



# THE CLEANING VALIDATION

## | CHAPTER 19 |

May 21, 2024

Reference Guidelines: ISPE | APIC | PDA | EMA

### POINTS TO CONSIDER WHEN USING QRM TOOLS FOR CLEANING PROGRAMS

#### RISK PRIORITIZATION

Risk Priority Numbers (RPN) can be derived from a matrix that take inion, and to consideration the likeliness, detection, & impact of risks to produce a scalable value.

Once the risks are prioritized, a mitigation strategy can be agreed to.

RPN Value	Severity	Occurrence	Detection
10	Injury to a patient or employee; ADE < 1 µg/day	More than once per batch	Not detectable by current methods
7	Cause extreme customer dissatisfaction; ADE = 1 > 10 µg/day	Once per batch	All manually inspected
5	Something likely to result in a complaint; ADE = 10 > 100 µg/day	Once per six months	Statistical Sampling
3	Minor nuisance resulting in no loss; ADE = 100 > 1000 µg/day	Once every one to three years	100% Inspection
1	Be unnoticed and not affect performance ; ADE ≥ 1000 µg/day	One occurrence in greater than five years	Obvious or controlled and monitored & alarmed by control system

FMEA Scoring

# Points To Consider For Cleaning Validation

**Carmen Medina**



## **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      **WHO Expert Committee on Specifications for Pharmaceutical Preparations** ,2021-04-26 The Expert Committee on Specifications for Pharmaceutical Preparations works towards clear independent and practical standards and guidelines for the quality assurance of medicines and provision of global regulatory tools Standards are developed by the Expert Committee through worldwide consultation and an international consensus building process The following new guidance texts were adopted and recommended for use Guidelines and guidance texts adopted by the Expert Committee on Specifications for Pharmaceutical Preparations Points to consider when including Health Based Exposure Limits HBELs in cleaning validation Good manufacturing practices water for pharmaceutical use Guideline on data integrity WHO United Nations Population Fund recommendations for condom storage and shipping temperatures WHO United Nations Population Fund guidance on testing of male latex condoms WHO United Nations Population Fund guidance on conducting post market surveillance of condoms WHO Biowaiver List proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate release solid oral dosage forms WHO Certification Scheme on the quality of pharmaceutical products moving in international commerce Good reliance practices in the regulation of medical products high level principles and considerations and Good regulatory practices in the regulations of medical products All of the above are included in this report and recommended for implementation      Developments in Surface Contamination and Cleaning, Volume 7 Rajiv Kohli,Kashmiri L. Mittal,2014-11-18 As device sizes in the semiconductor industries are shrinking they become more vulnerable to smaller contaminant particles and most conventional cleaning techniques employed in the industry are not as effective at smaller scales The book series *Developments in Surface Contamination and Cleaning* as a whole provides an excellent source of information on these alternative cleaning techniques as well as methods for characterization and validation of surface contamination Each volume has a particular topical focus covering the key

techniques and recent developments in the area The chapters in this Volume address the sources of surface contaminants and various methods for their collection and characterization as well as methods for cleanliness validation Regulatory aspects of cleaning are also covered The collection of topics in this book is unique and complements other volumes in this series Edited by the leading experts in small scale particle surface contamination cleaning and cleaning control these books will be an invaluable reference for researchers and engineers in R D manufacturing quality control and procurement specification situated in a multitude of industries such as aerospace automotive biomedical defense energy manufacturing microelectronics optics and xerography Provides a state of the art survey and best practice guidance for scientists and engineers engaged in surface cleaning or handling the consequences of surface contamination Addresses the continuing trends of shrinking device size and contamination vulnerability in a range of industries spearheaded by the semiconductor industry and others Includes new regulatory aspects 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 Validation in Pharmaceutical Processes, Fourth Edition James Agalloco, Phil DeSantis, Anthony Grilli, Anthony Pavell, 2021-10-28 Revised to reflect significant advances in pharmaceutical production and regulatory expectations Handbook of Validation in Pharmaceutical Processes Fourth Edition examines and blueprints every step of the validation process needed to remain compliant and competitive This book blends the use of theoretical knowledge with recent technological advancements to achieve applied practical solutions As the industry s leading source for validation of sterile pharmaceutical processes for more than 10 years this greatly expanded work is a comprehensive analysis of all the fundamental elements of pharmaceutical and bio pharmaceutical production processes Handbook of Validation in Pharmaceutical Processes Fourth Edition is essential for all global health care manufacturers and pharmaceutical industry professionals Key Features Provides an in depth discussion of recent advances in sterilization Identifies obstacles that may be encountered at any stage of the validation program and suggests the newest and most advanced solutions Explores distinctive and specific process steps and identifies critical process control points to reach acceptable results New chapters include disposable systems combination products nano technology rapid microbial methods contamination control in non sterile products liquid chemical sterilization and medical device manufacture 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

**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 risk based 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

*WHO Drug Information*, 2021-02-18

**Parenteral Medications, Fourth Edition** Sandeep Nema, John D. Ludwig, 2019-07-19 Parenteral Medications is an authoritative comprehensive reference work on the formulation and manufacturing of parenteral dosage forms effectively balancing theoretical considerations with practical aspects of their development Previously published as a three volume set all volumes have been combined into one comprehensive publication that addresses the plethora of changes in the science and considerable advances in the technology associated with these products and routes of administration Key Features Provides a comprehensive reference work on the formulation and manufacturing of parenteral dosage forms Addresses changes in the science and advances in the technology associated with parenteral medications and routes of administration Includes 13 new chapters and updated chapters throughout Contains the

contributors of leading researchers in the field of parenteral medications Uses full color detailed illustrations enhancing the learning process The fourth edition not only reflects enhanced content in all the chapters but also highlights the rapidly advancing formulation processing manufacturing parenteral technology including advanced delivery and cell therapies The book is divided into seven sections Section 1 Parenteral Drug Administration and Delivery Devices Section 2 Formulation Design and Development Section 3 Specialized Drug Delivery Systems Section 4 Primary Packaging and Container Closure Integrity Section 5 Facility Design and Environmental Control Section 6 Sterilization and Pharmaceutical Processing Section 7 Quality Testing and Regulatory Requirements

**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

**WHO Expert Committee on Specifications for Pharmaceutical Preparations** World Health Organization, 2022-12-22 *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

**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 second 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

**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

**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

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