



THE CLEANING VALIDATION

| CHAPTER 19 |

May 21, 2024

Reference Guidelines: ISPE | APIC | PDA | EMA

POINTS TO CONSIDER WHEN USING QRM TOOLS FOR CLEANING PROGRAMS

SEVERITY: When evaluating severity, a decision must be made to assess toxicological severity [i.e. low ADE/PDE values (high hazard), biological, topical] from an industry perspective. It is recommended to assess risk from a patient perspective.

TOPICS TO CONSIDER WHEN ASSESSING SEVERITY

Severity	Rating Factors				
	5	4	3	2	1
Equipment use	Shared				Dedicated
Direct or Indirect	Product		Excipient		Buffers
Type of Product	Low ADE/PDE (High Hazard)	R _x (Prescription)	Over the Counter (OTC)	Nutritional	Cosmetics
HBEL	≤ 1 µg/day		≤ 10 µg/day		≤ 100 µg/day
Stability of Active	Stable	25% deactivated/degraded	50% deactivated/degraded	75% deactivated/degraded	Completely deactivated/degraded
Route of Administration	Intravenous		Oral		Topical
Cleaning Agents	Formulated		Commodity		Water Only
Microbial Concerns	Dry manufacturing processing step	Dry processing	Bacteriostatic or Low water activity Process Material	Sanitization steps prior to use	Sterilization steps prior to use
Proximity to Patient or further purification steps	Filling	Formulation*	Final Purification	Initial Purification or Recovery	Fermentation

*For drug product facilities, the risk factors could be 5 & 1 for filling or tableting, respectively. 5 = High Severity / 1 = Low Severity

Points To Consider For Cleaning Validation

Stanley Nusim



Points To Consider For Cleaning Validation:

Points to consider for cleaning validation PDA Pharmaceutical Cleaning Validation Task Force, 1998 Points to Consider for Cleaning Validation, 1998 Pharmaceutical Calibration, Validation and Qualification: A Comprehensive Approach Shiv Shankar Shukla, Ravindra Kumar Pandey, Beena Gidwani, Gunjan Kalyani, 2023-02-14 This up to date and unique monograph covers the different aspects of pharmaceutical validation calibration qualification and documentation It discusses the various methods and processes under all these heads It includes eight major sections and exhaustively covers each topic The book includes interesting and timely topics like the Validation of herbals considering the increasing reliance on herbal medicines It includes a section of validation of dosage forms which is an essential topic for any pharmaceutical scientist The chapters provide lucid illustrations figures flowcharts and other diagrams to facilitate understanding A final section on expert opinion provides a rundown about the global scenario to the readers The book serves as a complete reference material for students researchers and industry experts in the field of pharmaceutical sciences medicinal chemistry and pharmacology Compliance Handbook for Pharmaceuticals, Medical Devices, and Biologics Carmen Medina, 2003-12-09 This text lists the necessary steps for meeting compliance requirements during the drug development process It presents comprehensive approaches for validating analytical methods for pharmaceutical applications

Handbook of Process Chromatography Gunter Jagschies, Gail K. Sofer, Lars Hagel, 2007-12-08 This book will update the original edition published in 1997 Since the publication of the first edition the biotechnology and biologics industries have gained extensive knowledge and experience in downstream processing using chromatography and other technologies associated with recovery and purification unit operations This book will tie that experience together for the next generation of readers Updates include sources and productivity types of products made today experiences in clinical and licensed products economics current status of validation illustrations and tables automated column packing automated systems New topics include the use of disposables multiproduct versus dedicated production design principles for chromatography media and filters ultrafiltration principles and optimization risk assessments characterization studies design space platform technologies process analytical technologies PATs biogenerics comparability assessments Key Features new approaches to process optimization use of platform technologies applying risk assessment to process design *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 WHO Drug Information, 2021-02-18 **WHO Expert Committee on Specifications for**

Pharmaceutical Preparations World Health Organization, 2022-12-22 *Microbial Limit and Bioburden Tests* Lucia Clontz, 2008-10-14 In recent years the field of pharmaceutical microbiology has experienced numerous technological advances accompanied by the publication of new and harmonized compendial methods It is therefore imperative for those who are responsible for monitoring the microbial quality of pharmaceutical biopharmaceutical products to keep abreast of the latest c 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 **Active Pharmaceutical Ingredients** Stanley Nusim, 2016-04-19 To successfully bring an Active Pharmaceutical Ingredient API to market many steps must be followed to ensure compliance with governmental regulations This book is an unparalleled guide to the development manufacturing and regulation of the preparation and use of APIs globally This secoond edition brings readers up to date with the quality control regulations for APIs that have been added or amended since the first edition These updates help ensure that pharmaceutical professionals and drug manufacturers meet the established and required guidelines set forth by the US and international regulatory industries

Pharmaceutical Quality Systems Oliver Schmidt, 2000-04-30 When a pharmaceutical company decides to build a Quality System it has to face the fact that there aren t any guideline that define exactly how such a system has to be built With terms such as quality system quality assurance and quality management used interchangeably even defining the system s objectives is a problem This book provides a pr **Process Validation in Manufacturing of Biopharmaceuticals, Third Edition** Anurag S. Rathore, Gail Sofer, 2012-05-09 Process Validation in Manufacturing of Biopharmaceuticals Third Edition delves into the key aspects and current practices of process validation It includes discussion on the final version of the FDA 2011 Guidance for Industry on Process Validation Principles and Practices commonly referred to as the Process Validation Guidance or PVG issued in final form on January 24 2011 The book also provides guidelines and current practices as well as industrial case studies illustrating the different approaches that can be taken for successful validation of biopharmaceutical processes Case studies include Process validation for membrane chromatography Leveraging multivariate analysis tools to qualify scale down models A matrix approach for process validation of a multivalent bacterial vaccine Purification validation for a therapeutic monoclonal antibody expressed and secreted by Chinese Hamster Ovary CHO cells

Viral clearance validation studies for a product produced in a human cell line A much needed resource this book presents process characterization techniques for scaling down unit operations in biopharmaceutical manufacturing including chromatography chemical modification reactions ultrafiltration and microfiltration It also provides practical methods to test raw materials and in process samples Stressing the importance of taking a risk based approach towards computerized system compliance this book will help you and your team ascertain process validation is carried out and exceeds expectations

Sterile Manufacturing Sam A. Hout, 2021-07-04 This book highlights key ideas and factors to coach and guide professionals involved in learning about Sterile Manufacturing and operational requirements It covers regulations and guidelines instituted by the FDA ISPE EMA MHRA and ICH emphasizing good manufacturing practice and inspection requirements in the manufacturing of medicinal products Additionally this book provides the fundamentals of aseptic techniques quality by design risk assessment and management in support of sterile operations applications It creates a link to the implementation of business practices in drug manufacturing and healthcare and forms a correlation between design strategies including a step by step process to ensure reliability safety and efficacy of healthcare products for human and animal use The book also provides a connection between drug production and regulated applications by offering a review of the basic elements of sterile processing and how to remain viable with solid strategic planning The book is a concise reference for professionals and learners in the field of sterile operations that governs primarily pharmaceutical and medical device space but can also extend to food and cosmetics that require clean aseptic manufacturing applications It also helps compounding pharmacists and GMP inspectors and auditors *Handbook of Cell and Gene Therapy* Hazel

Aranha, Humberto Vega-Mercado, 2023-03-17 This handbook provides an in depth review of information across the developmental spectrum of gene and cell therapy products From introductory information to state of the art technologies and concepts the book provides insights into upstream processes such as vector design and construction purification formulation and fill finish as well as delivery options Planning steps for compliance with current good manufacturing practice cGMP to readiness for chemistry manufacturing and controls CMC are also discussed This book wraps up with examples of successes and pitfalls addressed by experts who have navigated the multiple challenges that are part of any innovative endeavor Features Provides the most up to date information on the development of gene therapy from the technology involved to gene correction and genome editing Discusses siRNA mRNA and plasmid manufacturing Describes the importance of supplier sponsor synergies on the path to commercialization Written for a diverse audience with a large number of individuals in the core technologies and supportive practices It is intended as a one stop resource for the availability of state of the art information related to cell and gene therapy products for researchers scientists management and other academic and research institutions Bioseparation Engineering I. Endo, T. Nagamune, S. Katoh, T. Yonemoto, 2000-03-17 The bioseparation engineering of today includes downstream process engineering such as waste water material and gas

treatment Taking this tendency into account bioseparation engineers gathered in Japan as a special research group under the main theme of Recovery and Recycle of Resources to Protect the Global Environment The scope of this book is based on the conference and deals not only with recent advances in bioseparation engineering in a narrow sense but also the environmental engineering which includes waste water treatment and bioremediation The contributors of this book cover many disciplines such as chemical engineering analytical chemistry biochemistry and microbiology Bioseparation Engineering will stimulate young engineers and scientists who will develop bioseparation engineering further in the 21st century and contribute to a world wide attention to the global environment **Points to Consider for Biotechnology**

Cleaning Validation, 2010 *Statistical Applications for Chemistry, Manufacturing and Controls (CMC) in the Pharmaceutical Industry* Richard K. Burdick, David J. LeBlond, Lori B. Pfahler, Jorge Quiroz, Leslie Sidor, Kimberly Vukovinsky, Lanju Zhang, 2017-02-14 This book examines statistical techniques that are critically important to Chemistry Manufacturing and Control CMC activities Statistical methods are presented with a focus on applications unique to the CMC in the pharmaceutical industry The target audience consists of statisticians and other scientists who are responsible for performing statistical analyses within a CMC environment Basic statistical concepts are addressed in Chapter 2 followed by applications to specific topics related to development and manufacturing The mathematical level assumes an elementary understanding of statistical methods The ability to use Excel or statistical packages such as Minitab JMP SAS or R will provide more value to the reader The motivation for this book came from an American Association of Pharmaceutical Scientists AAPS short course on statistical methods applied to CMC applications presented by four of the authors One of the course participants asked us for a good reference book and the only book recommended was written over 20 years ago by Chow and Liu 1995 We agreed that a more recent book would serve a need in our industry Since we began this project an edited book has been published on the same topic by Zhang 2016 The chapters in Zhang discuss statistical methods for CMC as well as drug discovery and nonclinical development We believe our book complements Zhang by providing more detailed statistical analyses and examples *Enhancing compliance to good manufacturing practices and pharmaceutical quality system requirements in vaccine production* World Health Organization, 2024-06-25 *Industrial Pharmacy - II* Mr. Rohit Manglik, 2024-04-06 EduGorilla Publication is a trusted name in the education sector committed to empowering learners with high quality study materials and resources Specializing in competitive exams and academic support EduGorilla provides comprehensive and well structured content tailored to meet the needs of students across various streams and levels

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