

# 21 CFR Part 11 Validation



**The Client:** Client is Asia's leading biopharmaceutical company which manufactures generic active pharmaceutical ingredients.



## Business Requirement



Validate the cloud based Learning Management System for 21 CFR Part 11 regulatory compliance



Design and execute test cases for Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ)



End to end validation for different user roles and document all validation activities including test protocols, test scripts, test evidences and test reports



## Our Solutions



Leveraged our jumpstart kit that includes Template, Guidelines, Checklists and Reports for 21 CFR Part 11 assessments



Developed and executed 1500+ test cases for IQ, OQ & PQ and 73 critical defects were reported



Performed exploratory testing as value addition and proposed a list of recommendations from user perspective



Created traceability Matrix that includes test cases linking requirements of 21 CFR Part 11



14 test cases were developed and reported to assess the System for 21 CFR Part 11 compliance



## Business Impact



Successfully passed the external compliance audit



Documentation for all the validation activities with evidences for the purpose of audit trail

**Technologies:** Software: Microsoft Azure Cloud service | Defect Tracking: Customized tool specialised for project

# 21 Cfr Part 11 Validation

**RJ Shavelson**



## **21 Cfr Part 11 Validation:**

**21 CFR Part 11** Orlando López,2004-01-15 Covering regulatory requirements stipulated by the FDA this book delineates the organization planning verification and documentation activities and procedural controls required for compliance with worldwide computer systems validation regulations The author introduces supporting technologies such as encryption and digital signatures and places **Ensuring the Integrity of Electronic Health Records** Orlando López,2020-12-21 Data integrity is a critical aspect to the design implementation and usage of any system which stores processes or retrieves data The overall intent of any data integrity technique is the same ensure data is recorded exactly as intended and upon later retrieval ensure the data is the same as it was when originally recorded Any alternation to the data is then traced to the person who made the modification The integrity of data in a patient s electronic health record is critical to ensuring the safety of the patient This book is relevant to production systems and quality control systems associated with the manufacture of pharmaceuticals and medical device products and updates the practical information to enable better understanding of the controls applicable to e records The book highlights the e records suitability implementation and associated risk assessed controls and e records handling The book also provides updated regulatory standards from global regulatory organizations such as MHRA Medicines and Healthcare Products Regulatory Agency UK FDA Food and Drug Administration US National Medical Products Association China TGA Therapeutic Goods Administration Australia SIMGP Russia State Institute of Medicines and Good Practices and the World Health Organization to name a few Practical Pharmaceutical Engineering Gary Prager,2018-11-28 A practical guide to all key the elements of pharmaceuticals and biotech manufacturing and design Engineers working in the pharmaceutical and biotech industries are routinely called upon to handle operational issues outside of their fields of expertise Traditionally the competencies required to fulfill those tasks were achieved piecemeal through years of self teaching and on the job experience until now Practical Pharmaceutical Engineering provides readers with the technical information and tools needed to deal with most common engineering issues that can arise in the course of day to day operations of pharmaceutical biotech research and manufacturing Engineers working in pharma biotech wear many hats They are involved in the conception design construction and operation of research facilities and manufacturing plants as well as the scale up manufacturing packaging and labeling processes They have to implement FDA regulations validation assurance quality control and Good Manufacturing Practices GMP compliance measures and to maintain a high level of personal and environmental safety This book provides readers from a range of engineering specialties with a detailed blueprint and the technical knowledge needed to tackle those critical responsibilities with confidence At minimum after reading this book readers will have the knowledge needed to constructively participate in contractor user briefings Provides pharmaceutical industry professionals with an overview of how all the parts fit together and a level of expertise that can take years of on the job experience to acquire Addresses topics not covered in university courses but which are crucial to working

effectively in the pharma biotech industry Fills a gap in the literature providing important information on pharmaceutical operation issues required for meeting regulatory guidelines plant support design and project engineering Covers the basics of HVAC systems water systems electric systems reliability maintainability and quality assurance relevant to pharmaceutical engineering Practical Pharmaceutical Engineering is an indispensable tool of the trade for chemical engineers mechanical engineers and pharmaceutical engineers employed by pharmaceutical and biotech companies engineering firms and consulting firms It also is a must read for engineering students pharmacy students chemistry students and others considering a career in pharmaceuticals

**Managing the Documentation Maze** Janet Gough, David Nettleton, 2010-03-16 The accessible easy to follow guide that demystifies documentation management When it comes to receiving documentation to confirm good science U S and international regulators place high demands on the healthcare industry As a result companies developing and manufacturing therapeutic products must implement a strategy that allows them to properly manage their records and documents since they must comply with rigorous standards and be available for regulatory review or inspection at a moment s notice Written in a user friendly Q A style for quick reference Managing the Documentation Maze provides answers to 750 questions the authors encounter frequently in their roles as consultants and trainers In simple terms this handy guide breaks down the key components that facilitate successful document management and shows why it needs to be a core discipline in the industry with information on Compliance with regulations in pharmaceutical biological and device record keeping Electronic systems hybrid systems and the entire scope of documentation that companies must manage How to write and edit documents that meet regulatory compliance Making the transition to an electronic system including how to validate and document the process Anyone responsible for managing documents in the health field will find this book to be a trusted partner in unraveling the bureaucratic web of confusion while it initiates a plan on how to put an effective lasting system in place one that will stand up to any type of scrutiny

**Handbook of Computer and Computerized System Validation for the Pharmaceutical Industry** Stephen Robert Goldman, 2003 This handbook details methods for sustainable compliance with GxPs and 21 CFR Part 11 validation requirements regarding computerized systems in the pharmaceutical biotechnology and medical device industry The handbook follows FDA guidelines and best industry practices in defining roles responsib

[SQL Server in Healthcare and Life Sciences: Building Compliant, Secure, and Intelligent Data Platforms](#) Selvamurugan Ramamoorthy, SQL Server in Healthcare and Life Sciences is a practical guide to building secure compliant and reliable data platforms using SQL Server This book explains how healthcare and life science organizations can design systems that protect sensitive data meet global regulations and support modern analytics You will learn how to use SQL Server for encryption auditing access control cloud and hybrid deployments and compliance with GxP HIPAA and 21 CFR Part 11 The book also includes clear frameworks best practices and real case studies from healthcare and research environments This is an easy to follow resource for data engineers DBAs architects and IT teams who want to create trusted

intelligent and audit ready data systems      **SAS Programming in the Pharmaceutical Industry, Second Edition** Jack Shostak,2014-03-01 This comprehensive resource provides on the job training for statistical programmers who use SAS in the pharmaceutical industry This one stop resource offers a complete review of what entry to intermediate level statistical programmers need to know in order to help with the analysis and reporting of clinical trial data in the pharmaceutical industry SAS Programming in the Pharmaceutical Industry Second Edition begins with an introduction to the pharmaceutical industry and the work environment of a statistical programmer Then it gives a chronological explanation of what you need to know to do the job It includes information on importing and massaging data into analysis data sets producing clinical trial output and exporting data This edition has been updated for SAS 9 4 and it features new graphics as well as all new examples using CDISC SDTM or ADaM model data structures Whether you re a novice seeking an introduction to SAS programming in the pharmaceutical industry or a junior level programmer exploring new approaches to problem solving this real world reference guide offers a wealth of practical suggestions to help you sharpen your skills This book is part of the SAS Press program      *Guidance for industry* ,2001      **American Biotechnology Laboratory** ,2008      Expert Resumes for Engineers Wendy S. Enelow,Louise Kursmark,2009 Expert Resumes for Engineers features an impressive collection of more than 180 pages of professionally written resume samples for all of the most prevalent types of engineers including civil mechanical industrial electrical electronics computer and more Plus top professional resume writers Enelow and Kursmark share tips and strategies for writing outstanding engineering resumes and finding the best jobs      **Endotoxins** Kevin L. Williams,2007-02-23 This source expertly examines the discovery biological structure control and continued clarification of endotoxin from a parenteral manufacturing perspective with in depth discussion of state of the art technologies involving Limulus amebocyte lysate LAL such as assay development automation depyrogenation Completely revised and expanded this Third Edition contains the knowledge necessary to apply endotoxin testing in the increasingly complex pharmaceutical environment featuring sections detailing the latest information regarding clinical advances regulation standards and validation procedures for computerized kinetic tests      **Food, Drug, Cosmetic Law Reporter** ,1963      Food Engineering ,2005      **Genome Research** ,2004      *Consultants & Consulting Organizations Directory: Descriptive listings and indexes* ,2009      **Control Solutions** ,2002      **The Chemical Engineer** ,2007      Chemical Engineering Progress ,2007      **American Laboratory** ,2006      Chemical Engineering ,2005

The Top Books of the Year 21 Cfr Part 11 Validation The year 2023 has witnessed a remarkable surge in literary brilliance, with numerous engrossing novels captivating the hearts of readers worldwide. Lets delve into the realm of bestselling books, exploring the fascinating narratives that have captivated audiences this year. The Must-Read : Colleen Hoovers "It Ends with Us" This heartfelt tale of love, loss, and resilience has captivated readers with its raw and emotional exploration of domestic abuse. Hoover expertly weaves a story of hope and healing, reminding us that even in the darkest of times, the human spirit can succeed. 21 Cfr Part 11 Validation : Taylor Jenkins Reids "The Seven Husbands of Evelyn Hugo" This captivating historical fiction novel unravels the life of Evelyn Hugo, a Hollywood icon who defies expectations and societal norms to pursue her dreams. Reids absorbing storytelling and compelling characters transport readers to a bygone era, immersing them in a world of glamour, ambition, and self-discovery. 21 Cfr Part 11 Validation : Delia Owens "Where the Crawdads Sing" This evocative coming-of-age story follows Kya Clark, a young woman who grows up alone in the marshes of North Carolina. Owens spins a tale of resilience, survival, and the transformative power of nature, entrancing readers with its evocative prose and mesmerizing setting. These top-selling novels represent just a fraction of the literary treasures that have emerged in 2023. Whether you seek tales of romance, adventure, or personal growth, the world of literature offers an abundance of engaging stories waiting to be discovered. The novel begins with Richard Papen, a bright but troubled young man, arriving at Hampden College. Richard is immediately drawn to the group of students who call themselves the Classics Club. The club is led by Henry Winter, a brilliant and charismatic young man. Henry is obsessed with Greek mythology and philosophy, and he quickly draws Richard into his world. The other members of the Classics Club are equally as fascinating. Bunny Corcoran is a wealthy and spoiled young man who is always looking for a good time. Charles Tavis is a quiet and reserved young man who is deeply in love with Henry. Camilla Macaulay is a beautiful and intelligent young woman who is drawn to the power and danger of the Classics Club. The students are all deeply in love with Morrow, and they are willing to do anything to please him. Morrow is a complex and mysterious figure, and he seems to be manipulating the students for his own purposes. As the students become more involved with Morrow, they begin to commit increasingly dangerous acts. The Secret History is a masterful and gripping novel that will keep you wondering until the very end. The novel is a warning tale about the dangers of obsession and the power of evil.

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