

# 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 specialized for project

# 21 Cfr Part 11 Validation

**Kevin L. Williams**

A decorative graphic element consisting of a light blue horizontal bar with a rounded right end, and a red circular glow behind it.

## **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

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**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 **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

*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

**American Biotechnology Laboratory** ,2008 *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

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web the column headings on the isr outline each achievement level and the scale score range associated with each achievement level four achievement levels i e not proficient level 3 level 4 and level 5 are reported for eog and eoc tests

**author notes american society of hematology** - Feb 26 2022

web nov 5 2020 multivariate analysis confirmed the association between ecog and tol basic p 0 05 extended p 0 01 as well as the lack of association of tol with gah or lee categories table 4 roc analysis showed that ecog score 0 4 explains 61 of the observed variability of basic tol auc 95 ci 0 48 0 74 and 68 of extended tol

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*what are eog scores synonym* - Jan 08 2023

web eog scores are ranked on a scale of one to four achievement levels with the fourth achievement level being the highest the exact number needed to reach each achievement level varies depending on the subject 3 significance students in grades 3 5 and 8 must post an eog score at achievement level three in order to advance to the next grade

**assessments understanding eog eoc test results** - May 12 2023

web the report provides you a summary of your child s score on one of the eog eoc or nnextend1 tests your child s performance is reflected in up to four data elements these elements are achievement level not proficient 3 4 or 5 for eogs and eocs or not proficient 3 or 4 for nnextend1 scale score percentile rank

**end of grade eog nc dpi** - Aug 15 2023

web the north carolina end of grade eog tests are designed to measure student performance on the goals objectives and grade level competencies specified in the north carolina standard course of study mathematics grades 3 8

north carolina end of grade tests reading mathematics and - Mar 30 2022

web the north carolina end of grade eog tests are standards based achievement tests in the areas of reading and mathematics at grades 3 8 and science at grades 5 and 8 the reading and mathematics tests are aligned to the north carolina standard course of study ncscs and the science tests are aligned to the north carolina essential standards

*national assessment scores say nc must help young readers* - Dec 27 2021

web oct 28 2022 when looking at other southern states surrounding states fourth grade reading scores were not significantly different from nc the average fourth grade reading scale score in virginia was 214 in tennessee was 214 in georgia was 216 and in south carolina was 216

**eog mathematics grades 3 8 test specifications nc dpi** - Nov 06 2022

web may 18 2021 the grades 3 8 end of grade eog mathematics tests measure students proficiency on the nc standard course of study ncscos for mathematics adopted by the north carolina state board of education in june 2017 test results will be used for school and district accountability under the accountability model and for federal reporting

**eog scale score range paulding county school district** - Jun 01 2022

web eog scale score range content area grade lowest obtainable scale score loss developing learner cut score proficient learner cut score distinguished learner cut score highest obtainable scale score hoss science grade 3 275 475 525 566 695 grade 4 230 475 525 578 730 grade 5 160 475 525 595 780 grade 6 175 475 525 610

**g eorgia mi lesto ne s georgia department of education** - Sep 04 2022

web for example a scale score of 525 on the grade 4 english language arts eog assessment from one form of the test or from one administration indicates the same examinee ability as a score of 525 from any other form or administration of the grade 4 english language arts eog assessment