

INSIDE THE CHAPTER

- WHO adverse reaction terminology
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5.1 THE WHO ADVERSE REACTION TERMINOLOGY

This terminology has been developed over more than 30 years to serve as a basis for rational coding of adverse reaction terms. Because new drugs and new indications produce new terms to be incorporated, the structure of the terminology is flexible enough to allow new developments to be incorporated whilst maintaining the structure of the terminology and without losing previous relationships. The basic logic allowing such flexibility is a hierarchical structure starting with Body System/organ level, within which there are grouping terms (General or High level) which are useful for the broadest view of drug problems. Within these broad categories the specific, frequently used 'Preferred terms' provide for precise identification of drug problems. Preferred terms allow for precision, but everyday experience shows that adverse reaction reports contain colloquial terms. In this case the WHO 'Included terms' help by pointing to the closest Preferred term, but still allowing the actual reported term to remain unaltered. Many users simply make up their own Included term list based upon their own experience. Users are encouraged to let the Uppsala Monitoring Centre know about any useful Included terms so that they can be incorporated in the official WHO-ACT with appropriate relationship to Preferred terms. Also, if a frequently used, clearly defined term is considered by users as a possible Preferred term, this can be requested. A final decision on incorporation is made after consultation with experts in the field. The UMC is also using a glossary list of terms which are synonyms for Preferred terms. WHO-ACT is developed in English, but there are also more or less complete translations into French, Spanish, German, Italian and Portuguese. WHO-ACT is a widely used terminology by both regulatory agencies and pharmaceutical manufacturers.

Dictionary Of Pharmacovigilance

Gerhard Nahler



Dictionary Of Pharmacovigilance:

Dictionary of Pharmacovigilance Amer Alghabban, 2004 Pharmacovigilance is in essence the process of monitoring the everyday use of medicines to identify previously unrecognised adverse drug reactions thereby assessing their risk benefit balance in order to determine what action if any is necessary to improve their safe use As a discipline pharmacovigilance impacts on many specialist areas such as pharmacoepidemiology medical practice public health but is most intimately linked to clinical research development and drug licensing The discipline along with its operational and legal facets for both regulatory authorities and pharmaceutical industry envelop colossal terminology that has precise legal and scientific significance Such terminology may vary from country to country or more confusingly different countries may use identical or similar abbreviations terms or phrases to mean different entities The Dictionary of Pharmacovigilance contains a comprehensive list of abbreviations terms and phrases in English giving definitions of commonly and rarely encountered pharmacovigilance terms Examples include Absolute Risk Increase ARI Bayesian Confidence Propagation Neural Network BCPNN Confounding Factor Case narrative Causality Assessment Company Core Safety Information CCSI Data mining 15 day report Rechallenge Directive 2001 83 EC EU Birth Date Expert report FDA Form 1639 Historical control Number Needed to Harm Toxokinetics Post Marketing Surveillance Qualified Person Source Data Verification SDV Spontaneous Reporting Vaccine Adverse Event Reporting System VAERS Warning Letter Product Withdrawal **Dictionary of**

Pharmaceutical Medicine Gerhard Nahler, 2013-06-29 This dictionary is aimed primarily at the beginners entering the new discipline of Pharmaceutical Medicine an area comprising aspects of toxicology pharmacology pharmaceuticals epidemiology statistics drug regulatory and legal affairs medicine and marketing But also more experienced colleagues in departments engaged in clinical development as well as researchers and marketing experts in the pharmaceutical industry will find concise and up to date information The book is completed by a list of about 1000 abbreviations encountered in pharmaceutical medicine and a compilation of important addresses of national and international health authorities

Veterinary Pharmacovigilance Kevin Woodward, 2009-11-24 Veterinary Pharmacovigilance Adverse Reactions to Veterinary Medicinal Products is an in depth examination of veterinary pharmacovigilance looking at the scientific methodologies involved the role of regulatory agencies and legislation and the underpinning science Edited by a renowned expert with over 20 years of experience in the field it draws together the expertise of authors from around the world

Stephens' Detection of New Adverse Drug Reactions John Talbot, Patrick Waller, 2004-03-08 A key text for all those involved in pharmacovigilance Detection of new adverse drug reactions is fundamental to the protection of patients from harm that may occur as a result of medication This book explores the methods used to investigate new adverse drug reactions discussing all elements from the scientific background and animal toxicology through to worldwide regulatory and ethical issues Stephens Detection of New Adverse Drug Reactions provides comprehensive and up to date coverage of

material fundamentally important to all those active in the field whether they work in the pharmaceutical industry drug regulatory authorities or in academia The fifth edition of this classic reference work includes new chapters on vaccine safety surveillance managing drug safety issues with marketed products operational aspects of drug safety function safety of biotechnology products future of pharmacovigilance Reviews of previous editions This book surpasses all its educational aims Not only is the subject matter covered comprehensively but the material is presented in a very user friendly manner The editors have succeeded in producing a highly specific definitive reference book which doubles as a most enjoyable read Commended by the 1999 BMA Medical Book Competition For anyone entering the field of adverse reaction monitoring one could not wish for a better primer International Journal of Risk and Safety in Medicine

Information Society in Pharmaceuticals José Luis Valverde, 2001 Organizations contemplate information technology and the Internet as a unique opportunity to enhance knowledge work and to improve quality of service Electronic regulatory reporting electronic document archival and data retrieval automatic transactions between collaborative enterprise resources wide availability and dissemination of information to the public these are a few of the facets enabled by the information society and the digital revolution

A Magnificent Text Book Of Pharmacovigilance ZAKIR HUSSAIN, Mr. Sabareesh, Dr. K. Kranthi Kumar, Mr. Sudheer Kumar, 2019-12-28 A Magnificent text book of pharmacovigilance post marketing surveillance is most demanded and recommended text book now a days as the material provided in this book is gathered from different universities framed in their curriculum accordingly we prepared the manuscript to reach the customer demand more over it provides a brief history and background of pharmacovigilance the student can easy understand the language and score good marks in their exam the present books available in market either provide with less information or not upto the bench mark I have tried my level best to provide the maximum information for the betterment of student and accademic faculties

Stephens' Detection and Evaluation of Adverse Drug Reactions John Talbot, Jeffrey K. Aronson, 2011-12-19 The detection and evaluation of adverse drug reactions is crucial for understanding the safety of medicines and for preventing harm in patients Not only is it necessary to detect new adverse drug reactions but the principles and practice of pharmacovigilance apply to the surveillance of a wide range of medicinal products Stephens Detection and Evaluation of Adverse Drug Reactions provides a comprehensive review of all aspects of adverse drug reactions throughout the life cycle of a medicine from toxicology and clinical trials through to pharmacovigilance risk management and legal and regulatory requirements It also covers the safety of biotherapeutics and vaccines and includes new chapters on pharmacogenetics proactive risk management societal considerations and the safety of drugs used in oncology and herbal medicines This sixth edition of the classic text on drug safety is an authoritative reference text for all those who work in pharmacovigilance or have an interest in adverse drug reactions whether in regulatory authorities pharmaceutical companies or academia Praise for previous editions This book presents a comprehensive and wide ranging overview of the science of pharmacovigilance For those

entering or already experienced in the pharmaceutical sciences this is an essential work from a review in E STREAMS a key text in the area of pharmacovigilance extensively referenced and well written a valuable resource from a review in The Pharmaceutical Journal

Regulatory Toxicology in the European Union Tim Marrs, Kevin Woodward, 2018-02-21

Consumer and environmental protection depend on the careful regulation of all classes of chemicals Toxicology is the key science used to evaluate safety and so underpins regulatory decisions on chemicals With the growing body of EU legislation involved in chemical regulation there is a concomitant need to understand the toxicological principles underlying safety assessments Regulatory Toxicology in the European Union is the first book to cover regulatory toxicology specifically in Europe It addresses the need for a wider understanding of the principles of regulatory toxicology and their application and presents the relationship between toxicology and legislative processes in regulating chemical commodities across Europe This title has a broad scope covering historical and current chemical regulation in Europe the role of European agencies and institutions and also the use of toxicology data for important classes of chemicals including human and veterinary medicines animal feed and food additives biocides pesticides and nanomaterials This book is therefore extremely pertinent and timely in the toxicology field at present This book is an essential reference for regulatory authorities industrialists academics undergraduates and postgraduates working within safety and hazards toxicology the biological sciences and the medicinal and pharmaceutical sciences across the European Union

Diccionario terminológico de las ciencias farmacéuticas Alfonso Domínguez-Gil Hurlé, Enrique Alcaraz Varó, Raquel Martínez Motos, 2007 El Diccionario Terminológico de Ciencias Farmacéuticas de la Real Academia Nacional de Farmacia y Editorial Ariel consta de dos partes La primera en inglés española tiene unos 15 000 términos y la segunda española en inglés más de 13 000 Todos ellos han sido ordenados en torno a los siguientes 25 campos semánticos 1 Análisis farmacéutico absorbance absorbancia bacteria bacteria etc 2 Asistencia sanitaria discharge alta hospitalaria relapse recaer etc 3 Biológica code of conduct código deontológico living will testamento vital etc 4 Biofarmacia bioavailability biodisponibilidad route vía de administración etc 5 Biología chromosome cromosoma dendrite dendrita etc 6 Bioquímica monosaccharide monosacrido peptidase peptidasa etc 7 Biotecnología epoetin eritropoyetina pegaspargase pegaspargasa etc 8 Derecho farmacéutico holder titular infringement violación etc 9 Dermofarmacia anti aging anti envejecimiento emollient emoliente etc 10 Farmaco abacavir abacavir clobazam clobazam etc 11 Farmacoeconomía brand switching cambio de marca co payment copago etc 12 Farmacología drug absorption absorción de fármaco reuptake recaptación etc 13 Farmacoterapia fast acting drug fármaco de acción rápida vaccine vacuna etc 14 Fisiología anatomía bronchi bronquios dura mater etc 15 Fitoterapia belladonna belladona ginger jengibre etc 16 General disposable desechable outcome desenlace etc 17 Historia de la farmacia alchemy alquimia Mithridatis Mitridates etc 18 Nutrición additive aditivo starch almidón etc 19 Patología acne acné asthma asma etc 20 Productos sanitarios cotton wool algodón sanitary pad compresa sanitaria etc 21 Química farmacéutica affinity afinidad dehydrogenation deshidrogenación etc 22 Salud pública cannabis

cannabis water supply abastecimiento de agua etc 23 Seguridad de medicamentos harmful effect efecto perjudicial drowsiness somnolencia etc 24 Tecnología a farmacéutica coat revestimiento packaging acondicionamiento etc 25 Toxicología accidental poisoning intoxicación involuntaria antidote antídoto etc Las ENTRADAS del diccionario siguen la pauta de estos ejemplos epinephrine1 en BIOQUÍMICA epinefrina hormona segregada en la glándula suprarrenal secreta por la masa medular de las glándulas suprarrenales the medulla of the adrenal glands y liberada en el flujo sanguíneo released in the bloodstream en respuesta a situaciones de ansiedad miedo etc Epinephrine is a hormone that initiates many bodily responses including the stimulation of heart action V metanefrina Exp epinephrine2 FARMACOLÓGICA epinefrina se prepara este fármaco con extractos suprarrenales adrenal extracts y también sintéticamente se emplea como hemostático hemostatic como estimulante cardíaco heart stimulant como vasoconstrictor vasoconstrictor como relajante del asma bronquial bronchial relaxant etc Epinephrine raises blood pressure V adrenalina adrenalin pressor evergreening en DERECHO reverdecimiento estrategias de renovación permanente de la validez de las patentes procedimiento de prolongación de la vida til shelf life de fármacos expirados expired drugs prolongación en el tiempo de las patentes farmacéuticas el término se utiliza también como verbo en la expresión to evergreen a patent con el significado de renovar constantemente o demorar al mismo tiempo la fecha de caducidad de una patente aprovechando en lo posible las escapatorias o lagunas jurídicas loopholes que se encuentran en las leyes con el fin de prolongar el ciclo de vida de muchos medicamentos a estos efectos algunas industrias farmacéuticas han conseguido prorrogar la vigencia validity de sus patentes con la consiguiente protección que estas ofrecen a sus medicamentos patentando por separado algunos de los atributos patentables autorizados por la ley eligible patentable attributes entre los que sobresalen el acondicionamiento packaging el régimen posológico dosing regimen los cambios en la formulación changes in the formulation las dianas biológicas biological targets los fármacos de la siguiente generación next generation drugs etc V patent expiry go off patent abortar1 v HEALTH CARE PATHOLOGY abort to have an abortion to have a miscarriage miscarry La mujer embarazada no debe tomar misoprostol porque corre el riesgo de abortar Exp abortar2 HEALTH CARE stop interrupt put an end to El salbutamol suele emplearse para abortar los ataques de asma S interrumpir abortivo PHARMACOTHERAPY abortient aborticide1 abortifacient drug abortion inducing drug a substance that destroys the fetus and induces abortion La píldora abortiva provoca que el feto rechace el embrión aborto HEALTH CARE abortion aborticide2 induced expulsion of a human fetus S embarazo dopa en BIOCHEMISTRY DRUG dopa acronym of dihidroxifenil alanina dihydroxyphenylalanine in English it is an amino acid aminoácido formed in the liver from tyrosine se forma en el hígado a partir de la tirosina and converted to dopamine in the brain se convierte en dopamina en el cerebro it is used for the treatment of Parkinson's disease enfermedad de Parkinson Pharmaco-Vigilance from A to Z Barton L. Cobert, MD, Pierre Biron, MD, 2001-07-05 Pharmacovigilance from A to Z is an authoritative text focusing on the common questions and procedures involved in prescribed drug monitoring The alphabetized format provides an easy to use reference while a

separate section of the book guides the reader logically from topic to topic to form related chapters Practical Drug Safety from A to Z Barton Cobert,Pierre Biron,2009-10-06 The Practical Drug Safety from A to Z is an alphabetical guide to drug safety monitoring pharmacovigilance covering literally the A to Z of maintaining drug safety Written by experts in the field this book is a perfect companion to the Manual of Drug Safety and Pharmacovigilance and an essential reference for pharmacists pharmacologists hospital administrators medical liability lawyers and others **The New Walford Guide to Reference Resources** Ray Lester,2005 The New Walford highlights the best resources to use when undertaking a search for accurate and relevant information saving you precious time and effort For those looking for a selective and evaluative reference resource that really delivers on its promise look no further In addition to print sources The New Walford naturally covers an extensive range of reference sources such as digital databanks digital reference services electronic journal collections meta search engines networked information services open archives resource discovery services and websites of premier organizations in both the public and private sectors But rather than supplying a list of all available known resources as a web search engine might The New Walford subject specialists have carefully selected and evaluated available resources to provide a definitive list of the most appropriate and useful With an emphasis on quality and sustainability the subject specialists have been careful to assess the differing ways that information is framed and communicated in different subject areas As a result the resource evaluations in each subject area are prefaced by an introductory overview of the structure of the relevant literature This ensures that The New Walford is clear easy to use and intuitive Publisher *Artificial Intelligence for Translational Pharmacology* Zhi-Liang Ji,Lixia Yao,Kartick Chandra Pramanik,Zhaohui John Cai,2020-07-28

A Dictionary of Pharmacology and Allied Topics D.R. Laurence,1998-08-19 This dictionary spans the practice of pharmacology and of allied sciences insofar as they are related to it with particular emphasis on the development regulation and use of human medicine It is offered to students as well as to professionals in pharmacology and allied sciences for reference and for browsing and as a bedside book and travelling companion Its size approximately 2000 entries is appropriate for these uses Features of this dictionary Provides definitions of terms in pharmacology both basic and clinical Gives information on new medicine development and official regulations Covers allied topics including statistics ethics scientific misconduct authorship publication and law Chronic Diseases in Canada ,2002 **Dictionary of Pharmacoepidemiology** Bernard Bégaud,2000-11-08 Written by an internationally renowned authority in the field this is the most complete dictionary devoted specifically to the terms currently used in pharmacoepidemiology The use of clear and consistent terminology in science has never been more important and this dictionary which has been translated from the third edition of a French original has been reworked to include suggestions made by pharmacoepidemiologists currently using existing versions It contains revised definitions for nearly all established terms in addition to comprehensive descriptions of new terms and is well illustrated with practical examples This outstandingly high quality dictionary will be

essential for all those whose work is within or touches upon this field regulatory authorities pharmaceutical physicians lawyers pharmacists researchers evaluators and students **Dictionary of Medicine** Svetolik P. Djordjević,2000 With over 110 000 entries this is the world s largest and most updated French English medical dictionary *Elsevier's Dictionary of Medicine* A. Hidalgo Simon,2004-03-19 This is a comprehensive medical and scientific dictionary for the 21st century New vocabulary is constantly being introduced into fast moving medico scientific disciplines such as genomics clinical trials medico legal health economics and pharmacovigilance This new terminology is included in this dictionary clearly defined and accurately translated into Spanish The dictionary contains more than 28 000 main entries and many subentries a medical terms used outside the medical community including colloquial usage b technical medical terms in current use in clinical practice and research c new technical terms in the fields of medicine medical research and basic scientific research applied to medicine defined in recent years The breadth of subjects covered and the accessibility of the definitions make it user friendly for the educated general public while the level of detail and state of the art coverage of recent terminology make it a unique tool for professionals **Dictionary of Pharmaceutical Medicine** Gerhard Nahler,2014-01-15 **The British National Bibliography** Arthur James Wells,2007

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