

# Good Laboratory Practice (GLP) Intermediate

Waktu Pelaksanaan 22 Juli 2023 09.00-13.00 WIB

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# **Good Laboratory Practice Indonesia**

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#### **Good Laboratory Practice Indonesia:**

Vaccine manufacturing workshop for South-East Asia and the Western Pacific Regions World Health Joint external evaluation of the International Health Regulations (2005) core capacities of Organization, 2022-06-16 Indonesia World Health Organization, 2024-11-08 The Joint External Evaluation JEE team would like to express its appreciation to Indonesia for volunteering for a second round of JEE This demonstrates commitment foresight and leadership from the highest levels of government crucial for long term success in building and sustaining Indonesia's core capacities under the International Health Regulations 2005 IHR The external team commends Indonesia for enhancing health security by implementing IHR through committed leadership which is of significant importance not just regionally but also globally As a large country spread over 17 000 islands Indonesia's size population and vulnerability to natural disasters along with its social economic and administrative diversity pose unique challenges to public health The country has robustly responded to these challenges taking public health leadership roles both regionally and globally **Haschek and Rousseaux's** Handbook of Toxicologic Pathology Wanda M Haschek, Colin G. Rousseaux, Matthew A. Wallig, Brad Bolon, Ricardo Ochoa, 2013-05-01 Haschek and Rousseaux s Handbook of Toxicologic Pathology is a key reference on the integration of structure and functional changes in tissues associated with the response to pharmaceuticals chemicals and biologics The 3e has been expanded by a full volume and covers aspects of safety assessment not discussed in the 2e Completely revised with many new chapters it remains the most authoritative reference on toxicologic pathology for scientists and researchers studying and making decisions on drugs biologics medical devices and other chemicals including agrochemicals and environmental contaminants New topics include safety assessment the drug life cycle risk assessment communication and management carcinogenicity assessment pharmacology and pharmacokinetics biomarkers in toxicologic pathology quality assurance peer review agrochemicals nanotechnology food and toxicologic pathology the environment and toxicologic pathology and more Provides new chapters and in depth discussion of timely topics in the area of toxicologic pathology and broadens the scope of the audience to include toxicologists and pathologists working in a variety of settings Offers high quality and trusted content in a multi contributed work written by leading international authorities in all areas of toxicologic pathology Features hundreds of full color images in both the print and electronic versions of the book to highlight difficult concepts with clear illustrations An American Experience in Indonesia Howard W. Beers, 2021-10-21 This book tells the story of an important experiment in international cooperation and inter university collaboration in educational development A team of educational and agricultural specialists from the University of Kentucky called Kenteam in the book lived and worked in Bogor Indonesia from 1957 through 1965 Their purpose to work with the Agricultural University in Bogor to develop a complete college of agriculture to the level of capability for self regeneration and growth Working against a background of political and economic turmoil Kenteam succeeded in helping the Indonesians build an institution capable of

achieving its goals once the restraints of a struggling economy could be removed This heartening story is replete with sociological insight but free of sociological jargon Written in a reportorial and evaluative style the book interweaves ideas of organizational development with close ups of the interagency and human problems involved telling an absorbing story of international cooperation in technical assistance It will be read with interest by Asian specialists and the many people concerned with social change and economic and educational development **Access and Benefit Sharing of Genetic** Resources, Information and Traditional Knowledge Charles Lawson, Michelle Rourke, Fran Humphries, 2022-10-14 Addressing the management of genetic resources this book offers a new assessment of the contemporary Access and Benefit Sharing ABS regime Debates about ABS have moved on The initial focus on the legal obligations established by international agreements like the United Nations Convention on Biological Diversity and the form of obligations for collecting physical biological materials have now shifted into a far more complex series of disputes and challenges about the ways ABS should be implemented and enforced These now cover a wide range of issues including digital sequence information the repatriation of resources technology transfer traditional knowledge and cultural expressions open access to information and knowledge naming conventions farmers rights new schemes for accessing pandemic viruses sharing DNA sequences and so on Drawing together perspectives from an interdisciplinary range of leading and emerging international scholars this book offers a new approach to the ABS landscape as it breaks from the standard regulatory analyses in order to explore alternative solutions to the intractable issues for the Access and Benefit Sharing of genetic resources Addressing these modern legal debates from a perspective that will appeal to both ABS scholars and those with broader legal concerns in the areas of intellectual property food governance Indigenous issues and so on this book will be a useful resource for scholars and students as well as those in government and in international institutions working in relevant areas **Laboratory Animals** Javier Guillen, 2017-10-25 Laboratory Animals Regulations and Recommendations for the Care and Use of Animals in Research Second Edition is the only publication to offer a global compilation of standards on the care welfare and use of animals in research The book provides updated information that will be of great interest to professionals across laboratory animal science and biomedical research Users will find a broad picture of the regulations required in other areas of the world that will be essential to appropriately manage animal care and use programs Offers a worldwide view and global compilation of regulations guidelines and recommendations for laboratory animal research Provides insight into factors that play key roles in the regulatory framework for countries and geographic regions Compares and contrasts regulations in different regions Written in layman's terms to easily understand legislation and regulations MANIPULATION OF DIGITAL EVIDENCE BY THE INDONESIAN NATIONAL POLICE FORENSIC LABORATORY: A CASE STUDY OF THE CYANIDE COFFEE **INCIDENT** RISMON HASIHOLAN SIANIPAR, 2025-09-03 The criminal case involving Jessica Wongso has unveiled the fragility of digital evidence integrity within Indonesia's criminal justice system CCTV recordings which should have served as

objective evidence were reprocessed using irrelevant software such as eRightSoft and Freemake by police digital forensic experts namely Muhammad Nuh al Azhar and Christopher Hariman Rianto This practice resulted in technical alterations including downscaling recompression and the loss of original metadata Consequently the recordings lost their validity as authentic evidence and produced far reaching implications during the trial process The manipulated video was subsequently employed as the basis for analysis by psychologists criminologists criminal law experts prosecutors and judges Interpretations of Jessica's nonverbal behavior became biased criminological assessments were rendered defective and legal constructions were built upon contaminated data Even more concerning the court accepted the footage without conducting authenticity tests in accordance with international standards This not only compromised the probative value of the evidence but also undermined the principle of a fair trial This case serves as a critical lesson on how easily digital evidence can be manipulated and how devastating its consequences can be for justice The integrity of evidence is the cornerstone of law Without such integrity the judicial process risks becoming an instrument of criminalization Accordingly this book seeks to reveal how digital evidence manipulation operates its impact on forensic psychology criminology criminal law and even public perception It is hoped that readers will recognize the urgency of safeguarding the integrity of digital evidence in order to uphold truth and justice

Accreditation Practices for Inspections, Tests, and Laboratories

Saving Costs in Chemicals Management How the OECD Ensures Benefits to Society OECD, 2019-01-28 The chemical industry is one of the largest industrial sectors in the world and is expected to grow fourfold by 2060 Indeed modern life without chemicals would be inconceivable Given the potential environmental and human health risks from exposure to chemicals governments and industry have a Innovative and Efficient Laboratory Management Godswill Ntsomboh Ntsefong, 2015-04-29 Since most research activities involve laboratory work there is need for efficient management of laboratory or test facilities to ensure quality controlled research and cost effective use of resources It is obvious that good laboratory and research management skills are necessary for scientists and scholars involved directly or indirectly in industrial clinical or bioscience research and or charged with management of laboratory facilities The essence of this write up is therefore to enhance good laboratory management practices that ensure stressless compliance with legal and regulatory frameworks for health and safety The aim is to promote scientific excellence by highlighting the conditions and skills necessary for efficient and innovative management of laboratory facilities while enhancing consciousness and efficacy in cost effective research management The issues addressed in the book include a proposal of the administrative setup of a laboratory or test facility laboratory design considerations which obviously have a significant impact on the quality of results generated The principles of good laboratory practices and the importance of biosafety and biosecurity are specially addressed The author also reiterates the importance of a procurement strategy for each laboratory or test facility whose aim should be to set out a planned approach for cost effective purchasing of required goods and services taking into account

several factors such as the timeline for procurement the funding and budget and the projected risks and opportunities Here the need for a defined and documented policy and procedures for selection and use of purchased external goods and services in addition to an inventory control system for laboratory supplies is highlighted Laboratory operators need to have an overview of different categories and types of laboratory equipment at their disposal with good knowledge of their safe handling operation and maintenance following well set schedules Besides this concern the book also dwells on laboratory information management system LIMS which is an important and integral part of laboratory operations relevant for efficient laboratory management A whole chapter is consecrated to quality control QC quality assurance QA and total quality management TQM as the three major elements of quality which effectively sets the stage for laboratory accreditation which demonstrates legitimacy and credibility of research results In fact laboratory accreditation is the process by which an independent and authorized agency certifies the quality system and competence of a laboratory on the basis of certain predefined standards It is the formal recognition authorization and registration of a laboratory that has demonstrated its capability competence and credibility to carry out the tasks it is claiming to be able to do In this book the reader will discover the whole process of laboratory accreditation with the various agencies involved as well as the benefits of laboratory accreditation The book closes up with ethical issues in research management It is obvious that the consideration of ethics in research should enhance mature decision making in harmony with changing technology. The chapter on this issue points out the fact that efficient research and laboratory management must be based on ethical principles that guarantee all stakeholders access to the benefits of new technologies with increased understanding of biological systems and responsible use of technology Some basic guidelines are given at the end on how to implement knowledge gained from the book to efficiently run a modern laboratory or research facility Food Toxicology and Safety Sofia Agriopoulou, Maria Tarapoulouzi, 2025-08-22 Food toxicology deals with the existence of dangerous toxic components that food may contain and various food processing contaminants are formed during the production process as a direct result of traditional and emerging food processing techniques This book brings together food toxicology and food safety linking them to several types of food processing It addresses the gaps in how contaminants are formed at different stages of food processing highlighting ongoing efforts related to food safety In addition it studies how processing technologies affect food products explaining the Medicine Andrew J. Fletcher, Lionel D. Edwards, Anthony W. Fox, Peter D. Stonier, 2003-01-31 Principles and Practice of Pharmaceutical Medicine begins with a detailed overview of its origins and goes on to examine current career opportunities education and training Encompassing the entire spectrum of pharmaceutical medicine it also discusses international drug development and registration including animal toxicology and human volunteers pharmacoeconomics and statistics medical services legal and ethical issues and business aspects It is the most up to date guide to drug development and marketing and

the only book with an international outlook The authors are all experts in their field and include an assessment of the current status of their specialities. This book provides an insight into how things may develop in the future. It is designed to be a guide for those who are actually practicing pharmaceutical medicine Indonesia, Post Report ,1986 **Biotechnology** Engineering Vinayaka B. Shet, Sandesh Kanthakere, Nabisab Mujawar Mubarak, Rama Rao Karri, Mohammad Hadi Dehghani, 2025-08-26 Biotechnology Engineering A Practical Approach on Bioprocess Development from Lab to Industrial Scale offers a comprehensive guide on biotechnology engineering focusing on transforming research and development into commercially viable industrial processes The book addresses the needs of the market by providing structured chapters practical methods and real world case studies Readers will gain valuable insights into bioprocessing basics scalable solutions optimization techniques and collaboration opportunities The text also covers essential regulatory compliance information bridging the gap between theoretical knowledge and practical applications. The book is a vital resource for academics scientists engineers and professionals in bioprocess development It includes detailed discussions calculations and case studies modern bioreactors and software tools used in the industry Serving as a desktop reference it effectively combines theory with real world applications to support the development of bioprocesses on all scales Helps readers understand the practical approach involved in bioprocess developments Includes calculations and case studies that are essential for independently scaling up bioprocesses from Erlenmeyer flask studies to bioreactors Provides insights into auditing requirements for the bioprocess industry BIOTECHNOLOGY - Volume XV Horst W. Doelle, J. Stefan Rokem, Marin Berovic ,2009-11-16 This Encyclopedia of Biotechnology is a component of the global Encyclopedia of Life Support Systems EOLSS which is an integrated compendium of twenty one Encyclopedias Biotechnology draws on the pure biological sciences genetics animal cell culture molecular biology microbiology biochemistry embryology cell biology and in many instances is also dependent on knowledge and methods from outside the sphere of biology chemical engineering bioprocess engineering information technology biorobotics This 15 volume set contains several chapters each of size 5000 30000 words with perspectives applications and extensive illustrations It carries state of the art knowledge in the field and is aimed by virtue of the several applications at the following five major target audiences University and College Students Educators Professional Practitioners Research Personnel and Policy Analysts Managers and Decision Makers and NGOs Haschek and Rousseaux's Handbook of Toxicologic Pathology, Volume 1: Principles and Practice of Toxicologic Pathology Wanda M. Haschek, Colin G. Rousseaux, Matthew A. Wallig, Brad Bolon, 2021-10-20 Haschek and Rousseaux s Handbook of Toxicologic Pathology recognized by many as the most authoritative single source of information in the field of toxicologic pathology has been extensively updated to continue its comprehensive and timely coverage The fourth edition has been expanded to four separate volumes due to an explosion of information in this field requiring new and updated chapters Completely revised with a number of new chapters Volume 1 Principles and the Practice of Toxicologic Pathology covers the practice of

toxicologic pathology in three parts Principles of Toxicologic Pathology Methods in Toxicologic Pathology and the Practice of Toxicologic Pathology Other volumes in this work round out the depth and breadth of coverage Volume 2 encompasses Toxicologic Pathology in Safety Assessment and Environmental Toxicologic Pathology These two sections cover the application of toxicologic pathology in developing specific product classes principles of data interpretation for safety assessment and toxicologic pathology of major classes of environmental toxicants Volumes 3 and 4 provide deep and broad treatment of Target Organ Toxicity emphasizing the comparative and correlative aspects of normal biology and toxicant induced dysfunction principal methods for toxicologic pathology evaluation and major mechanisms of toxicity These volumes comprise the most authoritative reference on toxicologic pathology for pathologists toxicologists research scientists and regulators studying and making decisions on drugs biologics medical devices and other chemicals including agrochemicals and environmental contaminants Each volume is being published separately Provides new chapters on digital pathology juvenile pathology in vitro in vivo correlation big data technologies and in depth discussion of timely topics in the area of toxicologic pathology Offers high quality and trusted content in a multi contributed work written by leading international authorities in all areas of toxicologic pathology Features hundreds of full color images in both the print and electronic versions of the book to highlight difficult concepts with clear illustrations Competition and Cooperation in Social and Political Sciences Isbandi Rukminto Adi, Rochman Achwan, 2017-12-01 The book contains essays on current issues in Social and Political Sciences such as the issues of governance and social order social development and community development global challenges and inequality civil society and social movement IT based community and social transformation poverty alleviation and corporate social responsibility and gender issues Asia and the Pacific are the particular regions that the conference focuses on as they have become new centers of social and political development Therefore this book covers areas that have been traditionally known as the social and political areas such as communication studies political studies governance studies criminology sociology social welfare anthropology and international relations International Cooperation, Convergence and Harmonization of Pharmaceutical Regulations Pierre-Louis Lezotre, 2013-12-05 International Cooperation Convergence and Harmonization of Pharmaceutical Regulations A Global Perspective provides the current status of the complex and broad phenomenon of cooperation convergence and harmonization in the pharmaceutical sector Part I thoroughly evaluates its added value and its critical parameters and influencing factors Part II in order to recommend actions and measures to support the next steps for cooperation convergence and harmonization Part III All of these recommendations in the book support the establishment of a better coordinated global pharmaceutical system which represents the best realistic alternative to fulfill the objective to establish a global coalition of regulators and to respond to an increased demand to further cooperation in the pharmaceutical sector This proposed framework which leverages all of the ongoing positive cooperation initiatives and uses as foundations all of the numerous harmonization projects developed over

the years presents advantages for all stakeholders and would definitively have significant added value to the promotion and protection of global public health The status of all major worldwide harmonization and cooperation initiatives at bilateral regional and global levels. The value of cooperation in the pharmaceutical sector and the driving factors behind harmonization The proposition of a structure for the global pharmaceutical system and timely recommendations for enhancing international cooperation as well as further discussion and policy changes in this area Functional Food Regulations in the United States and Around the World Debasis Bagchi, 2008-07-18 Globalization of the nutraceutical and functional food industries presents significant challenges not the least of which is the regulatory variance between countries active in the marketplace Nutraceutical and Functional Food Regulations in the United States and Around the World has been written by eminent experts in the field with the specific intention of addressing these important considerations Beginning with insights into the scope importance and growing opportunities in these industries the book demonstrates the global scenario on the acceptance and demand for nutraceuticals and functional foods It explores the regulatory hurdles and claim substantiation of these foods and dietary supplements as well as the intricate aspects of manufacturing procedures Including regulations from South America Canada European Union Australia New Zealand Africa Japan Korea China India and Southeast Asia as well as the United States Nutraceutical and Functional Food Regulations in the United States and Around the World provides a valuable resource for understanding the key considerations of operating in this rapidly expanding area Overview of nutraceutical and functional food regulations around the world Discusses the important of GRAS status and DSHEA regulations Provides insight on quality manufacturing techniques cGMP and standardized analytical techniques Includes salient features on overcoming regulatory hurdles Addresses the importance of safety efficacy and human clinical studies for worldwide acceptance Highlights anti terrorism safety assurance through traceability Explores the significance of intellectual property trademark and branding on marketing Indonesia .1997

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# **Good Laboratory Practice Indonesia Introduction**

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