

# 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

# 1 Cfr Part 11 Validation

**Wenkui Li, Jie Zhang, Francis L. S. Tse**

## **1 Cfr Part 11 Validation:**

**Design and Analysis of Clinical Trials** Shein-Chung Chow, Jen-Pei Liu, 2013-09-30 Praise for the Second Edition a grand feast for biostatisticians It stands ready to satisfy the appetite of any pharmaceutical scientist with a respectable statistical appetite Journal of Clinical Research Best Practices The Third Edition of Design and Analysis of Clinical Trials provides complete comprehensive and expanded coverage of recent health treatments and interventions Featuring a unified presentation the book provides a well balanced summary of current regulatory requirements and recently developed statistical methods as well as an overview of the various designs and analyses that are utilized at different stages of clinical research and development Additional features of this Third Edition include New chapters on biomarker development and target clinical trials adaptive design trials for evaluating diagnostic devices statistical methods for translational medicine and traditional Chinese medicine A balanced overview of current and emerging clinical issues as well as newly developed statistical methodologies Practical examples of clinical trials that demonstrate everyday applicability with illustrations and examples to explain key concepts New sections on bridging studies and global trials QT studies multinational trials comparative effectiveness trials and the analysis of QT QTc prolongation A complete and balanced presentation of clinical and scientific issues statistical concepts and methodologies for bridging clinical and statistical disciplines An update of each chapter that reflects changes in regulatory requirements for the drug review and approval process and recent developments in statistical design and methodology for clinical research and development Design and Analysis of Clinical Trials Third Edition continues to be an ideal clinical research reference for academic pharmaceutical medical and regulatory scientists researchers statisticians and graduate level students

**Writing In-House Medical Device Software in Compliance with EU, UK, and US Regulations** Philip S. Cosgriff, Matthew J. Memmott, 2024-03-26 This book is a comprehensive guide to producing medical software for routine clinical use It is a practical guidebook for medical professionals developing software to ensure compliance with medical device regulations for software products intended to be sold commercially shared with healthcare colleagues in other hospitals or simply used in house It compares requirements and latest regulations in different global territories including the most recent EU regulations as well as UK and US regulations This book is a valuable resource for practising clinical scientists producing medical software in house in addition to other medical staff writing small apps for clinical use clinical scientist trainees and software engineers considering a move into healthcare The academic level is post graduate as readers will require a basic knowledge of software engineering principles and practice Key Features Up to date with the latest regulations in the UK the EU and the US Useful for those producing medical software for routine clinical use Contains best practice

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

**Data Integrity in Pharmaceutical and Medical Devices Regulation Operations** Orlando Lopez,2016-11-03 Data integrity is fundamental in a pharmaceutical and medical devices quality system This book provides practical information to enable compliance with data integrity while highlighting and efficiently integrating worldwide regulation into the subject The ideas presented in this book are based on many years experience in regulated industries in various computer systems development maintenance and quality functions In addition to case studies a practical approach will be presented to increase efficiency and to ensure that the design and testing of the data integrity controls are correctly achieved

**Handbook of LC-MS Bioanalysis** Wenkui Li,Jie Zhang,Francis L. S. Tse,2013-09-03 Consolidates the information LC MS bioanalytical scientists need to analyze small molecules and macromolecules The field of bioanalysis has advanced rapidly propelled by new approaches for developing bioanalytical methods new liquid chromatographic LC techniques and new mass spectrometric MS instruments Moreover there are a host of guidelines and regulations designed to ensure the quality of bioanalytical results Presenting the best practices experimental protocols and the latest understanding of regulations this book offers a comprehensive review of LC MS bioanalysis of small molecules and macromolecules It not only addresses the needs of bioanalytical scientists working on routine projects but also explores advanced and emerging technologies such as high resolution mass spectrometry and dried blood spot microsampling Handbook of LC MS Bioanalysis features contributions from an international team of leading bioanalytical scientists Their contributions reflect a review of the latest findings practices and regulations as well as their own firsthand analytical laboratory experience The book thoroughly examines Fundamentals of LC MS bioanalysis in drug discovery drug development and therapeutic drug monitoring The current understanding of regulations governing LC MS bioanalysis Best practices and detailed technical instructions for LC MS bioanalysis method development validation and stability assessment of analyte s of interest Experimental guidelines and protocols for quantitative LC MS bioanalysis of challenging molecules including pro drugs acyl glucuronides N oxides reactive compounds and photosensitive and autooxidative compounds With its focus on current bioanalytical practice

Handbook of LC MS Bioanalysis enables bioanalytical scientists to develop and validate robust LC MS assay methods all in compliance with current regulations and standards [Wiley Encyclopedia of Clinical Trials](#) Joseph Massaro,2008 Here you ll find more than 500 entries from the world s leading experts in the field on the basic concepts methodologies and applications in clinical trials The range of topics includes basic statistical concepts design and analysis of clinical trials ethics regulatory issues and methodologies for clinical data management and analysis [Chemical Engineering](#) ,2005 **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 **Technical Manual** American Association of Blood Banks,2002 Manual includes many changes since the previous edition including a description of the 10 Quality System Essentials QSEs that make up Section A in the newest series of standards published by the American Association of Blood Banks Includes a new chapter on platelet and granulocyte antigens and antibodies *Code of Federal Regulations, Title 40, Protection of Environment, Pt. 63 (Sec. 63.8980-End), Revised as of July 1, 2011* Office of the Federal Register (U.S.) Staff,U S Office of the Federal Register,2011-10-30 *ASQC ... Annual Quality Congress Proceedings* ,2003 [Genome Research](#) ,2004 *California. Court of Appeal (1st Appellate District). Records and Briefs* California (State)., **Genetic Engineering & Biotechnology News** ,2008 **Science** John Michels (Journalist),2003 [American Laboratory](#) ,2006 **OSHA Standards for General Industry** CCH Incorporated,2006-02 **OSHA Standards for General Industry as of August 2007** CCH Incorporated,Debra Levin,2007-07 *Oregon Administrative Rules* ,2001

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web oct 7 2022 as we discussed yesterday i would like to request a formal leave of absence from my job for family reasons i plan to be away from november 2 2022 to december 30 2022 returning to work on january 3 2023 if approved i would be glad to help with a plan to cover my workload in my absence

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web a request for advanced sick leave is essentially a request for sick leave therefore the medical documentation requirements for granting of sick leave apply for details on supporting evidence for the use of sick leave please see our fact sheet entitled sick leave general information

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web jul 31 2023 begin your letter by explicitly stating that you are requesting sick leave mention the specific dates you need to be absent from work provide a valid reason briefly explain the reason for your sick leave you don t need to go into great detail but mention the illness or health condition that necessitates your absence be honest and transparent

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web acknowledge and agree that any sick leave advanced to me is considered a debt and that beginning with the first pay period after the advancement is approved i am required to repay the city of bothell by applying my future sick leave accruals each pay period

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web jul 31 2023 whatever the case if you need extended time away from work you should submit a leave of absence request to your employer in this article we offer several tips to help you compose a professional leave of absence request that appropriately addresses you and your employer s needs

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web the details of the bank guarantee are as follows bank guarantee number insert number amount of bank guarantee insert amount date of issuance insert date i request that the bank guarantee be cancelled with immediate effect as it is no longer required for the purpose for which it was issued

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web dec 11 2020 overview when writing a bank guarantee cancellation letter this means that you want to inform the bank manager that you have canceled the bank guarantee that you handed out to you as part of our obligations in project name or contract and released the funds back to your account often due to issues with the delivery by the supplier

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web 1 mention the date the account number and the amount of the guarantee 2 justify the reason s why you want to release return the guarantee 3 request from the bank to cancel release return refund or discharge the funds 4 request for the funds to available for withdrawal or transfer

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web cancellation application for issuance of a bank guarantee amendment of bank guarantee provide new details only of bank guarantee guarantee no 2 1 name and address of instructing party the customer 2 2 contact for customer 2 3 customer tel number 2 6 relationship of the applicant to the instructing party 3 1 beneficiary 3 2

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web what is an expiry date the expiry date is effectively the end date of your bank guarantee it s when your obligations to the favouree and the bank under the bank guarantee ends an expiry date ensures that at some point you will be able to get your security back provided there is no claim made by the favouree

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web nov 28 2020 date date subject cancellation of bank guarantee respected sir madam we request you to cancel bank guarantee in the name of name reason being not required wrongly created expired any other reason the following are details for your reference bank

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web nov 28 2021 request to cancel the letter of guarantee you can request to cancel a letter of guarantee with a status of given to beneficiary a letter of guarantee can be canceled when the validity of the letter ends to cancel a letter of guarantee the beneficiary must submit the original letter of guarantee and request that the bank

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web the bank guarantee cancellation request email visiting your nearest commonwealth bank of australia branch contacting our business banking team on 13 19 98 or your customer s relationship manager

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web application for bank issue of a guarantee amendment of a bank guarantee provide new details only renewal of a bank guarantee provide new expiry date or new guarantee amount with effective date if other than amendment date cancellation of a bank guarantee no 2 1 name and address of instructing party the customer 2 2 contact

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