

THE
ASQ

CERTIFIED PHARMACEUTICAL GMP PROFESSIONAL

THIRD EDITION

HANDBOOK

MARK ALLEN DURIVAGE, Editor



Certified Pharmaceutical Gmp Professional Handbook

Mark Allen Durivage



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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

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