



# DATACOR NEWSBREAKS

The "Chempax Product Features" Resource

## CHEMPAX VB: VALIDATION TOOLKIT

For U.S. Food and Drug Administration (FDA) regulated industries, software system validation is required to ensure that the operation of the software 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 VB.

SAVE THE DATE

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CHEMPAX User Conference

May 16 - 19, 2017  
Harrah's Resort Atlantic City  
Atlantic City, NJ

## 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."





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 create documented evidence that applicable computer systems (Chempax) 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 VB 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 VB.



## CHEMPAX VB 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 requires the end user of the software to perform the 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 VB.

## 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 VB:

#	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.VB.002.DQ

Section Three: **General Ledger.**

	Required	Comments
<b>A. General Items.</b>		
1 Ability to store data for several years (previous and historical data).		
2 Ability to drill down on consolidated entries.		
3 Ability to perform a historical inquiry of transactions in an account.		
4 Support for automatically reversing journal entries.		
5 Support for recurring journal entries with a start and finish date.		
6 Ability to add ranges of accounts.		
7 Ability to copy ranges of accounts for a department or location.		
8 Ability to post by batches.		
9 Ability to specify recurring entries with the same amount each time.		
10 Ability to specify recurring entries without specifying an amount until posting the entries (as a template).		
11 Ability to post transactions with quantity values for comparison purposes.		
12 Ability to drill back through source modules to inquire on the source transaction details.		
13 Flexible account definition of X segments and Y characters.		
14 Support for multiple bank accounts in multiple currencies.		
15 Support for user defined periods in a financial year.		
16 Support for a user defined fiscal year.		
17 Support for foreign currencies interfacing from Accounts Payable.		
18 Support for foreign currencies interfacing from Accounts Receivable.		
19 Ability to inactivate accounts with no activity this year.		
20 Ability to automatically number journal entries.		
21 Ability to force balanced journal entries.		
22 Ability to track running balance of credits and debits during journal entry procedure.		
23 Maintains full account audit trails and history.		
24 All general ledger entries to be interfaced are double sided and self-balancing.		
25 All modules must have an interface to General		

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Installation Qualification Doc #: TK.VB.007.IQI

**Test Case # 2**

**Title:** Check that all Chempax folders have been installed in the Verify folder

**Purpose:** To determine if all the necessary folders were created and the proper number of files were built.

**Acceptance Criteria:**

- View and verify that the subfolders and EXE files of Chempax VB – Verify folders exists

Step	Procedure	Expected Result	Actual Result	P/F	Init.	Date
1	Find - main folders Chempax VB-Verify	Folders ChempaxVB-Verify exists				
2	Find CPX Databases Errorlog Install-Workstation Labelpax Offline ReportChanges ReportOutput VB.NET in the chempaxVB folder	All folders exist				
3	Find EXE files in the ChempaxVB folder. They are: AccessSecurity.exe Cpx6.exe Cpx6Launcher.exe Cpxarchive.exe Cpxclose.exe Cpxcompact.exe cpxcopyDatabase.exe cpxDButils.exe cpxDocumentDistribution.exe cpxExtension.exe cpxfixlinks.exe cpxfixsql.exe cpxLicenseInfo.exe cpxlink.exe	All EXE files exist – check them off				

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Operational Qualification Doc #: TK.VB.009.OQ

**Appendix A**  
Test Cases


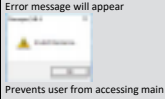
**Test Case # 1**

**Title:** Initial sign-on

**Purpose:** To determine if the end-user sign-on is properly validated and the end-user can successfully sign-on to Chempax VB.

**Acceptance Criteria:**

- View and access the Chempax Main Menu and Programs
- View and Verify that the About information matches the Installation documentation. This assumes that user has permission and access to all programs.

Step	Procedure	Expected Result	Actual Result	P/F	Init.	Date
1	Find and select Chempax VB icon	The icon is on the desktop  Sign on screen will appear.				
2	Type in invalid ID or invalid password and hit enter	Error message will appear  Prevents user from accessing main menu. Returns to sign on screen.				
2.1	Type in valid ID and Password and hit enter	Id and password will be validated – main menu will appear.				

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## HOW TO OBTAIN A COPY

If you are currently utilizing, or in the process of implementing Chempax VB, and are subject to the FDA regulation or want to improve your GxP documentation, please contact our sales team at [sales@datacor.com](mailto:sales@datacor.com) to obtain a copy of the toolkit. A sales representative will be in touch shortly to discuss any questions or concerns you may have.

## CONTACT US

**Datacor, Inc.**  
25 Hanover Road, Bldg. B, Ste. 300  
Florham Park, New Jersey 07932  
T: (973) 822-1551 | F: (973) 822-3976  
[marketing@datacor.com](mailto:marketing@datacor.com) | [www.datacor.com](http://www.datacor.com)

## ANY QUESTIONS?

If you have any questions regarding the Chempax VB Validation Toolkit please contact your primary support representative or e-mail [vbssupport@datacor.com](mailto:vbssupport@datacor.com).

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