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KEY=ELECTRONIC - KERR HUERTA

ENSURING THE INTEGRITY OF ELECTRONIC HEALTH RECORDS

THE BEST PRACTICES FOR E-RECORDS COMPLIANCE

CRC Press **Data integrity is a critical aspect to the design, implementation, and usage of any system which stores, processes, or retrieves data. The overall intent of any data integrity technique is the same: ensure data is recorded exactly as intended and, upon later retrieval, ensure the data is the same as it was when originally recorded. Any alternation to the data is then traced to the person who made the modification. The integrity of data in a patient's electronic health record is critical to ensuring the safety of the patient. This book is relevant to production systems and quality control systems associated with the manufacture of pharmaceuticals and medical device products and updates the practical information to enable better understanding of the controls applicable to e-records. The book highlights the e-records suitability implementation and associated risk-assessed controls, and e-records handling. The book also provides updated regulatory standards from global regulatory organizations such as MHRA, Medicines and Healthcare Products Regulatory Agency (UK); FDA, Food and Drug Administration (US); National Medical Products Association (China); TGA, Therapeutic Goods Administration (Australia); SIMGP, Russia State Institute of Medicines and Good Practices; and the World Health Organization, to name a few.**

DATA INTEGRITY IN PHARMACEUTICAL AND MEDICAL DEVICES REGULATION OPERATIONS

BEST PRACTICES GUIDE TO ELECTRONIC RECORDS COMPLIANCE

CRC Press **Data integrity is fundamental in a pharmaceutical and medical devices quality system. This book provides practical information to enable compliance with data integrity, while highlighting and efficiently integrating worldwide regulation into the subject. The ideas presented in this book are based on many years' experience in regulated industries in various computer systems development, maintenance, and quality functions. In addition to case studies, a practical approach will be presented to increase efficiency and to ensure that the design and testing of the data integrity controls are correctly achieved.**

VALIDATION OF CHROMATOGRAPHY DATA SYSTEMS

ENSURING DATA INTEGRITY, MEETING BUSINESS AND REGULATORY REQUIREMENTS

Royal Society of Chemistry **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.**

PHARMACEUTICAL AND MEDICAL DEVICES MANUFACTURING COMPUTER SYSTEMS VALIDATION

Taylor & Francis **Validation of computer systems is the process that assures the formal assessment and report of quality and performance measures for all the life-cycle stages of software and system development, its implementation, qualification and acceptance, operation, modification, requalification, maintenance and retirement (PICS CSV PI 011-3). It is a process that demonstrates the compliance of computer systems functional and non-functional requirements, data integrity, regulated company procedures and safety requirements, industry standards, and applicable regulatory authority's requirements. Compliance is a state of being in adherence to application-related standards or conventions or regulations in laws and similar prescriptions. This book, which is relevant to the pharmaceutical and medical devices regulated operations, provides practical information to assist in the computer validation to production systems, while highlighting and efficiently integrating worldwide regulation into the subject. A practical approach is presented to increase efficiency and to ensure that the validation of computer systems is correctly achieved.**

REGISTRIES FOR EVALUATING PATIENT OUTCOMES

A USER'S GUIDE

Government Printing Office **This User's Guide is intended to support the design, implementation, analysis, interpretation, and quality evaluation of registries created to increase understanding of patient outcomes. For the purposes of this guide, a patient registry is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes. A registry database is a file (or files) derived from the registry. Although registries can serve many purposes, this guide focuses on registries created for one or more of the following purposes: to describe the natural history of disease, to determine clinical effectiveness or cost-effectiveness of health care products and services, to measure or monitor safety and harm, and/or to measure quality of care. Registries are classified according to how their populations are defined. For example, product registries include patients who have been exposed to biopharmaceutical products or medical devices. Health services registries consist of patients who have had a common procedure, clinical encounter, or hospitalization. Disease or condition registries are defined by patients having the same diagnosis, such as cystic fibrosis or heart failure. The User's Guide was created by researchers affiliated with AHRQ's Effective Health Care Program, particularly those who participated in AHRQ's DEcIDE (Developing Evidence to Inform Decisions About Effectiveness) program. Chapters were subject to multiple internal and external independent reviews.**

PRACTICAL GUIDE TO CLINICAL DATA MANAGEMENT

CRC Press **The management of clinical data, from its collection during a trial to its extraction for analysis, has become a critical element in the steps to prepare a regulatory submission and to obtain approval to market a treatment. Groundbreaking on its initial publication nearly fourteen years ago, and evolving with the field in each iteration since then,**

CARING FOR DIGITAL DATA IN ARCHAEOLOGY

A GUIDE TO GOOD PRACTICE

Oxbow Books **A wide variety of organizations are both creating and retaining digital data from archaeological projects. While current methods for preservation and access to data vary widely, nearly all of these organizations agree that careful management of digital archaeological resources is an important aspect of responsible archaeological stewardship. This guide provides information on the best way to create, manage, and document digital data files produced during the course of an archaeological project and aims to improve the practice of depositing and preserving digital information safely within an archive for future use. It is structured in three main parts: Digital Archiving - looks at the fundamentals of digital preservation and covers general preservation themes within the context of archaeological investigations, research, and resource management, with an overview of digital archiving practice and guidance; The Project Lifecycle - looks at common project lifecycle elements such as file naming, metadata creation, and copyright and covers general, broad themes that should be considered at the outset of a project; Basic Components - looks at selected technique and file type-specific issues together with archive structuring and deposit. This section covers common file types that are frequently present in archaeological archives, irrespective of a project's primary technique or focus.**

EU ANNEX 11 GUIDE TO COMPUTER VALIDATION COMPLIANCE FOR THE WORLDWIDE HEALTH AGENCY GMP

CRC Press **Good Manufacturing Practice (GMP) ensures medicinal products are produced consistently and controlled to the quality standards appropriate for their intended use and as required by product specifications or marketing authorization. Annex 11 details the European Medicines Agency (EMA) GMP requirements for computer systems.The purpose of Annex 11 is**

A DENTIST'S GUIDE TO THE LAW

228 THINGS EVERY DENTIST SHOULD KNOW

American Dental Association **Provides legal guidance for dental practice formation, marketing, employment, privacy and data security, disability access, contracts, antitrust, insurance, collections, reimbursement, patient treatment, and more. Covers the Physician Payment Sunshine Act, website accessibility, online ratings sites, Children's Online Privacy Protection Act (COPPA). Includes sample agreements for associateships.**

VALIDATION OF CHROMATOGRAPHY DATA SYSTEMS

MEETING BUSINESS AND REGULATORY REQUIREMENTS

Royal Society of Chemistry **Validation of Chromatography Data Systems: Meeting Business and Regulatory Requirements introduces the basics of computer validation. It looks in detail at the requirements throughout the life cycle of a CDS for any regulated laboratory, from its concept, through writing the user requirements specification to selecting the system, testing and operational release, including using electronic signatures. This logical and uniquely organised book provides the background to the regulatory requirements, interpretation of the regulations and documented evidence needed to support a claim that a system is validated. Development of the system, risk management, operation and finally system retirement and data migration are discussed. Case studies and practical examples are provided where appropriate.**

IMPROVING EIA PRACTICE: BEST PRACTICE GUIDE FOR PUBLISHING PRIMARY BIODIVERSITY DATA

GBIF

INFORMATION DISCOVERY ON ELECTRONIC HEALTH RECORDS

CRC Press **Exploiting the rich information found in electronic health records (EHRs) can facilitate better medical research and improve the quality of medical practice. Until now, a trivial amount of research has been published on the challenges of leveraging this information. Addressing these challenges, Information Discovery on Electronic Health Records explores the technology to unleash the data stored in EHRs. Assembling a truly interdisciplinary team of experts, the book tackles medical privacy concerns, the lack of standardization for the representation of EHRs, missing or incorrect values, and the availability of multiple rich health ontologies. It looks at how to search the EHR collection given a user query and return relevant fragments from the EHRs. It also explains how to mine the EHR collection to extract interesting patterns, group entities to various classes, or decide whether an EHR satisfies a given property. Most of the book focuses on textual or numeric data of EHRs, where more searching and mining progress has occurred. A chapter on the processing of medical images is also included. Maintaining a uniform style across chapters and minimizing technical jargon, this book presents the various ways to extract useful knowledge from EHRs. It skillfully discusses how EHR data can be effectively searched and mined.**

RECORDING, DOCUMENTATION AND INFORMATION MANAGEMENT FOR THE CONSERVATION OF HERITAGE PLACES

Routledge **This two volume guide provides a comprehensive overview of the fundamental principles and guidelines for documenting cultural heritage places. It seeks to aid heritage managers and decision makers in understanding their roles and responsibilities inn this essential activity. Volume 1 (Guiding Principles) explains why heritage managers must make sure that heritage information fully integrated into all research, investigation and conservation activities. Through the discussion of basic principles, benefits and new approaches, it assists those in charge of preserving immovable cultural heritage by bringing current heritage information practices to a new level. By recording we create a reference for evaluating change and add to the understanding of a site. By documenting we guarantee that information is systematically collected and preserved for future use. By managing the information we make it available and provide a basis for sharing our knowledge and understanding. Volume 2 presents illustrated examples from around the world. Good documentation of a site allows for better understanding of the site's value. Recognizing value and significance is often the first step toward a site's eventual conservation. The information obtained through the documentation process allows conservation professionals to record current conditions, consider appropriate conservation options, plan interventions, apply treatments, and finally, measure the results of their efforts. Documentation can be a tool in resolving a conservation issue. This volume presents several illustration examples from around the world, in various stages of conservation.**

CLINICAL TRIALS HANDBOOK

John Wiley & Sons **Best practices for conducting effective and safe clinical trials Clinical trials are arguably the most important steps in proving drug effectiveness and safety for public use. They require intensive planning and organization and involve a wide range of disciplines: data management, biostatistics, pharmacology, toxicology, modeling and simulation, regulatory monitoring, ethics, and particular issues for given disease areas. Clinical Trials Handbook provides a comprehensive and thorough reference on the basics and practices of clinical trials. With contributions from a range of international authors, the book takes the reader through each trial phase, technique, and issue. Chapters cover every key aspect of preparing and conducting clinical trials, including: Interdisciplinary topics that have to be coordinated for a successful clinical trialData management (and adverse event reporting systems) Biostatistics, pharmacology, and toxicology Modeling and simulation Regulatory monitoring and ethics Particular issues for given disease areas-cardiology, oncology, cognitive, dementia, dermatology, neuroscience, and more With unique information on such current issues as adverse event reporting (AER) systems, adaptive trial designs, and crossover trial designs, Clinical Trials Handbook will be a ready reference for pharmaceutical scientists, statisticians, researchers, and the many other professionals involved in drug development.**

THE CLINICIAN'S GUIDE TO SURVIVING IT

Radcliffe Publishing **The NHS is currently in the middle of the biggest information technology project in Western Europe, which will fundamentally change the working practices of all NHS staff over the next five years. This book explains to ordinary clinicians why they should be bothered with IT, and what their responsibilities are in making it work. This book provides an enlightening and reassuring read that dispels ignorance and suspicion. The user friendly style is helpful, and friendly panels with tips, warnings, reflective pauses and key points highlight important details. It is also suitable for use as a student textbook. The Clinician's Guide to Surviving I.T. is a must for every doctor, nurse and midwife in the NHS.**

PRACTICAL GUIDE TO THE EVALUATION OF CLINICAL COMPETENCE E-BOOK

Elsevier Health Sciences **Designed to help medical educators implement better assessment methods, tools, and models directly into training programs, Practical Guide to the Evaluation of Clinical Competence, 2nd Edition, by Drs. Eric S. Holmboe, Steven J. Durning, and Richard E. Hawkins, is a hands-on, authoritative guide to outcomes-based assessment in clinical education. National and international experts present an organized, multifaceted approach and a diverse combination of methods to help you perform effective assessments. This thoroughly revised edition is a valuable resource for developing, implementing, and sustaining effective systems for evaluating clinical competence in medical school, residency, and fellowship programs. Each chapter provides practical suggestions and assessment models that can be implemented directly into training programs, tools that can be used to measure clinical performance, overviews of key educational theories, and strengths and weaknesses of every method. Guidelines that apply across the medical education spectrum allow you to implement the book's methods in any educational situation. New chapters on high-quality assessment of clinical reasoning and assessment of procedural competence, as well as a new chapter on practical approaches to feedback. Reorganized for ease of use, with expanded coverage of Milestones/Entrustable Professional Assessments (EPAs), cognitive assessment techniques, work-based procedural assessments, and frameworks. The expert editorial team, renowned leaders in assessment, is joined by global leader in medical education and clinical reasoning, Dr. Steven Durning.**

HEALTH INFORMATION - E-BOOK

MANAGEMENT OF A STRATEGIC RESOURCE

Elsevier Health Sciences **Following the AHIMA standards for education for both two-year HIT programs and four-year HIA programs, Health Information: Management of a Strategic Resource, 4th Edition describes the deployment of information technology and your role as a HIM professional in the development of the electronic health record. It provides clear coverage of health information infrastructure and systems along with health care informatics including technology, applications, and security. Practical applications provide hands-on experience in abstracting and manipulating health information data. From well-known HIM experts Mervat Abdelhak, Sara S. Grostick, and Mary Alice Hanken, this book includes examples from diverse areas of health care delivery such as long-term care, public health, home health care, and ambulatory care. An e-book version makes it even easier to learn to manage and use health data electronically. A focus on the electronic health care record helps you learn electronic methods of organizing, maintaining, and abstracting from the patient health care record. Learning features include a chapter outline, key words, common abbreviations, and learning objectives at the beginning of each chapter, and references at the end. Unique! Availability in the e-book format helps you in researching, abstracting, and managing data electronically. A study guide on the companion Evolve website includes interactive exercises and cases containing real-life medical records, letting you apply what you've learned from the book and in the classroom. Evolve logos within the textbook connect the material to the Evolve website, tying together the textbook, student study guide and online resources. Well-known and respected authors include Mervat Abdelhak and Mary Alice Hanken, past presidents of the American Health Information Management Association (AHIMA), and Sara S. Grostick, a 2007 AHIMA Triumph Award winner for excellence in education. Self-assessment quizzes test your learning and retention, with answers available on the companion Evolve website. Did You Know? boxes highlight interesting facts to enhance learning.**

LEADERSHIP AND NURSING CARE MANAGEMENT - E-BOOK

Elsevier Health Sciences **Develop your management and leadership skills. Leadership and Nursing Care Management, 6th Edition maintains its AONE competencies, and features the most up-to-date, evidence-based blend of practice and theory related to the issues that impact nursing management and leadership today. A fresh, conversational writing style provides you with an easy-to-understand, in-depth look at these prevalent issues. Key topics include the nursing professional's role in law and ethics, staffing and scheduling,**

delegation, cultural considerations, care management, human resources, outcomes management, safe work environments, preventing employee injury, and time and stress management. UNIQUE! Chapters divided according to AONE competencies for nurse leaders, managers, and executives. Research Notes in each chapter summarize relevant nursing leadership and management studies and highlight the practical applications of research findings. Case Studies at the end of each chapter present real-world leadership and management situations and illustrate how key concepts can be applied to actual practice. Critical Thinking Questions at the end of each chapter present clinical situations followed by critical thinking questions that allow you to reflect on chapter content, critically analyze the information, and apply it to the situation. Full-color design and photos makes content more vivid. Updated! Chapter on the Prevention of Workplace Violence emphasizes the AONE, Joint Commission's, and OSHA's leadership regarding ethical issues with disruptive behaviors of incivility, bullying, and other workplace violence. Updated! Chapter on Workplace Diversity includes the latest information on how hospitals and other healthcare facilities address and enhance awareness of diversity. Updated! Chapter on Data Management and Clinical Informatics covers how new technology helps patients be informed, connected, and activated through social networks; and how care providers access information through mobile devices, data dashboards, and virtual learning systems.

DIGITAL MAPPING TECHNIQUES '03, WORKSHOP PROCEEDINGS

JUNE 1-4, 2003, MILLERSVILLE, PENNSYLVANIA

ANNUAL BOOK OF ASTM STANDARDS

STUDY GUIDE AND PROCEDURE CHECKLIST MANUAL FOR KINN'S THE MEDICAL ASSISTANT - E-BOOK

AN APPLIED LEARNING APPROACH

Elsevier Health Sciences Designed to support the trusted content in Kinn's The Medical Assistant, 15th Edition, this study guide is an essential review and practice companion to reinforce key concepts, encourage critical thinking, and help you apply medical assisting content. This robust companion guide offers a wide range of activities to strengthen your understanding of common administrative and clinical skills -- including certification preparation questions, a review of medical terminology and anatomy, and application exercises. Trusted for more than 65 years as a key part of the journey from classroom to career, it also features competency checklists to accurately measure your progress and performance from day one until you land your first job as a medical assistant. Comprehensive coverage of all administrative and clinical procedures complies with accreditation requirements. Approximately 190 step-by-step procedure checklists enable you to assess and track your performance for every procedure included in the textbook. Chapter-by-chapter correlation with the textbook allows you to easily follow core textbook competencies. Matching and acronym activities reinforce your understanding of medical terminology, anatomy and physiology, and chapter vocabulary. Short-answer and fill-in-the-blank exercises strengthen your comprehension of key concepts. Multiple-choice questions help you prepare for classroom and board exams. Workplace application exercises promote critical thinking and job readiness before you enter practice. Internet exercises offer ideas for expanded and project-based learning. NEW! Content aligns to 2022 Medical Assisting educational competencies. NEW! Advanced Clinical Skills unit features three new chapters on IV therapy, radiology basics, and radiology positioning to support expanded medical assisting functions. NEW! Coverage of telemedicine, enhanced infection control related to COVID-19, and catheterization. NEW! Procedures address IV therapy, limited-scope radiography, applying a sling, and coaching for stool collection. UPDATED! Coverage of administrative functions includes insurance, coding, privacy, security, and more. EXPANDED! Information on physical medicine and rehabilitation. EXPANDED! Content on specimen collection, including wound swab, nasal, and nasopharyngeal specimen collections.

LEXISNEXIS PRACTICE GUIDE NEW YORK E-DISCOVERY AND EVIDENCE

LexisNexis Your Starting Point for New York e-Discovery Comprehensive in scope, New York e-Discovery and Evidence: • Describes the creation, storage, and production of electronically stored information. • Suggests how to deal with the dynamic information stored in metadata. • Discusses the need to avoid spoliation and retrieve, restore, or translate the material before it is produced. • Examines issues regarding relevance and privilege. • Explains how to use electronically stored information at trial. Targeted Practical Guidance: • Task-based checklists, with cites to applicable court rules and case law, take litigators step-by-step through the various areas of e-discovery. A master checklist serves as a starting point for performing any task in the e-discovery process. • Real World Practice Tips-- including strategic points, warnings, timing and exceptions -- raise critical issues and prevent missteps. • Dozens of easily downloaded attorney-drafted and court-tested forms save time and streamline work flow. This eBook features links to Lexis Advance for further legal research options.

DATA ANALYSIS AND APPLICATIONS 4

FINANCIAL DATA ANALYSIS AND METHODS

John Wiley & Sons Data analysis as an area of importance has grown exponentially, especially during the past couple of decades. This can be attributed to a rapidly growing computer industry and the wide applicability of computational techniques, in conjunction with new advances of analytic tools. This being the case, the need for literature that addresses this is self-evident. New publications are appearing, covering the need for information from all fields of science and engineering, thanks to the universal relevance of data analysis and statistics packages. This book is a collective work by a number of leading scientists, analysts, engineers, mathematicians and statisticians who have been working at the forefront of data analysis. The chapters included in this volume represent a cross-section of current concerns and research interests in these scientific areas. The material is divided into three parts: Financial Data Analysis and Methods, Statistics and Stochastic Data Analysis and Methods, and Demographic Methods and Data Analysis- providing the reader with both theoretical and applied information on data analysis methods, models and techniques and appropriate applications.

ELECTRONIC MEDICAL RECORDS

A GUIDE FOR CLINICIANS AND ADMINISTRATORS

ACP Press Clinical Infomation Systems are increasingly important in Medical Practice. This work is a two-part book detailing the importance, selection and implementation of information systems in the health care setting. Volume One discusses the technical, organizational, clinical and administrative issues pertaining to EMR implementation. Highlighted topics include: infrastructure of the electronic patient records for administrators and clinicians, understanding processes and outcomes, and preparing for an EMR. The second workbook is filled with sample charts and questions, guiding the reader through the actual EMR implementation process.

HANDBOOK OF PHARMACEUTICAL MANUFACTURING FORMULATIONS

VOLUME TWO, UNCOMPRESSED SOLID PRODUCTS

CRC Press Providing methodologies that can serve as a reference point for new formulations, the second volume covers uncompressed solids, which include formulations of powders, capsules, powders ready for reconstitution, and other similar products.Highlights from Uncompressed Solid Products, Volume Two include:the fundamental issues of good manufacturin

THE OPERATIONAL AUDITING HANDBOOK

AUDITING BUSINESS AND IT PROCESSES

John Wiley & Sons The operational auditing HANDBOOK Auditing Business and IT Processes Second Edition Never out of print since 1997, and substantially updated for this second edition, The Operational Auditing Handbook has earned an international reputation as a hands-on, practical manual for internal auditors and managers to enable them to carry out audits and reviews of a wide range of business activities including: Finance and accounting Sarbanes-Oxley compliance Purchasing Operations and production Marketing and sales Distribution Personnel and management development Research and development Information technology Security Environmental responsibility Subsidiaries and remote operating units The Operational Auditing Handbook clari???es the underlying issues, risks and objectives for a wide range of operations and activities and is a professional companion, with many checklists, for those who design self-assessment and audit programmes of business processes in all sectors. Re???ecting the strategic importance of information technology today, this second edition is considerably expanded in this area with leading edge material. Other completely new material includes clear, authoritative guidance on how to achieve effective of governance, risk management and internal control processes.

CREASY AND RESNIK'S MATERNAL-FETAL MEDICINE: PRINCIPLES AND PRACTICE E-BOOK

EXPERT CONSULT PREMIUM EDITION - ENHANCED ONLINE FEATURES

Elsevier Health Sciences Minimize complications with Creasy and Resnik's Maternal-Fetal Medicine. This medical reference book puts the most recent advances in basic science, clinical diagnosis, and management at your fingertips, equipping you with the up-to date evidence-based guidelines and knowledge you need to ensure the best possible outcomes in maternal-fetal medicine. Consult this title on your favorite e-reader, conduct rapid searches, and adjust font sizes for optimal readability. Apply today's best practices in maternal-fetal medicine with an increased emphasis on evidence-based medicine. Find dependable, state-of-the-art answers to any clinical question with comprehensive coverage of maternal-fetal medicine from the foremost researchers and practitioners in obstetrics, gynecology and perinatology. Take advantage of the most recent diagnostic advances with a new section on Obstetrical Imaging, complemented by online ultrasound clips as well as cross references and links to genetic disorder databases. Stay on top of rapidly evolving maternal-fetal medicine through new chapters on Recurrent Spontaneous Abortion, Stillbirth, Patient Safety, Maternal Mortality, and Substance Abuse, as well as comprehensive updates on the biology of parturition, fetal DNA testing from maternal blood, fetal growth, prenatal genetic screening and diagnosis, fetal cardiac malformations and arrhythmias, thyroid disease and pregnancy, management of depression and psychoses during pregnancy and the puerperium, and much more. Access the complete contents online at Expert

Consult.

CARE OF THE ACUTELY ILL ADULT

AN ESSENTIAL GUIDE FOR NURSES

OUP Oxford **Aimed at all nurses, this key textbook equips them with the knowledge and skills required to care for the deteriorating patient in the clinical environment. The assessment, recognition and rapid escalation of the deteriorating patient is emphasized throughout the book. Using a unique system-based approach, each chapter contains structured learning outcomes and concludes with a competence-based skills assessment, which can be used to assess practice skills. These skills are recommended as essential for every nurse in an acute area and key to successful practice. Using real life case studies to link knowledge to actual practice and written by senior nurses for nurses, this book is an essential purchase for all nurses who work in acute care settings.**

GUIDE TO EU PHARMACEUTICAL REGULATORY LAW

Kluwer Law International B.V. **In the European Union (EU) and its Member States, as elsewhere, the marketing of pharmaceuticals has become subject to an increasingly complex web of legislation and regulation, resulting from the intense scrutiny necessary to ensure such essential products are not only efficacious but safe. This useful volume lays out this system with extraordinary clarity and logic. Adopting a Europe-wide perspective on the law governing pharmaceuticals, expert authors from the law firm Bird & Bird LLP map the life cycle of a medicinal product or medical device from development to clinical trials to product launch and ongoing pharmacovigilance, offering comprehensive and unambiguous guidance at every stage. A brief overview of how the proposed exit from the EU by the UK will affect the regulatory regime is also included. Following an introductory overview focusing on the regulatory framework for pharmaceuticals in Europe – from its underlying rationales to the relevant committees and agencies – each of fifteen incisive chapters examines a particular process or subject. Among the many topics and issues covered are the following: - obtaining a marketing authorisation; - stages and standards for creating a product dossier; - clinical trials; - how and when an abridged procedure can be used; - criteria for conditional marketing authorisations; - generic products and 'essential similarity'; - paediatric use and the requisite additional trials; - biologicals and 'biosimilars'; - homeopathic and herbal medicines; - reporting procedures; - pharmacovigilance; - parallel trade; - relevant competition law and intellectual property rights; and - advertising. In addition, national variation charts in many of the chapters illustrate eight major jurisdictions (Belgium, France, Germany, Italy, The Netherlands, Spain, Sweden, and the UK). Sample forms and URLs for the most important Directives are included. 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.**

GOING PAPERLESS

A GUIDE TO COMPUTERISATION IN PRIMARY CARE

Radcliffe Publishing **Annotation. A practical guide to successfully achieving a fully computerised system in primary care.**

DIETARY SUPPLEMENT GOOD MANUFACTURING PRACTICES

PREPARING FOR COMPLIANCE

CRC Press **Dietary Supplement GMP is a one-stop "how-to" road map to the final dietary supplement GMP regulations recently issued by the FDA covering the manufacture, packaging, and holding of dietary supplement products. The recent regulations, outlining broad goals, intentionally avoid specifics to allow for future technological advances—leaving implementation to the discretion of each firm. Given this latitude and flexibility, this new resource is an essential source of workable and practical suggestions on ways the industry can best meet the goals. Based on broad experience with GMP compliance techniques worked out over the years in the food, drug, and medical device industries, it is a must-have guide for all DS companies, especially the many smaller firms for whom this is new territory. Dietary Supplement GMP provides: a practical guide in easy to understand language to help navigate through the requirements for systems covering process and quality control suggestions and practical recommendations on "how-to" achieve full compliance explanation of the FDA's role regarding inspection, enforcement, recall/seizure of products and prosecution Dietary Supplement Good Manufacturing Practices (GMP) covers: Personnel Plants and Grounds Equipment and Utensils Sanitation of Buildings and Equipment Quality Assurance and Laboratory Operations The Quality Control Unit Production and Process Controls**

GUIDE TO HEALTH INFORMATICS, 2ED

CRC Press **This brilliant guide to medical informatics is an easy to read overview of the basic concepts of information and communication technologies in healthcare. Not only does the book cover the complexities and implications of the increasing use of information technology in healthcare, but it also explores the basic principles of informatics that govern**

ICEL2015-10TH INTERNATIONAL CONFERENCE ON E-LEARNING

ICEL 2015

Academic Conferences and publishing limited **These proceedings represent the work of researchers participating in the 10th International Conference on e-Learning (ICEL 2015) which is being hosted this year by the College of the Bahamas, Nassau on the 25-26 June 2015. ICEL is a recognised event on the International research conferences calendar and provides a valuable platform for individuals to present their research findings, display their work in progress and discuss conceptual advances in the area of e-Learning. It provides an important opportunity for researchers and managers to come together with peers to share their experiences of using the varied and expanding range of e-Learning available to them. With an initial submission of 91 abstracts, after the double blind, peer review process there are 41 academic Research papers and 2 PhD papers Research papers published in these Conference Proceedings. These papers come from some many different countries including: Australia, Belgium, Brazil, Canada, China, Germany, Greece, Hong Kong, Malaysia, Portugal, Republic of Macedonia, Romania, Slovakia, South Africa, Sweden, United Arab Emirates, UK and the USA. A selection of the best papers – those agreed by a panel of reviewers and the editor will be published in a conference edition of EJEL (the Electronic Journal of e-Learning www.ejel.com). These will be chosen for their quality of writing and relevance to the Journal's objective of publishing papers that offer new insights or practical help into the application e-Learning.**

ADVANCES IN CHROMATOGRAPHY

CRC Press **For more than four decades, scientists and researchers have relied on the Advances in Chromatography series for the most up-to-date information on a wide range of developments in chromatographic methods and applications. Volume 44 of this authoritative series once again compiles the work of expert contributors in order to present timely and cutting-edge reviews on a variety of related topics. Each author's clear presentation of topics and vivid illustrations make the material in Advances in Chromatography: Volume 44 accessible and engaging to biochemists and analytical, organic, polymer, and pharmaceutical chemists at all levels of technical skill.**

A TEXTBOOK OF CHILDREN'S AND YOUNG PEOPLE'S NURSING E-BOOK

Elsevier Health Sciences **nurse for life – electronic access only Get to all of the high-quality content from Elsevier faster than ever! Your favourite textbooks are now available as e-books through nurse for life, allowing you to: Electronically search the book Create and share notes and highlights Save time with automatic referencing Load it up and change the way you learn! What do I get? You will be emailed a PIN code that will give you perpetual access to the electronic version of the book through nurse for life. Book description This title is directed primarily towards health care professionals outside of the United States. Covering the full age and specialty spectrum this text brings together for the first time, individual chapters from among the most respected children's nurses. This textbook is rooted in child-centred health care within a family context and draws upon best contemporary practice throughout the UK and further afield. This innovative text harnesses new design parameters in enquiry-based/problem-based learning, providing up-to-date information on a wide range of topics. In an exciting addition each chapter offers readers additional material on an Evolve website. Full Microsoft PowerPoint presentations augment the written chapters and provide extra information that includes case studies, moving image, photographs and text. Each chapter offers readers additional material on an Evolve website. Full Microsoft PowerPoint presentations augment the written chapters and provide extra information that includes case studies, moving image, photographs and text. Aims, objectives, learning outcomes, a summary box in each chapter and key points assist learning and understanding Professional conversation boxes enliven the text on the page and make it more interesting to dip into Suggestions for seminar discussion topics to help teachers Case studies help to relate theory to practice Prompts to promote reflective practice Activity boxes/suggested visits Evidence based practice boxes which highlight key research studies, annotated bibliographies including details of web-sites and full contemporary references to the evidence base Resource lists including recommended web-site addresses**

DATA MANAGEMENT

A PRACTICAL GUIDE FOR LIBRARIANS

Rowman & Littlefield **Libraries organize information and data is information, so it is natural that librarians should help people who need to find, organize, use, or store data. Organizations need evidence for decision making; data provides that evidence. Inventors and creators build upon data collected by others. All around us, people need data. Librarians can help increase the relevance of their library to the research and education mission of their institution by learning more about data and how to manage it. Data Management will guide readers through: Understanding data management basics and best practices. Using the reference interview to help with data management Writing data management plans for grants. Starting and growing a data management service. Finding collaborators inside and outside the library. Collecting and using data in different disciplines.**

CONCEPTS FOR NURSING PRACTICE E-BOOK

Elsevier Health Sciences **Learn the core concepts of nursing care and apply them to the clinical setting! Concepts for Nursing Practice, 3rd Edition uses a simplified, intuitive approach to describe 57 important concepts relating to all areas of nursing practice. For easier understanding, this book also makes connections among related concepts and links you to other nursing textbooks. Exemplars for each concept provide useful examples and models, showing how concepts are successfully applied to practice. New to this edition are updated research evidence and a new Population Health concept. Written by conceptual learning expert Jean Giddens, this text will help you build clinical reasoning skills and prepare confidently for almost any clinical nursing situation. Authoritative content written by expert contributors and meticulously edited by concept-based learning expert Jean Giddens sets the standard for the rapidly growing concept-based curriculum movement. A total of 57 important nursing concepts are clearly defined and analyzed, spanning the areas of patient physiology, patient behavior, and the professional nursing environment. Case studies in each chapter make it easier to apply knowledge of nursing concepts to real-world situations. UNIQUE! Featured Exemplars sections describe selected exemplars related to each nursing concept, covering the entire lifespan and all clinical settings, and help you assimilate concepts into practice. UNIQUE! Logical framework of concepts by units and themes helps you form immediate connections among related concepts --- a key to conceptual learning. UNIQUE! Interrelated Concepts illustrations provide visual cues to understanding and help you make connections across concepts. NEW! UPDATED content reflects the latest research evidence and national and international practice guidelines. NEW! Population Health concept reflects the future of nursing, in which health care organizations learn to deliver care that is high in quality, patient-centered, cost-effective, and evidence-based. NEW! Featured Exemplars sections provide a brief explanation of some of the most important exemplars. NEW! Discussion questions in case studies reinforce your understanding of each concept. NEW! UPDATED exemplar links connect you to concept exemplars in other RN- and LPN/LVN-level Elsevier nursing titles.**

FRAUD

THE COUNTER FRAUD PRACTITIONER'S HANDBOOK

CRC Press **Fraud: The Counter Fraud Practitioner's Handbook looks at fraud investigation methods and explores the practical options for preventing and remedying fraud. An effective fraud and financial crime strategy involves intelligence and prevention, criminal and civil legal procedures, and asset recovery, all of which may involve investigators, internal auditors, security managers, in-house and external legal counsel and advisors. Your strategy depends on the outcomes you are seeking, the nature of the fraud or crime committed and the countries involved. Fraud provides a clear picture of the role of compliance, civil and criminal legal process in any fraud strategy. Chapters then cover investigation strategies for each of the following types of fraud: benefit, health, procurement, employee, telecoms, fiscal, corporate, charity, legal and accounting. Part Three explores the practical options for fraud prevention and remediation, including both civil and criminal asset recovery. This is an essential reference for both public and private sector fraud and security specialists who need to understand the strengths and weaknesses of each element of their organization's strategy against fraud and are seeking to learn from the approach of their colleagues in other industries or organizations. Written by and for practitioners, it is a handbook that deals with the knowledge, detail and the craft that underpins all effective anti-fraud work.**

REGISTRIES FOR EVALUATING PATIENT OUTCOMES

A USER'S GUIDE

Government Printing Office **This User's Guide is intended to support the design, implementation, analysis, interpretation, and quality evaluation of registries created to increase understanding of patient outcomes. For the purposes of this guide, a patient registry is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes. A registry database is a file (or files) derived from the registry. Although registries can serve many purposes, this guide focuses on registries created for one or more of the following purposes: to describe the natural history of disease, to determine clinical effectiveness or cost-effectiveness of health care products and services, to measure or monitor safety and harm, and/or to measure quality of care. Registries are classified according to how their populations are defined. For example, product registries include patients who have been exposed to biopharmaceutical products or medical devices. Health services registries consist of patients who have had a common procedure, clinical encounter, or hospitalization. Disease or condition registries are defined by patients having the same diagnosis, such as cystic fibrosis or heart failure. The User's Guide was created by researchers affiliated with AHRQ's Effective Health Care Program, particularly those who participated in AHRQ's DEcIDE (Developing Evidence to Inform Decisions About Effectiveness) program. Chapters were subject to multiple internal and external independent reviews.**

MANUAL ON STATISTICS OF INTERNATIONAL TRADE IN SERVICES 2010 COMPILER'S GUIDE

United Nations **The Guide provides practical support on the compilation of service transactions between residents—non-residents transactions utilizing the EBOPS classification with special emphasis on the partner country break-down, the foreign affiliates statistics (FATS) and also on flows by modes of supply. The overarching aim is to increase the availability and quality of SITS in order to fulfil the urgent needs and demands for such data by policy makers, researchers, market analysts and the public in general. While the international standards in economic statistics are in the process of being implemented, this Guide comes timely, providing the statistical community with guidelines, best practices, case studies, and practical advice on the compilation of SITS.**