CERTIFIED PHARMACEUTICAL GMP PROFESSIONAL

MARK ALLEN DURIVAGE, Editor



The Certified Pharmaceutical Gmp Professional Handbook

Mark Allen Durivage

The Certified Pharmaceutical Gmp Professional Handbook:

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
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raw materials including active pharmaceutical ingredients APIs and excipients and packaging and labeling operations

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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 Rodríquez-Pérez, 2014-08-15 This quidance 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 is also included Finally a comprehensive GMP exam is also included

Quality Culture in the Pharmaceutical Industry 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 The Serials The GMP Handbook ,2020 The GMP Handbook Anna Lundén, 2014 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 Anna Lundén, 2024

Handbook of Investigation and Effective CAPA Systems, Second Edition José Rodríguez-Pérez, 2016-04-04 Understanding and improving the CAPA system as a whole is the focal point of this book the only of its kind dealing exclusively with this critical system within highly regulated industries Features include Information about the importance of the CAPA system within the quality system for the medical products regulated industry Fully updated with current versions of regulations U S FDA EU ISO 13485 and so on and a new section covers the regulatory expectation of customer complaint investigations Investigation and CAPA elements of the 2015 revision of the ISO 9001 standard New coverage on the investigation plan and the new U S FDA quality metric guidance as well as a section discussing the tight relationship between CAPAs and FMEA A new chapter fully devoted to human errors and human factors and their impact in the investigation and CAPA system Discussion of a dozen of the most common pitfalls commonly encountered in the investigation and CAPA world of regulated companies An example of an investigation and CAPA expert certification program being used for many companies Forms and

examples of the different elements investigation report root causes checklist human error investigation CAPA plan and so on covered in the book Fully usable forms are also included in the companion CD in Microsoft Word format While the first edition of this book was aimed solely at the FDA regulated industry the title of this second edition reflects the importance of the investigation root cause analysis stage as the necessary preceding step of any effective corrective and preventive action system Investigation and CAPA are concepts used in many sectors besides the FDA regulated industry such as automotive electronics aerospace telecommunications process industry and many more This book will become an essential reference for Pharmaceutical Manufacturing Handbook Shayne Cox Gad, 2008-03-11 With its coverage those in these other industries of Food and Drug Administration regulations international regulations good manufacturing practices and process analytical technology this handbook offers complete coverage of the regulations and guality control issues that govern pharmaceutical manufacturing In addition the book discusses quality assurance and validation drug stability and contamination control all key aspects of pharmaceutical manufacturing that are heavily influenced by regulatory guidelines. The team of expert authors offer you advice based on their own firsthand experience in all phases of pharmaceutical manufacturing **GMP Audits in Pharmaceutical and Biotechnology Industries** Mustafa Edik, 2024-06-28 The fact that good manufacturing practice GMP audits in the pharmaceutical and biotechnology industries have to be evaluated and with very limited resources has created a gap in this field The lack of trained and qualified GMP auditors is on the rise in all organizations that are required to implement FDA EMA MHRA WHO TGA and PIC S regulations This volume is an essential reference source for those organizations operating in the field of health and presents the basic knowledge needed to perform audits The author also provides useful tips and a selection of samples about GMP audits that are indispensable for professionals and health inspectors working in industry and health authorities Features An essential reference source for those organizations operating in the field of health and presents the basic knowledge needed to perform audits Anyone working in the manufacturing sector needs to be aware of GMP be able to identify operational flaws as well as legal violations and have a clear understanding of how to meet GMP standards Assists readers in understanding the importance of GMP and how they can apply each aspect in their working environment Covers a global regulatory landscape Suitable for relevant degree courses including industrial pharmaceutics and pharmaceutical biotechnology 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 **Practical Attribute and Variable** Measurement Systems Analysis (MSA) Mark Allen Durivage, 2015-07-27 This book a result of 30 years of quality related work experience was written to aid quality technicians and engineers It provides the quality professional working in virtually any industry a guick 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 **Basics of Pharmaceutical** Manufacturing and Quality Operations Erfan Syed Asif, Shahid Bader Usmani, 2024-03-14 This book provides guidance on how to meet the requirements of the pharmaceutical industry as a beginner It includes procedures for production and packaging batch auditing as well as all quality measures used in the pharmaceutical industry This book also provides questions and answers with each chapter for institutes and trainers providing basic training to the new graduates and new comers to the industry Basics of Pharmaceutical Manufacturing and Quality Operations A Comprehensive Guide is primarily written for anyone in the pharmaceutical industry interested in development and manufacturing of active pharmaceutical ingredient API and finished pharmaceutical manufacturers in both sterile and non sterile areas The book is a simple concise and easy to use reference tool covering basic quality concepts required by the pharmaceutical educational institutions and professional certification bodies It describes details of all GXP activities that are directly related to Quality Safety and Efficacy of the products manufactured under the umbrella of Quality Operations common testing methods which are used in any modern industry Requirements of Validation and Qualification of equipment facilities and processes integral segments of Drug product manufacturing storage and distribution practices The material provides stepwise guidance on how to evaluate audit qualify and approve a pharmaceutical product to enhance the GMP within the industry The book is written with the idea of providing basic knowledge to undergraduate students who are preparing to enter the industry at the end of their graduation The book would also be beneficial for institutions conducting pharmaceutical technology study courses in terms of GMP and GLP applications Features Provides readers and front line health care product manufacturers all the information they need to know to develop a GMP oriented industry with trained and skilled personnel and manufacture products that meet GMP and regulatory requirements Provides stepwise guidance on how to evaluate audit qualify and approve a

pharmaceutical product and packaging material to enhance the GMP within the industry Includes significant processes and steps in production for all common dosage forms Explains how in process and finished products are released Provides an ideal and effective tool for anyone starting Quality Assurance Quality control Production responsibilities **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

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