SOFTWARECPR®
CRISIS PREVENTION AND RECOVERY, LLC

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Legal Disclaimer
The training document that follows should only be applied in the appropriate context with oversight by regulatory and software professionals with direct knowledge and experience with the topics presented**.** The document should not be used as a cookbook since it is not adequate for some situations and may be excessive for others.

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Software Validation Form
SoftwareCPR® Training Example for Discussion

Date:

Project Name:		**Project Leader:**	
Supplier **Risk Level** **Status:**	□ In-house □ Vendor □High □Medium □ Low □ In Development □ Released	**Installations:**	
Deliverable Names(s):		**Masters' Location:**	
Records Location(s):		**Notes:**	

Purpose and Scope:

Comments:

Planning Version Approvals: _____

Completed Validation Approvals :_____

1. Software Requirements

<Define intended use and explain risk/impact on quality system, product, support, and regulatory records as appropriate.>>

<< Define high level or detailed requirements(depending on type of application, criticality, and complexity) as appropriate or reference other requirements documents, quality system procedures, product specifications, hardware documentation, as relevant. Include security and electronic record/signature requirements if relevant.>>

<< Include normal and abnormal conditions. Reference a separate software requirements specification if necessary. More risk and complexity more detail.>

2. Design Description

< Describe the software's design or reference a separate design description if necessary. Indicate role of third party packages, use of vendor supplied software. Except for large systems keep this simple.>

3.Programming

< Indicate method of master source control,coding standards, revision naming, directory structure, physical location, and security methods. Indicate any specific options to setup, configuration files or tables.>

4. Testing

<Define or reference test plans, protocols, cases or include protocol for inclusion in Equipment/Installation Qualification. Define or reference independent test methods and test equipment. Reference evidence of testing including printout and protocol results. Describe how all test types have been addressed and requirements have been addressed..>

< If output of application is fully or partially verified by other activities downstream (e.g., device software testing, product testing, equipment qualification etc.) explain how this contributes to validation evidence and reference where objective evidence can be found. Relevant to many tools such as compilers as well as upstream design and manufacturing automation.>

5. Configuration Management

<Reference SOPs for change control or define change control, release naming and control, backups, archives & distribution.>

6. Tools & Software Environment

< Identify tools and software operating environment including specific version numbers>

7. HW & Ambient Environment

<Specify hardware platform, minimum resource requirements, power requirements, and ambient environment (e.g., light levels, ESD control, dust, temperature) as relevant.>

8. User Training & Documentation

<Define or reference user training and reference materials including vendor supplied manuals if to be supplied to users>

9. Operation

< Define or reference procedures for periodic monitoring (include checks on software revision proper operation, anomaly reporting and analysis), administration, security

patches, evaluation of COTS/vendor issues lists and release notes, security, backups, recovery, maintenance, environmental and platform control, usage, and auditing.>

10 Other Relevant SOPs

<List existing SOPs and/or an SQA plan that apply to this software>

11. Other:

< If OTSS/SOUP used include vendor/package qualification information and results of review of known issues lists for each.>

< If application/tool validated previously or partially by other company groups or by vendor explain here, reference relevant evidence and provide rationale for reduced validation for this instance>>

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