

Tools Customization & Validation

for Design Control

Trace/coverage tools

Change control and defect tracking tools

Requirements management tools

Source code control tools

Tailored to your process & preferences

Initial Evaluation / Analysis

Tool Validations for 820.70(i) Compliance

Onsite or remote tools supported

On-site Training courses

...Turn for details



Tool Customization and Validation for Design Control

- **Customized to your needs**
- **For complex product development Lifecycles**
- **Onsite or Offsite systems supported**

We will work with you to plan your tool development and validation activities. SoftwareCPR[®] has the experience to integrate a multitude of tools with the rest of your design, and validation tools. We will prepare the necessary documents, install, customize, validate, and maintain the tools needed according to your processes. Our clients range from large corporations to small start-up companies. Many start-up companies find that having us provide hands-on support for all of their tool validation activities helps speed up the product development lifecycle and alleviates the need for hiring extra staff to support these tools.

Our approach is simple and compliant, integrating semi-automated change management tools early in the process can help to prevent costly changes found late in the development cycle. Our services are tailored to your needs, your products, your regulatory perspective, and your business objectives – services range from review and evaluation to full hands-on integration.

Our staff has years of experience managing, developing and testing regulated products. Alan Kusnitz, SoftwareCPR[®]'s Managing Partner, is the lead instructor for public AAMI/FDA Software Validation Training courses and has performed internal training for FDA staff. We understand regulatory agency expectations and how best to articulate your approach.

Tool Documentation – We can help prepare the software documents including the related Procedures, Plans, Requirements and Tool Validation Test Cases, Test Summaries, and Trace/coverage maps as well as any other required elements.

Requirements Management Tools – Requirements are the foundation for a software product. We can help install, configure, document, validate and maintain your products requirements in a tool that enhances requirement traceability. No one requirement should be left behind.

Source Code Management – We can help Install, configure, document, validate and maintain a multitude of SCM tools that are on the market today. Our staff includes programmers that have experience designing and developing a wide range of regulated products and the tools that support these products.

Defect Tracking – We can help Install, configure, document, validate and maintain a multitude of Defect Tracking tools that are on the market today. Whether web based or local to your servers. With the advanced configurability and scalability of tools together with our experience can aide all team members in being informed and on schedule.

Process documents – We can help you create the necessary plans and procedures that are essential for software development compliance when using these tools.

Onsite or Offsite, we understand the need for these tools is one thing but tailoring them to your process and validating and maintaining them is another. We provide both tool integration onsite or we can manage separate scalable client/server solution that are housed on a SoftwareCPR[®] tools server offsite. This gives our clients the ultimate flexibility.