2020 SoftwareCPR® Public Training Course

IEC 62304 and Emerging Standards and FDA Expectations for Medical Device and Health IT Software

Agenda

Regulatory bodies and Standards

SOUP / Off-The-Shelf Software (OTSS) / Legacy

Software Risk Management

Requirements

Architecture and Design

Unit Implementation and Verification

Integration, Integration Verification, & SW System Verification

Release

Software Configuration Management

Maintenance & Problem Resolution

Planning

Tracing & Documentation

Design Validation, Usability

This three-day course provides a clear understanding of applying IEC 62304 standard for medical device software and much more. The course compares and contrasts 62304 with FDA expectations and discusses approaches for alignment. In addition, participants will learn of other relevant standards and technical reports pertinent to medical device software, HealthIT, medical mobile apps, and Software as a Medical Device (SaMD) products (e.g., 82304, 80002-1, 14971, 80001-2-*x*, 62366).

Participants will gain practical advice and pragmatic experience with all types of medical software. Participants will leave with a clear understanding of how to effectively and efficiently integrate 62304 compliance into their software development lifecycle (SDLC).

Key topics:

- Brief Regulatory Background - US FDA, EU
- Types of Software - Medical Devices, Health-IT, General Wellness, Cloud Services, Mobile Medical Apps, Personal Health Software
- Design Controls / 62304 in the context of a system
- Overview of related standards and guidance 60601-PEMS, 82304 Health Software, 80002-1 Risk Management Background and Structure, 80001-1 IT Networks, 62366 Usability
- Software risk management / Device risk management / Process as risk control / Cyber risk
- 62304 Safety Classifications / FDA LOC
- Probability and severity related to software
- Development Process Planning / Agile methods Planning
- SOUP, Off-the-shelf, and Legacy Software
- Requirements / Product level vs software / Formative usability
- Architecture and detailed design
- Implementation, coding, unit verification
- Integration and integration testing
- Managing risk after release
- Document hierarchies and traceability / Electronic records
- Maintenance Process / Change Control / Problem issue management
- Validation / 82304 / Summative usability / Cybersecurity
- Mobile medical apps, cloud-based health software, and general wellness
- Release / Configuration management / Rapid & frequent release

SOFTWARECPR®
CRISIS PREVENTION AND RECOVERY, LLC

COURSE DATES: Sep 22-24, 2020
TRAINING LOCATION: Zoom Virtual (8:30 am – 5:00 pm EDT)

About the Instructor:

Brian Pate

Brian has over 35 years in the medical device industry as a biomedical and software engineer, various levels of management in medical device companies, and now is a Partner and General Manager of SoftwareCPR®. Brian has taught software validation courses at FDA, for AAMI, and both public and private courses for SoftwareCPR®. Brian helped create both AAMI TIR32 and AAMI TIR45 is a member of the UL Standards Technical Panel 5500, Remote Software Updates.

For more information, or to register for this course,
email training@softwarecpr.com