards for creating a product dossier obtaining a marketing authorisation how and when an abridged marketing authorisation procedure can be used criteria for conditional marketing authorisations generic products and essential similarity paediatric use and the requisite additional trials orphan medicinal products biologicals and biosimilars homoeopathic herbal and similar medicines medical devices pandemics epidemics and vaccines pharmacovigilance parallel trade advertising and relevant competition law intellectual property rights and data protection regulation Pharmaceutical lawyers and regulatory advisers both in house and in private practice will welcome this unique book It offers immeasurable value for all who need to understand the process of bringing a medicinal product or medical device to market and the continuing rights and obligations

Computer Systems Validation

Guy Wingate,2003-12-18 Both pervasive and ubiquitous computerized systems are now an integral component of every corporate strategy in pharmaceutical and healthcare companies However when technology is combined with high risk public safety projects or the production and control of life saving medicines or devices it is necessary to ensure that it is reliable quality

Validation of Chromatography Data Systems Robert D McDowall,2016-11-23 Guiding chromatographers working in regulated industries and helping them to validate their chromatography data systems to meet data integrity business and regulatory needs This book is a detailed look at the life cycle and documented evidence required to ensure a system is fit for purpose throughout the lifecycle Initially providing the regulatory data integrity and system life cycle requirements for computerised system validation the book then develops into a guide on planning specifying managing risk configuring and testing a chromatography data system before release This is followed by operational aspects such as training integration and IT support and finally retirement All areas are discussed in detail with case studies and practical examples provided as appropriate The book has been carefully written and is right up to date including recently released FDA data integrity guidance It provides detailed guidance on good practice and expands on the first edition making it an invaluable addition to a chromatographer's book shelf

Oxford Handbook of Clinical and Healthcare Research Sumantra Ray,Sue Fitzpatrick,Rajna Golubic,Susan Fisher,Sarah Gibbings,2016-03-03 The Oxford Handbook of Clinical and Healthcare Research is an evidence based succinct and easy to use reference for the full range of clinical and healthcare research topics Providing a wide breadth of essential knowledge this comprehensive text takes the researcher through the steps from general good clinical

practice in healthcare research to the process and management of research This handbook includes clear instructions on the legislative and practical requirements of commissioning conducting analysing and reporting research for those in clinical or healthcare practice education or training Written with Good Clinical Practice GCP education in mind it includes valuable information needed for the accredited certificates and diploma level benchmark exams now commonly required by employers This is a definitive text for all clinical and healthcare research students as well as graduates with an interest in clinical and healthcare research

Data Integrity and Data Governance Robert D McDowall,2018-11-06 Data integrity is the hottest topic in the pharmaceutical industry Global regulatory agencies have issued guidance after guidance after guidance in the past few years most of which does not offer practical advice on how to implement policies procedures and processes to ensure integrity These guidances state what but not how Additionally key stages of analysis that impact data integrity are omitted entirely The aim of this book is to provide practical and detailed help on how to implement data integrity and data governance for regulated analytical laboratories working in or for the pharmaceutical industry It provides clarification of the regulatory issues and trends and gives practical methods for meeting regulatory requirements and guidance Using a data integrity model as a basis the principles of data integrity and data governance are expanded into practical steps for regulated laboratories to implement The author uses case study examples to illustrate his points and provides instructions for applying the principles of data integrity and data governance to individual laboratory needs This book is a useful reference for analytical chemists and scientists management and senior management working in regulated laboratories requiring either an understanding about data integrity or help in implementing practical solutions Consultants will also benefit from the practical guidance provided

Cobert's Manual Of Drug Safety And Pharmacovigilance (Third Edition) Barton Cobert,William Gregory,Jean-loup Thomas,2019-04-09 Completely revised and updated Cobert s Manual of Drug Safety and Pharmacovigilance Third Edition is a how to manual for those working in the fields of drug safety clinical research

pharmacology regulatory affairs risk management quality compliance and in government and legal professions This comprehensive and practical guide discusses the theory and the practicalities of drug safety also known as pharmacovigilance and provides essential information on drug safety and regulations in the United States Europe Union and more including recognizing monitoring reporting and cataloging serious adverse drug reactions Cobert s Manual of Drug Safety and Pharmacovigilance Third Edition teaches the daily practice of drug safety in industry hospitals the FDA and other health agencies both in the United States and around the world and provides critical information about what to do when confronted with a drug safety problem Related Link s

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Traditional and Alternative Medicine Tuley De Silva,2009 Proceedings of the International Workshop on Herbal Medicinal Plants and Traditional Herb Remedies held at Hanoi during 20 21 September 2007 organized by the Centre

Development and Control of Medicines and Medical Devices Robin J. Harman,2004 This new title describes the tests and processes undertaken to bring new medicines and medical devices to the market and the work of the government agencies which ensure products of the highest standard The text covers the controls to prove quality safety and efficacy prior to marketing and postmarketing pharmacovigilance requirements The different European registration processes for both medicines and medical devices are explained Important ethical issues in their development are also reviewed The role of the UK and pan European regulatory authorities for medicines and medicinal devices the MHRA and the EMEA and of the National Institute for Clinical Excellence NICE are explained A review of the ICH process and of the activities of the US FDA and the World Health Organization WHO in drug and device regulation illustrate how other countries control these products Providing a comprehensive single volume review Development and Control of Medicines and Medicinal Devices is an invaluable reference for all students undertaking healthcare studies and for all pharmacists It is also an essential source for all working in the pharmaceutical and medical devices industries and in government agencies involved in the control of medicines and medical devices

Guide to the Social Services Family Welfare Association (Great Britain),2004

Encyclopedia of Forensic and Legal Medicine Roger Byard,Tracey Corey,Carol Henderson,2005-06-10 The Encyclopedia of Forensic Legal Medicine comprehensively covers forensic and legal medicine including related specialities and scientific technical and legal issues and is available online and in three printed volumes offering any practitioner in a forensic medical healthcare legal judicial or investigative field easily accessible and authoritative overviews on a wide range of topics The work is edited and written by experienced professionals with medical legal or dual training and who are internationally renowned for their experience or expertise within their areas of specialty The Editorial Board reflects the multidisciplinary multi jurisdictional and global emphasis of forensic and legal medicine The individual articles are written in a clear and concise manner and are supplemented by diagrams tables and full color images Key further reading and extensive cross referencing make this work an invaluable reference source for undergraduates and graduates looking for an introduction to key fields and experts reading outside their specialization

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Global Regulations and Inspections - Research Quality Assurance Konstanze Frank,2005-07-10 Essay from the year 2004 in the subject Medicine Other grade good Anglia Ruskin University language English abstract In 2001 when the Clinical Trial Directive 2001/20 EG was released in the European Union Article 15 stated the regulations and legislation for government inspections of trial sites to be implemented by the Member States The competent authorities of the Member States shall verify protection of the rights and welfare of trial subjects compliance with the provisions of good clinical practice and the quality of data generated in clinical trials by appointing inspectors to inspect the sites concerned with any clinical trial The European Medicines Agency EMEA which needs to be informed about the inspections shall coordinate them The inspections

are performed on behalf of the European Union the results should be accepted by all Member States In Germany authorisation of inspections is detailed in the German Drug Law and the corresponding GCP ordinance The BfArM Bundesinstitut f r Arzneimittel und Medizinprodukte is the responsible German regulatory authority The UK competent authority is The Medicines and Healthcare products Regulatory Agency MHRA In the US inspections are regulated by the Food and Drug Administration FDA The specific instructions for inspecting Clinical Research Organisations CROs are given in the Bioresearch Monitoring Compliance Program No 7348 810 What is an inspection The definitions given in the different regulations are very similar The ICH GCP Guidelines 1 29 1 state Inspection the act by a regulatory authority ies of conducting an official review of documents facilities records and any other resources that are deemed by the authority ies to be related to the clinical trial and that may be located at the site of the trial at the sponsor s and or contract research organisation s CRO s facilities or at other establishment deemed appropriate by the regulatory authority ies

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