SOFTWARECPR®
CRISIS PREVENTION AND RECOVERY, LLC

Software Validation & Preparation

for Premarket Submissions

Tailored to your process & preferences

Articulation in FDA Terminology

Planning, review, or outsourcing

FDA Interaction and negotiation

PMAs, IDEs, 510(k)s, 513(g)s

Software Information Sections

Full Submission Preparation

CDRH and CBER Submissions

On-site Training courses

…Turn for details

For more information contact us at info@softwarecpr.com, www.softwarecpr.com, or by phone at 781-721-2921

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www.softwarecpr.com

Software Validation and Preparation for Premarket Submissions

- **Customized to your needs**
- **Risk-based approach**
- **Planning, review, or outsourcing**

We will work with you to plan your medical device software development and documentation (prospectively or retrospectively). We will prepare documentation and perform the tasks necessary for FDA submission and associated supporting documentation. 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 validation activities helps speed up product submissions and alleviates the need for hiring extra staff.

Our approach is risk-based, emphasizing risk analysis early in the process to help prevent costly changes late in the development cycle and to provide the safest products possible. Our services are tailored to your needs, your products, your regulatory perspective, and your business objectives – services range from review and evaluation to hands-on testing.

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

Submission Documentation – We can help prepare the software documents for 510(k), PMA, and IDE Submissions including the related Procedures, Plans, Requirements and Design Specifications, Risk Analysis, Test Plans, Test Cases, Test Summaries, and Trace/coverage maps as well as all other required elements. We can also provide support for your entire submission – not only the software section.

Requirements Documents – Requirements are the foundation for a software product. We can help create this important documentation that forms the basis for your product and for its validation.

Design – We can help document your existing design, or perform technical design reviews. Our staff includes programmers that have experience designing and developing a wide range of regulated products.

Risk Analysis – We can help you perform risk analysis for your software and your product. Proper risk analysis is essential for successful software submissions, but it can be difficult and confusing. Our senior staff includes risk management experts recognized by public standards organizations and FDA. We have performed risk analysis for products ranging from low to high risk and know how to scale and document this difficult task. Our involvement often results in a safer product as well as a successful submission.

Code Review – Our staff can establish a review process for your organization, help you create software coding guidelines, or perform independent code reviews.

Test Planning, Test Execution and Traceability – Our staff can help you plan and execute unit, integration and system tests. Testing work may be done at your site, or off-site. Testing work also includes documents to trace the requirements, risk mitigations and software components to the tests that cover these areas. We can work with your staff, your contractors, or provide full support.

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

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