



**PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME**

Pi 006-3
25 September 2007

**RECOMMENDATIONS
ON**

**VALIDATION MASTER PLAN
INSTALLATION AND OPERATIONAL
QUALIFICATION
NON-STERILE PROCESS VALIDATION
CLEANING VALIDATION**

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Pi 006 3 Recommendation On Validation Master Plan

Johann Harer, Christian Baumgartner



Pi 006 3 Recommendation On Validation Master Plan:

GMP-Qualifizierung und Validierung von Wirkstoffanlagen Ralf Gengenbach, 2012-02-16 Unter Validierung bzw. Qualifizierung versteht man die Beweisführung, dass Verfahren, Prozesse, Ausrüstungsgegenstände, Materialien, Arbeitsgänge oder Systeme tatsächlich zu den erwarteten Ergebnissen führen. Betroffen sind alle Unternehmen, die Rohstoffe, Halbfertig- oder Fertigprodukte für medizinische Geräte, Pharmazeutika, Diagnostika, Lebensmittel herstellen. Ebenso sind Labore betroffen, die Dienstleistungen anbieten, deren Ergebnisse direkt in den Herstellungsprozess einfließen. Dieses Buch liefert harte Fakten hinsichtlich der Durchführung von praxiserprobten Qualifizierungs- und Validierungsmaßnahmen. Ein Must-have für Wirkstoff- und Arzneimittelhersteller sowie deren Zulieferer. Der deutsche Titel zur Validierung und Qualifizierung: Biosimilars and Interchangeable Biologics Sarfaraz K. Niazi, 2016-01-05. What's the Deal with Biosimilars: Biosimilars are gaining momentum as new protein therapeutic candidates that can help fill a vital need in the healthcare industry. The biological drugs are produced by recombinant DNA technology that allows for large-scale production and an overall reduction in costs and development time. Part of a two-volume set. Reinraumtechnik Lothar Gail, Udo Gommel, Hans-Peter Hörtig, 2012-02-03. Vom Mobiltelefon über Kraftfahrzeugtechnik und Mikroelektronik bis hin zu modernen Arzneimitteln ist Reinraumtechnik überall dort anzutreffen, wo Produktentwicklung und -herstellung gesteigerten Qualitätsanforderungen genügen müssen. Die Neuauflage des Buches bringt neue Anwendungen und neue Methoden, aktuelle Ergebnisse der nationalen VDI und internationalen Reinraumkongresse ICCCS sowie neue Reinraum-Regulierungen der Pharmazie, EC-GMP, FDA und neue Richtlinien VDI 2083 und ISO 14644. Das Spektrum der Störeinflüsse, die durch Reinraumtechnik kontrolliert werden müssen, erweitert sich ständig. Themen wie Biokontamination, Molekulare Kontamination, Elektrostatik, Reinraumtauglichkeit und Isolortechnik gewinnen weiter an Gewicht. Das Buch mit seiner breiten Darstellung aller wichtigen Themenbereiche soll dem Anwender zugleich als Kompass und Ratgeber dienen. Es richtet sich an die Nutzer der Reinraumtechnik in allen Bereichen der Forschung und Industrie sowie an die Planer reinraumtechnischer Einrichtungen und die Hersteller von Geräten und Ausrüstungen. Anforderungen an Medizinprodukte Johann Harer, Christian Baumgartner, 2021-11-08. Alle relevanten Informationen und Anforderungen rund um Medizinprodukte und in vitro Diagnostika. Als Hersteller von Medizinprodukten und in vitro Diagnostika oder als deren Zulieferer müssen Sie eine immer größere Zahl an gesetzlichen Vorgaben und Qualitätsanforderungen erfüllen. ISO-Normen, EU-Richtlinien sowie länderspezifische Gesetze und Ausführungsbestimmungen. Dieses Buch navigiert Sie durch diese vielschichtigen Anforderungen an Medizinprodukte und in vitro Diagnostika. Die einzelnen Anforderungen werden dabei praxisorientiert vorgestellt, wobei Sie einen konkreten Leitfaden zu deren Umsetzung erhalten. Unter besonderer Berücksichtigung der neuen EU-Verordnungen und der aktuellen ISO 13485. Viele Beispiele, Tipps und Hinweise auf Stolpersteine erleichtern die Umsetzung in der Praxis. Highlights: Konkreter Leitfaden zur Umsetzung der regulatorischen Anforderungen. Berücksichtigt u.a. ISO 13485, MP und IVD.

VO cGMP Zum Download Praktische Arbeitshilfen und weiterf hrende Information The Certified Pharmaceutical GMP Professional Handbook Mark Allen Durivage,2016-05-23 The purpose of this handbook is to assist individuals for the Certified Pharmaceutical Good Manufacturing Practices Professional CPGP examination and provide a reference for the practitioner The second edition reflects the Body of Knowledge which was updated in 2015 This edition has also incorporated additional information including updated references The updates reflect the current trends and expectations of the evolving pharmaceutical industry driven by consumer expectations and regulatory oversight This handbook covers compliance with good manufacturing practices GMPs as regulated and guided by national and international agencies for the pharmaceutical industry It covers finished human and veterinary drugs and biologics and combination devices as well as their component raw materials including active pharmaceutical ingredients APIs and excipients and packaging and labeling operations

Practical Process Validation Mark Allen Durivage,Bob (Bhavan) Mehta,2016-07-14 For the past decade process validation issues ranked within the top six of Food and Drug Administration FDA form 483 observation findings issued each year This poses a substantial problem for the medical device industry and is the reason why the authors wanted to write this book The authors will share their collective knowledge to help organizations improve patient safety and increase profitability while maintaining a state of compliance with regulations and standards The intent of this book is to provide manufacturing quality professionals working in virtually any industry a quick convenient and comprehensive guide to properly conduct process validations that meet regulatory and certification requirements It will aid quality technicians engineers managers and others that need to plan conduct and monitor validation activities **The ASQ Certified Pharmaceutical GMP Professional Handbook**

Mark Allen Durivage,2024-09-30 The ASQ Certified Pharmaceutical GMP Professional Handbook assists candidates preparing for the Certified Pharmaceutical Good Manufacturing Practices Professional CPGP examination and serves as a handy reference guide for practitioners in the field This handbook covers compliance with good manufacturing practices GMPs as regulated and guided by national and international agencies for the pharmaceutical industry

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

chromatographer's book shelf GMP im Labor Nadine Frankenberg, 2022-07-15 GMP im Labor Der perfekte Leitfaden für Neulinge und Quereinsteigerinnen zur Etablierung eines GMP konformen Qualitätssystems mit besonderem Augenmerk auf die speziellen Bedürfnisse im Labor Good Manufacturing Practice GMP oder gute Herstellungspraxis ist ein System zur Qualitätssicherung von Herstellungsprozessen und Produkten basierend auf nationalen und internationalen Gesetzen Dabei beziehen sich die Richtlinien auf Produktionsabläufe und Umgebung in der Herstellung von Arzneimitteln und Wirkstoffen aber auch bei Kosmetika Lebens- und Futtermitteln GMP im Labor beschäftigt sich mit der Umsetzung von GMP Anforderungen in der Laborpraxis und präsentiert eine Grundlage für die Etablierung eines GMP konformen Qualitätssystems Besonders nützlich für Einsteigerinnen werden die speziellen Bedürfnisse im Laboralltag detailliert beleuchtet und praktische Lösungssansätze geboten Dabei wird genauer auf die gesetzlichen Grundlagen und Abgrenzung zu anderen Systemen GLP GCP ISO etc eingegangen und die verschiedenen Punkte eines Qualitätssystems wie etwa Dokumentation Validierung und Risikomanagement beleuchtet Des Weiteren werden die fundamentalen Prozesse in einem GMP konformen Qualitätssystem wie etwa Gerätequalifizierung Abweichungen und Selbstinspektionen behandelt und mit praktischen Lösungssansätzen präsentiert Dringend benötigt Das einzige Buch das einen umfassenden und doch komprimierten Einblick in die komplexe GMP Thematik bietet Praxisnah Es wird besondere Rücksicht auf die speziellen Bedürfnisse im Labor genommen und bietet praktische Lösungssansätze Leitfaden Behandelt die notwendigen Grundlagen und dient als Leitfaden zur Etablierung eines GMP konformen Qualitätssystems GMP im Labor richtet sich an Studierende in Bachelor und Master Studiengängen Doktorandinnen Naturwissenschaftlerinnen sowie Mitarbeiterinnen in Laboratorien und in der Industrie *Quality assurance of pharmaceuticals: a compendium of guidelines and related materials. Volume 2. Good manufacturing practices and inspection* World Health Organization, 2024-01-31 The GMP Compendium for Medical Products is a valuable resource for manufacturers regulators and other stakeholders involved in producing and distributing medical products It covers various topics from quality management systems to personnel hygiene equipment validation and complaint handling The guidance provided is based on the latest scientific and technical knowledge and considers the evolving regulatory landscape and the challenges faced by the industry **Hygienische Produktionstechnologie** Gerhard Hauser, 2012-02-28 Bei der Herstellung hochreiner Produkte spielt Hygienic Design moderner Anlagen Apparate Komponenten und Prozessräume eine entscheidende Rolle Die Lebensmittel Futtermittel Pharma Kosmetik und Bioindustrie sind aus hygienischen Gründen die Chemische und Farbenindustrie aus Gründen der Produktreinheit auf einwandfreie Sauberkeit ihrer Prozesseinrichtungen angewiesen Durch Optimierung der Reinigbarkeit lassen sich bei Produkten die für den menschlichen Konsum bestimmt sind Kontaminationen und Rückfaktionen vermindern bzw vermeiden und Anforderungen des Verbraucherschutzes leichter erfüllen In allen Industriezweigen können durch Hygienic Design erhebliche Kosten für den Reinigungsaufwand und zur Reduzierung der Umweltbelastung eingespart werden Das vorliegende Buch gibt u.a Antworten auf folgende Fragen Welche

Regelungen Leitlinien und Normen zur Gestaltung unter hygienischen bzw reinigungstechnischen Gesichtspunkten sind verfügbar und verpflichtend Was ist Stand der Technik Welches sind grundlegende Problembereiche Welche konstruktiven Verbesserungen sind möglich Neben rechtlichen Anforderungen werden theoretische Grundlagen Fragen des Einsatzes von Werkstoffen notwendige Oberflächenqualitäten sowie hygienegerechte Dichtungs- und Maschinenelemente diskutiert Für Anlagen Apparate Komponenten Prozessumgebung und räumliche Ausstattungen werden anhand vieler konstruktiver Praxisbeispiele Schwachstellen und Problembereiche sowie Möglichkeiten zu deren Verbesserung dargestellt Das Buch richtet sich an Ingenieure im konstruktiven Bereich der genannten Industriezweige im Anlagenbau und in der Zulieferindustrie Betriebsangehörige die für Risikoanalysen Qualität und Produktsicherheit bei der Produktherstellung verantwortlich sind erhalten viele praktische Hinweise auf apparatives Design

Single-Use Technology in Biopharmaceutical Manufacture Regine Eibl, Dieter Eibl, 2011-08-08 This book gives an overview of commonly used disposables in the manufacture of biopharmaceuticals their working principles characteristics engineering aspects economics and applications With this information readers will be able to come to an easier decision for or against disposable alternatives and to choose the appropriate system The book is divided into two parts the first is related to basic knowledge about disposable equipment and the second discusses applications through case studies that illustrate manufacturing quality assurance and environmental influence

Good Quality Practice (GQP) in Pharmaceutical Manufacturing: A Handbook Jordi Botet, 2015-09-28 Pharmaceutical manufacturing can be viewed as a supply chain which spans from the production and purchase of the starting and packaging materials through the manufacture of dosage forms until the safe reception of the finished product by the patient The entire chain comprises of several processes auditing materials purchase procurement production storage distribution quality control and quality assurance The quality standard for pharmaceutical production is current good manufacturing practice CGMP which is applied within the frame of a pharmaceutical quality system PQS This implementation however requires a scientific approach and has to take into account several elements such as risk assessment life cycle patient protection among other factors Hence pharmaceutical manufacturing is a complex subject in terms of regulation given the technical and managerial requirements This comprehensive handbook describes CGMP for new professionals who want to understand and apply the elements which build up pharmaceutical quality assurance The book gives details about basic quality control requirements such as risk management quality hazards and management systems documentation clean environments personnel training and gives guidelines on regulatory aspects This is an ideal handbook for undergraduates studying pharmaceutical or industrial manufacturing and supply chains as well for entrepreneurs and quality control professionals seeking to learn about CGMP standards and implementing quality assurance systems in the pharmaceutical sector

Data Integrity and Data Governance Robert D McDowall, 2018-11-06 Data integrity is the hottest topic in the pharmaceutical industry Global regulatory agencies have issued guidance after guidance

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

Environmental Monitoring for Cleanrooms and Controlled Environments Anne Marie Dixon, 2016-04-19 A critical technology in the science of contamination control environmental monitoring is a technique that provides important data on the quality of a process processing environment and final product which can aid scientists in identifying and eliminating potential sources of contamination in cleanrooms and controlled environments In response

Production of Plasma Proteins for Therapeutic Use Joseph Bertolini, Neil Goss, John Curling, 2012-12-06 Sets forth the state of the science and technology in plasma protein production With contributions from an international team of eighty leading experts and pioneers in the field Production of Plasma Proteins for Therapeutic Use presents a comprehensive overview of the current state of knowledge about the function use and production of blood plasma proteins In addition to details of the operational requirements for the production of plasma derivatives the book describes the biology development research manufacture and clinical indications of essentially all plasma proteins with established clinical use or therapeutic potential Production of Plasma Proteins for Therapeutic Use covers the key aspects of the plasma fractionation industry in five sections Section 1 Introduction to Plasma Fractionation initially describes the history of transfusion and then covers the emergence of plasma collection and fractionation from its earliest days to the present time with the commercial and not for profit sectors developing into a multi billion dollar industry Section 2 Plasma Proteins for Therapeutic Use contains 24 chapters dedicated to specific plasma proteins including coagulation factors albumin immunoglobulin and a comprehensive range of other plasma derived proteins with therapeutic indications Each chapter discusses the physiology biochemistry mechanism of action and manufacture of each plasma protein including viral safety issues and clinical uses Section 3 Pathogen Safety of Plasma Products examines issues and procedures for enhancing viral safety and reducing the risk of transmissible spongiform encephalopathy transmission Section 4 The Pharmaceutical Environment Applied to Plasma Fractionation details the requirements and activities associated with plasma collection

quality assurance compliance with regulatory requirements provision of medical affairs support and the manufacture of plasma products Section 5 The Market for Plasma Products and the Economics of Fractionation reviews the commercial environment and economics of the plasma fractionation industry including future trends highlighting regions such as Asia which have the potential to exert a major influence on the plasma fractionation industry in the twenty first century

Cleaning Validation Destin A. LeBlanc, 2022-12-23 Pharmaceutical manufacturers and upper management are encouraged to meet the challenges of the science based and risk based approaches to cleaning validation Using some of the principles and practices in this volume will help in designing a more effective and efficient cleaning validation program Features Timely coverage of cleaning validation for the pharmaceutical industry a dynamic area in terms of health based limits The author encourages pharmaceutical manufacturers and particularly upper management to meet the challenges of the science based and riskbased approaches to cleaning validation Draws on the author s vast experience in the field of cleaning validation and hazardous materials Discusses EMA vs ISPE on Cleaning Limits and revised Risk MaPP for highly hazardous products in shared facilities A diverse list of topics from protocol limits for yeasts and molds to cleaning validation for homeopathic drug products

Pharmazeutische Produkte und Verfahren Gerd Kutz, Armin Wolff, 2012-02-08 Die pharmazeutische Industrie geht weltweit zu den Kernbranchen und weist eine sehr lange und komplexe Wertschöpfungskette auf Dieses Buch bietet einen umfassenden Überblick über die Anforderungen an pharmazeutische Produkte und Herstellungsverfahren Es beschreibt detailliert die Vorgaben an pharmazeutische Produktionsanlagen Produktionsprozesse Geräte und Maschinen sowie die begleitenden Qualifizierungs und Validierungsmaßnahmen Es ist gleichermaßen geeignet für Ingenieure in der pharmazeutischen Industrie bzw in verwandten Industriezweigen Biotechnologie Lebensmittel Kosmetikindustrie sowie für Forscher und Studenten chemischer pharmazeutischer biotechnologischer und technischer Fachrichtungen

Good Clinical, Laboratory and Manufacturing Practices Philip Carson, Nigel Dent, 2007-10-31 Quality assurance and good laboratory practices are becoming essential knowledge for professionals in all sorts of industries This includes internal and external audit procedures for compliance with the requirements of good clinical laboratory and manufacturing practices Spanning chemical cosmetic and manufacturing industries Good Clinical Laboratory and Manufacturing Practices Techniques for the QA professional is aimed at chemists clinicians ecotoxicologists operation managers pharmaceutical process managers quality assurance officers technicians and toxicologists In addition sections on harmonisation of quality systems will be of value to safety health and environment advisors This comprehensive and high level reference will be an indispensable guide to research laboratories in academia and industry Additional training material is also included

Pharmaceutical Biotechnology Adalberto Pessoa, Michele Vitolo, Paul Frederick Long, 2021-07-15 Pharmaceutical Biotechnology A Focus on Industrial Application covers the development of new biopharmaceuticals as well as the improvement of those being produced The main purpose is to provide background and concepts related to

pharmaceutical biotechnology together with an industrial perspective This is a comprehensive text for undergraduates graduates and academics in biochemistry pharmacology and biopharmaceutics as well as professionals working on the interdisciplinary field of pharmaceutical biotechnology Written with educators in mind this book provides teachers with background material to enhance their classes and offers students and other readers an easy to read text that examines the step by step stages of the development of new biopharmaceuticals Features Discusses specific points of great current relevance in relation to new processes as well as traditional processes Addresses the main unitary operations used in the biopharmaceutical industry such as upstream and downstream Includes chapters that allow a broad evaluation of the production process Dr Adalberto Pessoa Jr is Full Professor at the School of Pharmaceutical Sciences of the University of S o Paulo and Visiting Senior Professor at King s College London He has experience in enzyme and fermentation technology and in the purification processes of biotechnological products such as liquid liquid extraction cross flow filtration and chromatography of interest to the pharmaceutical and food industries Dr Michele Vitolo is Full Professor at the School of Pharmaceutical Sciences of the University of S o Paulo He has experience in enzyme technology in immobilization techniques aiming the reuse of the biocatalyst and in the operation of membrane reactors for obtaining biotechnological products of interest to the pharmaceutical chemical and food industries Dr Paul F Long is Professor of Biotechnology at King s College London and Visiting International Research Professor at the University of S o Paulo He is a microbiologist by training and his research uses a combination of bioinformatics laboratory and field studies to discover new medicines from nature particularly from the marine environment

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