

THE CERTIFIED
**Pharmaceutical
GMP Professional**



HANDBOOK

SECOND EDITION

Mark Allen Durlivaga, Editor



Certified Pharmaceutical Gmp Professional Handbook

Mark Allen Durivage



Certified Pharmaceutical Gmp Professional Handbook:

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.

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.

The Certified Pharmaceutical GMP Professional Handbook Third Edition Mark Allen Durivage, 2024-02-28 *The Biomedical Quality Auditor Handbook, Third Edition* Heather Crawford, 2017-09-08 The Biomedical Quality Auditor Handbook was developed by the ASQ Biomedical Division in support of its mission to promote the awareness and use of quality principles, concepts, and technologies in the biomedical community. This third edition correlates to the 2013 exam Body of Knowledge BoK and reference list for ASQ's Certified Biomedical Auditor program. It includes updates and corrections to errors and omissions in the second edition. Most notably, it has been reorganized to align more closely with the BoK.

Practical Attribute and Variable Measurement Systems Analysis (MSA) Mark Allen Durivage, 2015-07-23 This book is a result of 30 years of quality-related work experience written to aid quality technicians and engineers. It provides the quality professional working in virtually any industry a quick, convenient, and comprehensive guide to properly conducting measurement systems analysis MSA. The intent of this book is to provide background and examples on the application of gage R. The simple answers are: profit, public health, and safety. Companies that are shipping product that is out of specification can be subjected to expensive litigation, especially in the aviation, pharmaceutical, and medical device industries. This book will be a useful reference when preparing for and taking many of the ASQ quality certification examinations, including the Certified Quality Technician CQT, Certified Calibration Technician CCT, Certified Quality Inspector CQI, Certified Six Sigma Green Belt CSSGB, Certified Quality Engineer CQE, Certified Six Sigma Black Belt CSSBB, and Certified Reliability Engineer CRE.

Practical Design of Experiments (DOE) Mark Allen Durivage, 2016-02-25 This book was written to aid quality

technicians and engineers It is a result of 30 years of quality related work experience To that end the intent of this book is to provide the quality professional working in virtually any industry a quick convenient and comprehensive guide to properly conducting design of experiments DOE for the purpose of process optimization This is a practical introduction to the basics of DOE intended for people who have never been exposed to design of experiments been intimidated in their attempts to learn about DOE or have not appreciated the potential of this family of tools in their process improvement and optimization efforts In addition this book is a useful reference when preparing for and taking many of the ASQ quality certification examinations including the Certified Quality Technician CQT Certified Six Sigma Green Belt CSSGB Certified Quality Engineer CQE Certified Six Sigma Black Belt CSSBB and Certified Reliability Engineer CRE

Managing Organizational Risk Using the Supplier Audit Program Lance B. Coleman, Sr, 2018-04-06 Risk elimination Risk management Risk mitigation These terms are an increasingly important part of the lexicon of executive level management as they strive to succeed in a business environment having global competition geographically diverse suppliers and new technologies In this new globally expansive marketplace more than 50 percent of value creation is achieved outside of an organization s walls or in other words through their suppliers This too is where the majority of product realization risk lies This book defines what risk based thinking is and how to apply it from the perspective of helping manage organizational risk through the supplier audit process It provides a detailed and useful discussion of the practical application of risk based supplier auditing principles It can be a primer for those new to the profession of supplier auditing and it also shares tips and best practices that would benefit experienced auditors as well The first section explores supplier management supplier auditing and the supplier audit process The second section discusses the skills both traditional and nontraditional needed to ensure a successful supplier audit Relevant aspects of ASQ s Certified Quality Auditor CQA and Certified Supplier Quality Professional CSQP Bodies of Knowledge are discussed in detail The author s friends and colleagues from around the globe shared their own stories in Case in Point vignettes interspersed throughout the book providing first hand case studies from among others the medical device logistics automotive and aerospace industries

Practical Engineering, Process, and Reliability Statistics Mark Allen Durivage, 2014-10-27 This book was written to aid quality technicians and engineers It is a compilation of 30 years of quality related work experience and the result of frustration at the number of books necessary at times to provide statistical support To that end the intent of this book is to provide the quality professional working in virtually any industry a quick convenient and comprehensive guide to properly utilize statistics in an efficient and effective manner This book will be a useful reference when preparing for and taking many of the ASQ quality certification examinations including the Certified Quality Technician CQT Certified Six Sigma Green Belt CSSGB Certified Quality Engineer CQE Certified Six Sigma Black Belt CSSBB and Certified Reliability Engineer CRE This book is an expansion of the work of Robert A Dovich in his books Quality Engineering Statistics and Reliability Statistics It builds on and expands Dovich s method of presenting statistical

applications in a simple easy to follow format *Human Error Reduction in Manufacturing* José Rodríguez-Pérez, 2018-08-27

For many years we considered human errors or mistakes as the cause of mishaps or problems In the manufacturing industries human error under whatever label procedures not followed lack of attention or simply error was the conclusion of any quality problem investigation The way we look at the human side of problems has evolved during the past few decades Now we see human errors as the symptoms of deeper causes In other words human errors are consequences not causes The basic objective of this book is to provide readers with useful information on theories methods and specific techniques that can be applied to control human failure It is a book of ideas concepts and examples from the manufacturing sector It presents a comprehensive overview of the subject focusing on the practical application of the subject specifically on the human side of quality and manufacturing errors In other words the primary focus of this book is human failure including its identification its causes and how it can be reasonably controlled or prevented in the manufacturing industry setting In addition to including a detailed discussion of human error the inadvertent or involuntary component of human failure a chapter is devoted to analysis and discussion related to voluntary intentional noncompliance Written in a direct style using simple industry language with abundant applied examples and practical references this book s insights on human failure reduction will improve individual organizational and social well being *Quality Risk Management in the FDA-Regulated Industry* José Rodríguez-Pérez, 2017-02-21

The purpose of this new edition is to offer an updated view of the risk management field as it applies to medical products Since the publication of the first edition 2012 the emphasis on risk based processes has growth exponentially across all sectors and risk management is now considered as significant as quality management ISO 9001 was revised and now requires that top management promote the use of risk based thinking ISO 13485 2016 which specifies the requirements for a quality management system specific to the medical devices industry also now shows a greater emphasis on risk management and risk based decision making In addition the FDA Food Safety Modernization Act FSMA is the most important reform of U S food safety laws in more than 70 years This indispensable book presents a systematic and comprehensive approach to quality risk management It will assist medical and food product manufacturers with the integration of a risk management system or risk management principles and activities into their existing quality management system by providing practical explanations and examples The appropriate use of quality risk management can facilitate compliance with regulatory requirements such as good manufacturing practice or good laboratory practice All chapters have been updated and revised and a new chapter has been added to discuss some of the most common pitfalls and misunderstandings regarding risk management specifically those related to the use of FMEA as the only element of risk management programs One of the appendices includes 12 case studies and the companion CD ROM contains dozens of U S FDA and European guidance documents as well as international harmonization documents ICH and GHTF IMDRF related to risk management activities as well as a 30 question exam with answers on the material discussed in the book **Practical**

Process Validation Mark Allen Durivage, Bob (Bhavan) Mehta, 2016-07-11 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 Serials Directory** ,1994 **The GMP Handbook** Brendan Cooper, 2017-07-17 CGMP Current Good Manufacturing Practices has legal and practical implications for manufacturers of medicinal products and medical devices The requirements to meet CGMP is legal requirement but it also ensures the patient receives products that are safe effective and of consistent quality The FDA WHO ICH PIC s AND Eudralex provide extensive guidance and regulations on many topics related to the manufacture of medicinal and drug products A large body of reference materials is available to manufacturers and engineering professionals This book brings together the key requirements of GMP and briefly examines the common themes and requirements published by the various authorities bodies and international organisations The book includes the following chapters Chapter 1 Overview of Good Manufacturing Practices Chapter 2 Quality Management Chapter 3 Personnel Chapter 4 Buildings and Facilities Chapter 5 Process Equipment Chapter 6 Documentation and Records Chapter 7 Materials Management Chapter 8 Rejection and re use of materials Chapter 9 Validation Chapter 10 Change Control Chapter 11 Complaints and recalls Page count 160 Paperback book Large 8 x 10 format [The FDA and Worldwide Current Good Manufacturing Practices and Quality System Requirements Guidebook for Finished Pharmaceuticals](#) José Rodríguez-Pérez, 2014-08-15 This guidance book is meant as a resource to manufacturers of pharmaceuticals providing up to date information concerning required and recommended quality system practices It should be used as a companion to the regulations standards themselves and texts on the specific processes and activities contained within the QMS This book includes chapters on US current Good Manufacturing Practice GMP international GMP global GMP guides and harmonization detailed analysis of the requirements and guidances missing subparts what inspectors are looking for and the price of noncompliance It also includes an appendix with two tabulated comparisons the first compares US European PIC S Canadian and WHO cGMPs while the second compares US cGMPs with effective quality system elements The companion CD contains cGMP regulations for sterile products produced by aseptic processing it also includes updated data of statistical enforcement by the FDA both domestically and abroad a detailed glossary and dozens of FDA guidance documents as well as international regulations EU and Canada and harmonization documents WHO PIC S and ICH A very comprehensive checklist for a cGMP audit that is based on risk management criteria

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Jose (Pepe) Rodríguez-Pérez, 2021-03-19 Why so many pharmaceutical companies are struggling to meet GMP and other regulatory requirements The reason is clear because they are trying to improve their quality management systems by fixing symptoms rather than by attacking the fundamental and primary root cause of their problems which is the lack of adequate quality and compliance culture The purpose of this book is to provide those leaders and senior managers with a clear roadmap to solve their regulatory problems and to return to the route of compliance by implementing a strong positive quality and compliance culture The recipe is simple all you need is good people including good leaders and senior managers good procedures and good training programs sailing into a strong and positive culture of quality and compliance When a company implements a behavior based quality and culture compliance they look into their problems as a whole and they understand that there are multiple factors including the soft ones related to personal and organizational behaviors that affect performance A very positive consequence of this systematic thinking is the shift from CAPA programs mostly correctives to ones where the systemic preventive actions are predominant Quality is everyone's responsibility but when it comes to creating strengthening or maintaining a culture within an organization there is one group who really owns it the leaders and senior managers The good news is that creating or strengthening a positive and sustainable quality culture is an achievable task although not an easy or quick one In this book you will find ten foundational principles of a strong and positive quality culture their associated desired behaviors and a set of leading indicators that can be used to monitor and enhance leadership engagement people engagement and culture and maturity

Quality Culture in the Pharmaceutical Industry Jose (Pepe) Rodríguez-Pérez, 2021-11-15 Why so many pharmaceutical companies are struggling to meet GMP and other regulatory requirements The reason is clear because they are trying to improve their quality management systems by fixing symptoms rather than by attacking the fundamental and primary root cause of their problems which is the lack of adequate quality and compliance culture The purpose of this book is to provide those leaders and senior managers with a clear roadmap to solve their regulatory problems and to return to the route of compliance by implementing a strong positive quality and compliance culture The recipe is simple all you need is good people including good leaders and senior managers good procedures and good training programs sailing into a strong and positive culture of quality and compliance When a company implements a behavior based quality and culture compliance they look into their problems as a whole and they understand that there are multiple factors including the soft ones related to personal and organizational behaviors that affect performance A very positive consequence of this systematic thinking is the shift from CAPA programs mostly correctives to ones where the systemic preventive actions are predominant Quality is everyone's responsibility but when it comes to creating strengthening or maintaining a culture within an organization there is one group who really owns it the leaders and senior managers The good news is that creating or strengthening a positive and sustainable quality culture is an achievable task although not an

easy or quick one In this book you will find ten foundational principles of a strong and positive quality culture their associated desired behaviors and a set of leading indicators that can be used to monitor and enhance leadership engagement people engagement and culture and maturity *The GMP Handbook* ,2020 **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 **The GMP Handbook (good Manufacturing Practice)** Anna Lundén,2008 **The GMP Handbook** Anna Lundén,2024

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