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Commissioning Training - Part 1 / 10 - OVERVIEW

~~Validation of Equipment | IQ OQ PQ | Qualification equipment |~~ **Equipment Qualification part-1 (urs,dq,fat,sat,iq,oq,pq)**

#PharmaGyan How are equipment qualified in pharmaceutical industry? IQ,OQ,PQ,VALIDATION

Knowing how to deal with the regulatory issues, understanding the impacts of

cleanliness, and recognizing the affect that poor facility layout will have on GMP spaces are only some of the issues an experienced Project Manager must focus on. Completely revised and updated, Sterile Product

Facility Design and Project Management, Second Edition provides comprehensive guidance on how to develop and execute biotech and other sterile drug facilities based on current industry best practices.

Each chapter highlights a specific issue centered on managing biotech facilities projects in a GMP environment. The author uses real-world examples of common industry practice to lead you through the

idiosyncrasies of a biotech project in an effort to answer some of the more common, and often perplexing, questions that can stand in the way of success. You get a mini seminar on each topic

covered. Breaking the project life-cycle into four phases, the text takes you through each phase from the Project Manager's viewpoint. Unlike other books that cover design, technology, and validation in general

terms, this book addresses the industry specific issues that make biotech facilities so costly and difficult to deliver. It puts the pieces of the puzzle together in a manner that increases your opportunity for success.

Pharmaceutical Extrusion Technology is the only resource to provide in-depth descriptions and analyses of the key parameters of extruders and extrusion processes. The book

highlights the applicability of melt extrusion in pharmaceutical drug development and product manufacturing, including controlled release, dissolution rate and bioavailability enhancement,

and granulation technology. It brings together the technical information necessary to develop and market pharmaceutical dosage forms that meet current quality and regulatory requirements and details

extruder hardware and controls, process definition and troubleshooting of single and twin screw extrusion processes, and more.

Pharmaceutical Isolators is

a new indispensable guide to the design, construction, commissioning, maintenance, use and monitoring of pharmaceutical isolators. The current validation protocols are explained and the book includes some

useful technical appendices. Written through the combined technical expertise of the Isolator Working Party, this new title will assist both experienced and new users to understand and manage this technology. The book will

also be a useful reference source for auditors, inspectors and all those involved in standard setting and monitoring.

A comprehensive introduction for scientists engaged in

new drug development, analysis, and approvals Each year the pharmaceutical industry worldwide recruits thousands of recent science graduates—especially chemistry, analytical chemistry, pharmacy, and

pharmaceutical majors—into its ranks. However, because of their limited background in pharmaceutical analysis most of those new recruits find making the transition from academia to industry very difficult. Designed to

assist both recent graduates, as well as experienced chemists or scientists with limited regulatory, compendial or pharmaceutical analysis background, make that transition, Pharmaceutical

Analysis for Small Molecules is a concise, yet comprehensive introduction to the drug development process and analysis of chemically synthesized, small molecule drugs. It features contributions by

distinguished experts in the field, including editor and author, Dr. Behnam Davani, an analytical chemist with decades of technical management and teaching experience in compendial, regulatory, and industry.

This book provides an introduction to pharmaceutical analysis for small molecules (non-biologics) using commonly used techniques for drug characterization and performance tests. The

driving force for industry to perform pharmaceutical analyses is submission of such data and supporting documents to regulatory bodies for drug approval in order to market their products. In addition,

related required supporting studies including good laboratory/documentation practices including analytical instrument qualification are highlighted in this book. Topics covered include: Drug

Approval Process and Regulatory Requirements (private standards) Pharmacopeias and Compendial Approval Process (public standards) Common methods in pharmaceutical analysis (typically compendial)

Common Calculations for assays and impurities and other specific tests Analytical Method Validation, Verification, Transfer Specifications including how to handle out of specification (OOS) and

out of trend (OOT)
Impurities including organic, inorganic, residual solvents and elemental impurities Good Documentation Practices for regulatory environment Management of Analytical

Laboratories Analytical Instrument Qualifications including IQ, OQ, PQ and VQ Due to global nature of pharmaceutical industry, other topics on both regulatory (ICH) and Compendial harmonization are

also highlighted.

Pharmaceutical Analysis for Small Molecules is a valuable working resource for scientists directly or indirectly involved with the drug development process, including analytical

chemists, pharmaceutical scientists, pharmacists, and quality control/quality assurance professionals. It also is an excellent text/reference for graduate students in analytical chemistry, pharmacy,

pharmaceutical and regulatory sciences.

Written by twenty-eight experts, filled with recommendations that can

immediately be put into action, this book provides the strategies and tactics required to link and harmonize manufacturing processes with GMP to achieve optimum operability and cost-effective

regulatory compliance. Drawn from name brand and generic companies and regulatory and contract organizations across the globe, the contributing authors bring readers a combined 450+ years of hands-on

experience. They offer thought-provoking questions to help readers diagnose their company's challenges, needs, and available options, all with the single purpose of achieving their ultimate goals: quality,

high productivity, and profitability.

To successfully bring an Active Pharmaceutical Ingredient (API) to market,

many steps must be followed to ensure compliance with governmental regulations. Active Pharmaceutical Ingredients is an unparalleled guide to the development, manufacturing, and regulation of the

preparation and use of APIs globally. Topics include:Safety, efficacy, and envi

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.

Pharmaceutical Production Facilities: Design and Applications considers the concepts and constraints that have to be considered

in the design of small, medium and large scale production plants. The layout, along with the flow of materials and personnel through facilities are considered with reference to ensuring compliance with

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