



DATACOR NEWSBREAKS

The "Chempax Product Features" Resource

CHEMPAX C/S: VALIDATION TOOLKIT

For U.S. Food and Drug Administration (FDA) regulated industries, software system validation is required to ensure that the software automated operations will consistently produce results meeting predetermined specifications. Additionally, software system validation can be used by organizations that want to improve GxP (good practice) procedures and documentation. Datacor has developed a comprehensive and easy-to-follow Validation Toolkit to help ease the burden of validation due diligence and regulatory compliance in a reasonable and cost effective manner. The Validation Toolkit will assist businesses with completing the appropriate validation documentation of Chempax C/S.

WHAT IS COMPUTER SYSTEM VALIDATION?

"Validation" is the development and execution of a written plan to control documentary evidence. This documentary evidence provides the confirmation that a computerized system will accurately, reliably and consistently perform the regulated functions that are required. Per FDA documentation, the definition of validation is:

"Establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specification and quality attributes."



UPCOMING TRADE SHOWS

Meet Datacor Representatives at upcoming industry trade shows.

November

9 - 12: NACD 44th Annual Meeting

December

7: SOCMA's 94th Annual Dinner

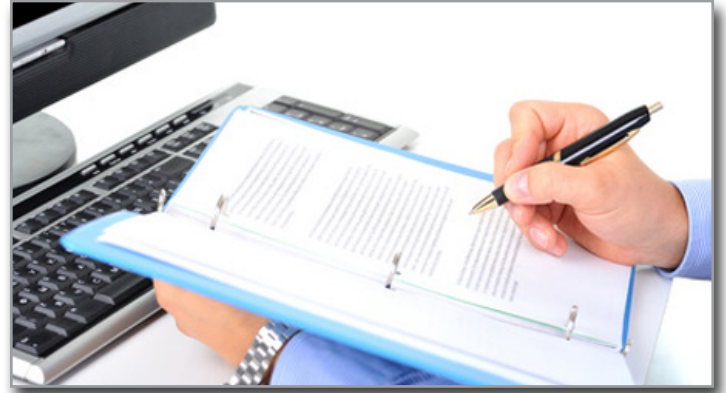
SAVE THE DATE

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CHEMPAX User Conference

May 11 - 13, 2016
Wyndham Hamilton Park
Hotel & Conference Center
Florham Park, NJ



Computer system validation is a technical documentation process that FDA compliant and high standard GxP organizations use to ensure that information technology applications fulfill their intended purpose. Stringent quality control requirements in FDA regulated industries impose the need for specific controls and procedures to be followed. Evidence that these controls and procedures have been followed and that they have resulted in a sound system which satisfies its requirements must be documented. The process of applying the appropriate controls and procedures and creating the necessary trail of documented evidence are all part of validating a computer system.



The objective of these controls and procedures is to document evidence that applicable computer systems will fulfill their intended purpose in a GxP production operation. The intention is to avoid software problems that could have a serious impact on the manufacturing and production cycle. Computer system validation requires a comprehensive set of equally important static testing activities that need to be conducted throughout the implementation and software development lifecycle.

WHO NEEDS TO BE VALIDATED?

Manufacturers who must comply with FDA regulations, including but not limited to: pharmaceuticals, botanicals, surgical instruments, medical devices, prosthetics, dental equipment and related supplies, orthopedics, medicinals, ophthalmic supplies, and diagnostic substances. These organizations must document that their related information technology systems applications fulfill their intended purposes to ensure that they meet the required production and inventory tracking standards.

Organizations who are also interested in creating and maintaining a high standard of GxP procedures can also benefit from completing a software validation of Chempax utilizing the Validation Toolkit. This will ensure that the organization has a sound production environment and has proper quality control procedures and documentation in place.





VALIDATION TOOLKIT ASSISTS IN THE VALIDATION PROCESS

Software validation within regulated chemical and process manufacturers can be a monumental task, especially for Enterprise Resource Planning ("ERP") systems such as Chempax C/S due to their large and complex nature. Datacor understands the unique challenges facing its FDA compliant users and offers a comprehensive Validation Toolkit to assist in complying with required software validation documentation. It provides a "roadmap" to follow throughout the validation process and is presented in an easy-to understand format. The Validation Toolkit also includes the necessary analyses, checklists, procedures, walkthroughs, reviews and test cases to assist users to quickly and effectively validate Chempax C/S.



CHEMPAX C/S VALIDATION TOOLKIT

The U.S. Food and Drug Administration validates an organization's implementation and use of a vendor's software rather than the software itself from the vendor. This therefore requires the end user of the software to perform a software validation and not the vendor. The documentation provided in the Validation Toolkit will assist the end user in capturing and documenting the required information for the implementation and on-going software lifecycle of Chempax C/S.

VALIDATION PLAN

Below is a high level chart of the 4Q life cycle Validation Plan (Design Qualification, Installation Qualification, Operational Qualification, and Performance Qualification) that Datacor utilizes:



VALIDATION TOOLKIT DOCUMENTS

The following documents are included in the Validation Toolkit to assist the end user in validating Chempax C/S:

#	Document
1	Introduction and Roadmap to Validation
2	Master Validation Plan
3	Design Qualification (DQ)
4	Risk Assessment and Management
5	Vendor Qualification (VQ)
6	Development and QC Protocol
7	Hardware Specifications (HS)
8	Installation Qualification (IQ) for Install
9	Installation Qualification (IQ) for Upgrades
10	Operational Qualification (OQ)
11	Performance Qualification (PQ)
12	Support and Maintenance
13	SOP and Change Control
14	Complying with U.S. FDA Title 21 CFR Part 11

VALIDATION TOOLKIT DOCUMENT EXAMPLES

Design Qualification Doc #: TK-CS.002.DQ

6.0 Design Qualification Check-List

Section One:

Required	Comments
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Purchasing & Receiving.

A. Blanket Purchase Orders

1	Ability to create blanket purchase orders and release materials as required.		
2	Support for blanket purchase orders for inventory.		
3	Support for blanket purchase orders for supplies.		
4	Ability to track and inquire on blanket releases.		
5	Ability to differentiate blanket releases from normal purchase orders.		
6	Support for header comments on the blanket order.		
7	Ability to change purchase order blanket expiration quantities.		
8	Ability to track quantity of product on order.		

B. Requisitions

1	Ability to create requisitions.		
2	Requisitions should be routed for approval to manager based on requisitioner.		
3	Ability to split requisitions between vendors.		
4	Ability to automatically notify requisitioner of change in status of requisition.		
5	Ability to convert a requisition to a purchase order.		
6	Automatic workflow routing of the requisition process based on user criteria.		
7	Ability to cancel open requisitions.		
8	Ability to merge multiple lines from multiple requisitions into one purchase order.		

C. Purchase Orders - General.

1	Ability to create order templates.		
2	Ability to close an order automatically based on tolerance percentages.		
3	Ability to cancel open orders.		
4	Ability to handle purchase orders where the total is not known in advance.		

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Installation Qualification Doc #: TK-CS.007.IQI

2. Enter the appropriate Progress Product Codes and Serial numbers

Server
 a. Client Networking - Serial #: _____ Control#: _____
 b. OE Studio - Serial #: _____ Control#: _____
 c. Database - Serial #: _____ Control#: _____

(ID _____; Date _____; P/F _____)

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Operational Qualification Doc #: TK-CS.009.OQ

Test Case # 6

Title: Inventory Stock Transactions and Quality Control

Purpose: To determine if the end-user can successfully update a Stock Transaction and edit and update a Quality Control Test. This will validate that Inventory control and Quality Control modules have been installed correctly and data can be written to the Progress database.

Acceptance Criteria:

- Open, view, edit and save the contents of a Stock Transaction in Inventory.
- Open, view, edit and save the contents of a QC Results Entry.

Step	Procedure	Expected Result	Actual Result	P/F	Init.	Date
1.0	Stock Transactions					
1.1	From the Chempax C/S menu, select Inventory Control >Entry> Stock Transaction Adjust Inventory	The Stock Transaction Adjust Inventory program opens without error				
1.1	Select a Product, a Warehouse, Lot and Location if required	The inventory qty and costs appear for each level				
1.2	Without changing any values, click OK.	A message will appear "Cost value is zero, would you like to continue"				
1.3	Click Yes	Adjust Inventory successful for Product code				
1.4	Click OK	Return to Stock Transaction Adjust Inventory Screen				
1.5	Click Exit	Message box appears - Do you want to exit from Stock Transaction Adjust Inventory screen				
1.6	Click Yes	Return to Menu				
2.0	QC Results Entry					

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HOW TO OBTAIN A COPY

If you are currently utilizing, or in the process of implementing Chempax C/S, and are subject to the FDA regulation or want to improve your GxP documentation, please contact our support team at cs-support@datacor.com to obtain a copy of the toolkit. A support specialist will be in touch shortly to discuss any questions or concerns you may have.

CONTACT US

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ANY QUESTIONS?

If you have any questions regarding the Chempax C/S Validation Toolkit please e-mail cs-support@datacor.com.

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