

Good Manufacturing Practice (GMP) Guidelines (Eudralex-Volume 4)

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ABSTRACT

The basic rules in any good manufacturing practice (GMP) regulations postulate that the pharmaceutical manufacturer must maintain appropriate documentation and records. Documentation helps to build up a detailed interpretation of what a manufacturing function has done in the past and what it is doing now and, thus, it provides a base for planning what it is going to do in the future. Regulatory evaluators, during their inspections of manufacturing sites, often devote much time on examining a company's documents and records. Effective documentation boosts the visibility of the quality assurance system.

KEY WORDS: GMP, 21 CFR, Part 210 and 211, Documentation, Regulations Agencies

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HISTORY OF GMP

- US patented medicine, first produced in 1861 in Chicago by former magician John Austen Hamlin and his brother Lysander Butler Hamlin
- Primarily sold and used as liniment for rheumatic pain and sore muscles
- Was also advertised as a treatment for cancer, pneumonia, diphtheria, earache, toothache headache and hydrophobia.
- Made of 50% - 70% alcohol containing camphor, ammonia, chloroform, sassafras, cloves and turpentine and was said to be usable both internally and topically In 1916, Lysander's son Lawrence B. Hamlin, was fined \$200 under the 1906 Pure Food and Drug Act for misbranding it as a "cancer drug"



Eudralex Volume 4

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Eudralex Volume 4:

Good Manufacturing Practice (GMP) Guidelines Mindy J. Allport-Settle, 2009-12 This title combines all of the human and veterinary Regulations Directives and guidance for medicinal products used by the pharmaceutical industry as their main source when manufacturing and distributing medicinal products in the European Union

Handbook of Pharmaceutical Manufacturing Formulations, Third Edition Sarfaraz K. Niazi, 2019-12-06 The Handbook of Pharmaceutical Manufacturing Formulations Third Edition Volume Four Semisolid Products is an authoritative and practical guide to the art and science of formulating drugs for commercial manufacturing With thoroughly revised and expanded content this fourth volume of a six volume set compiles data from FDA and EMA new drug applications patents and patent applications and other sources of generic and proprietary formulations including author's own experience to cover the broad spectrum of cGMP formulations and issues in using these formulations in a commercial setting A must have collection for pharmaceutical manufacturers educational institutions and regulatory authorities this is an excellent platform for drug companies to benchmark their products and for generic companies to formulate drugs coming off patent Features Largest source of authoritative and practical formulations cGMP compliance guidance and self audit suggestions Differs from other publications on formulation science in that it focuses on readily scalable commercial formulations that can be adopted for cGMP manufacturing Tackles common difficulties in formulating drugs and presents details on stability testing bioequivalence testing and full compliance with drug product safety elements Written by a well recognized authority on drug and dosage form development including biological drugs and alternative medicines

Pharmaceutical Medicine and Translational Clinical Research Divya Vohora, Gursharan Singh, 2017-11-14 Pharmaceutical Medicine and Translational Clinical Research covers clinical testing of medicines and the translation of pharmaceutical drug research into new medicines also focusing on the need to understand the safety profile of medicine and the benefit risk balance Pharmacoeconomics and the social impact of healthcare on patients and public health are also featured It is written in a clear and straightforward manner to enable rapid review and assimilation of complex information and contains reader friendly features As a greater understanding of these aspects is critical for students in the areas of pharmaceutical medicine clinical research pharmacology and pharmacy as well as professionals working in the pharmaceutical industry this book is an ideal resource Includes detailed coverage of current trends and key topics in pharmaceutical medicine including biosimilars biobetters super generics and Provides a comprehensive look at current and important aspects of the science and regulation of drug and biologics discovery

[The Handbook of Basic GMP Requirements](#) Karyn Noemi Santoro, 2020-10-23 This Handbook of Basic GMP Requirements is a collection of official guidelines reported in the Eudralex website Volume 4 Specifically all nine chapters from Part I Basic Requirements for Medicinal Products are here reported Since the pharmaceutical industry of the European Union maintains high standards of Quality Management in the development

manufacture and control of medicinal products a regulated system is required to ensure that all medicinal products are assessed by a competent authority to ensure compliance with contemporary requirements of safety quality and efficacy Building a good quality system ensures not only that all products shipped around the European market are manufactured imported only by authorised manufacturers but also that those activities are regularly inspected by the competent authorities using Quality Risk Management principles Pharmaceutical industries must follow these guidelines and thanking to their persistent effort they will be able to successfully manufacture a high quality deliverable stable medicine for human use and controlled according to quality standards appropriate to their intended use and as required by the marketing authorization Good Manufacturing Practice guidelines aimed primarily at diminishing the risks inherent in any pharmaceutical production and not place the patients health at risk due to inadequate safety quality or efficacy

Key Publications of the European Union, 2005 Technical Report Series, 1950 *Rift-lines within European regulatory framework for Biosimilars when taking heterogeneity and variation during lifecycle of the reference biologic and the biosimilar into account* Malik Osmane, 2013-10-15 Master's Thesis from the year 2013 in the subject Medicine Pharmacology Pharmacy grade 1 st CLASS HONS Dublin Institute of Technology Chemistry course Pharmaceutical Quality Assurance Regulatory Affairs language English abstract During the course of this thesis evidence was presented and discussed related to the research questions The fundamental question related to the heterogeneity and variation through the life cycle of the biosimilar and the reference biologic remains neglected based on the results collected during this thesis by the stakeholders mainly because those issues were not addressed in any official regulatory guidance document As clear guidance from the EMA is lacking with the only available guidance being that once a marketing authorization is issued it is accepted that the quality profiles of the reference biologic and the biosimilar will have different quality profiles Abstract Within the biosimilar development context there are unaddressed questions by the European Medicines Agency EMA with regard to the impacts of shifts of the quality profile purity and impurity levels of the reference biologic for the biosimilar development program This dynamic is an open issue has potentially implications on the comparability exercise of the before mentioned Opinions from experts involved in the guidance drafting process of EMA and other were evaluated with regard to the issue The Rules Governing Medicinal Products in the European Union Commission of the European Communities, European Commission, 1998 This guide is presented in chapters each headed by a principle of GMP outlining the Quality Assurance objectives of that chapter *The Rules Governing Medicinal Products in the European Union*, 1998 *The Qualified Person*, 2007

Liposome Technology Gregory Gregoriadis, 2006-09-12 Liposome Technology Volume I Liposome Preparation and Related Techniques Third Edition is a thoroughly updated and expanded new edition of a classic text in the field Including step by step technical details Volume I illustrates numerous methods for liposome preparation and auxiliary techniques necessary for the stabilization and characterization of liposomes This source also offers critical discussions of the

methodologies of each technology described so that readers can examine the benefits and limitations and compare it to other approaches Principles of Clinical Research Ignazio Di Giovanna,Gareth Hayes,2001 In an arena which has seen rapid change over the past decade this work provides a comprehensive and up to date guide to the planning organization and management of clinical trials *Vaccination Animale* Paul-Pierre Pastoret,Michel Lombard,A. A. Schudel,2007 Drug Information Bonnie Snow,2008 This is the long awaited third edition of the most comprehensive compilation of drug information resources available A co publication with the Medical Library Association it draws on industry expert Bonnie Snow s 30 years of experience with pharmaceutical information needs and applications Snow reviews 400 print and electronic resources More than a bibliography this readable guide brings together the best resources plus practical advice on everything from expert search techniques to core collections for libraries Subject areas covered include pharmaceutical technology legal and regulatory issues world wide industrial pharmacy market research product guides and prescribing information in the global marketplace drug interactions drug effects on pregnancy lactation and reproduction pharmacovigilance and much much more Completely revised reorganized and updated the third edition focuses on information sources not covered elsewhere Absolutely unique in its value as both a desk reference and a text for classroom use or self study this edition manages to meet the needs of students information professionals health care providers and pharmacy practitioners *European Pharmacopoeia* Service européen de la qualité du médicament (Éditeur scientifique).,2013 Key Publications of the European Union 2000-01 Commission of the European Communities,2000

San Diego International Law Journal ,2005 **Technical Reports Series** ,2009 **Pharmaceuticals in the European Union** European Commission. Enterprise DG.,2000 Analytical Chemistry Jean-Michel Mermet,Matthias Otto,Miguel Valcárcel Cases,2004-09-03 Why settle for less when you can have the whole of Analytical Chemistry in a single book The successful all in one guide to modern Analytical Chemistry is now available in a new and updated edition From the foundations of analytical science to state of the art techniques and instrumentation all you will ever need to know is explained here The text covers both general analytical chemistry and instrumental analysis and may be used for most analytical chemistry courses offered today Carefully chosen worked examples show how analytical problems can effectively be solved and how calculations should be performed Study questions and recommended reading for further study are provided for each learning unit The second edition has been carefully revised to keep up to date with advances in the technology of analytical methods in the laboratory and in the workplace including newly written chapters on multidimensional chromatography sensors and screening systems With its broad scope the text doubles as a reliable reference for virtually all analytical problems encountered during the course of study and beyond Analytical Chemistry will serve as an excellent text as well as a valued reference following completion of the student s course of study Journal of Medicinal Chemistry It is a book that should be on the shelves of all analytical chemistry and biochemistry professionals

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