SOFTWARECPR®
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SoftwareCPR® News:

Our most popular on-site training course continues to be: ***Efficient Use of Medical Device Software Standards 62304, 60601-1 PEMS, TIR32 and 14971 for Safety and Compliance.*** This course focuses on IEC 62304 but also covers many related standards as well as FDA regulations and guidance. We have provided similar training to Health Canada. This course includes a new module on **using Agile Methods in a conformant and compliant manner.** If you are interested in on-site training let us know and we'll work out a proposal that will include tailoring for your needs. Instructors for this course were directly involved in development of the standards and have technical and FDA compliance background as well. We can also provide consulting starting with our checklists and templates to map your current process to IEC 62304 and FDA guidance, identify gaps and develop improvements including harmonization across multiple divisions of your company.

Our next most popular courses relate to device and software risk management and these can be tailored to your current process and device type. Also highly effective is our involvement in technical review of your risk analyses by one or more of us that have been directly involved in software risk management standards development and risk analysis for a wide range of devices.

We have posted several training templates for annual subscribers providing example frameworks and explanations for a software development procedure, development plan, and risk analysis that can help ensure conformance to IEC 62304.

Standards and Regulatory Highlights:

IEC 80002-1 Medical Device Software Risk Management has been released. This standard includes some of the material in AAMI TIR32 with less focus on lifecycle activities and a primary focus and mapping to ISO 14971.

Health Canada has reclassified Patient Management Systems indicating they are considered medical device. In addition there are several initiatives underway in the EU that increase focus on these as well as other standalone software from a regulatory perspective.

IEC 62304 has been harmonized in the EU (including for In Vitro Diagnostic devices) and that together changes in the device directives effective next year that clarify the broad scope of software considered medical devices continue to increase the regulatory focus on and requirements for software.

Newsletter Instructions

The items listed on the following pages are organized according to their location in the **REFERENCE** section of www.softwarecpr.com . Some sections of this newsletter provide a complete index, others just recently added items. If you have trouble finding an item of interest, send email to office@softwarecpr.com. **Note: Items with the "$" symbol on the website including most of items in the Educational Documents category are only accessible to those with valid logins**. If you are not a subscriber, and would like more information on becoming one, right click Subscription Page.

SoftwareCPR® Consulting, training , and Annual Subscriptions

SoftwareCPR® provides training in FDA regulation, risk management, and software validation. Alan Kusinitz of SoftwareCPR® has provided in-house training to FDA and Health Canada and is on the AAMI Software Committee and involved in international software standards. Sherman Eagles chairs many of the international software working groups. Several other SoftwareCPR® partners have been involved in development of FDA recognized standards for medical device software and EU software guidance. Consider having us update you on current regulatory expectations.

SoftwareCPR® also performs auditing, consulting and crisis management for all aspects of FDA regulation including quality systems, design control, and premarket submissions as well as hands-on support for risk management and validation.

Remember if you are a paid subscriber you can submit questions on the website for guaranteed response from one of our experts, obtain word copies of any of our posted educational aides, and can receive all of our bulletins and newsletters.
If you are not a paid subscriber more information about the value of subscribing is available at http://www.softwarecpr.com/subscriptionramepage.HTM .

20 Berkshire Drive Winchester, MA 01890 USA
Telephone (781) 721-2921
email: office@softwarecpr.com

TOPIC PAGES
Selected popular items for specific topics

- **NASA, Military, and UK Software Safety Standards -** This topic includes links to software safety guidance from other safety related industries that have useful information that could be applied to medical device software. All of these and sometimes others are in the document library section of the website.
- **FDA Software Premarket Submissions -** This topic contains a number of FDA guidances and SoftwareCPR® training aides related to preparation of software information in premarket submissions for FDA including 510(k)s, PMAs, and IDEs.
- **Checklists** – includes some of our more popular checklists, including for IEC 62304, as well several FDA checklists.
- **Selected Presentations** – includes some FDA staff presentations as well as several SoftwareCPR® conference presentations
- **21 CFR Part 11 Selected References –** This topic contains selected references and training aides for electronic records and signatures compliance.
- **Device Software SOP & Document Examples** — This topic contains selected partial document and procedure training templates as well as assorted validation tips.
- **Selected Mfg. & QS SW Validation Training Materials** – includes several of our production and quality system validation training examples.
- **Articles & White Paper Reprints**– includes several recent and most popular article reprints by SoftwareCPR® and others that have submitted their articles to us.

Remember, the documents you see on the topic pages are just a subset of the many available in the website library.

We welcome your suggestions for additional topics of interest.

Software Regulatory News
(recent news updates only)

- 11/11/09 EU Borderline and Classification Committee SW group
- 11/11/09 CENELEC Proposal on Software and MDD
- 11/5/2009 - FDA Presentation on Wireless Guidance
- 11/4/2009 - FDA perspective on virtual machines
- 11/4/2009 - FDA CBER BECS Submissions Presentations
- 10/30/2009 - Health Canada reclassifies Patient Mgmt Software
- 10/1/2009 - New FDA Device Center address for submissions
- 9/27/2009 - IEC 80002-1 Software Risk TR Published
- 4/7/2009 - Update on status of MDDS rule

FDA Documents
(recently added or updated software related items only)

- FDA Presentation on IEC 62304
- FDA Presentation on Draft MDDS Rule
- FDA issues Cybersecurity Reminder Memo
- FDA issues draft imaging CADe detection guidance
- FDA Updates Standards Recognition list

LIBRARY
SoftwareCPR® Educational Material
(RECENTLY ADDED OR UPDATED ITEMS ONLY)
BROWSE OR SEARCH THE WEBSITE LIBRARY or TOPICS FOR THESE AND MANY OTHERS

- IED 62304 training templates for Software Development SOP, Software Development Plan and Risk Analysis$
- Software Risk Analysis Training Template Rev1$

Conferences and Public Training
(a few recent and upcoming FDA software related conferences)

4/7/2010 - ***AAMI FDA Software Validation Course***
11/4/2009 - FDA CBER Blood Bank 510(k) Software Workshop
10/29/2009 - ***AAMI Webinar on 62304***

*Conferences with SoftwareCPR® speakers are in bold.

20 Berkshire Drive Winchester, MA 01890 USA
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Warning Letters

(**recently added software**- related FDA warning letters)

11/9/09 - $All Warning Letter Excerpts in one pdf file$
10/14/2009 - Phoenix Bio-Tech Corporation
10/7/2009 - Phoenix Medical Devices, LLC
10/7/09 - Weartech International Inc.
7/8/2009 - Inditherm Medical
7/1/2009 - Brymill Corporation
5/29/2009 - UltraRad Corporat ion
5/27/2009 - Amsino Medical
5/27/09 - R4 LLC
5/20/2009 - CRY-AC Tracker®, the CRY-AC® and the CRY-AC3®
5/20/09 - Mainline Technology, Inc
.

Recalls

(recently added software-related recalls published by FDA)

11/9/2009 - $All Recall Excerpts in one pdf file$
10/28/2009 - Centricity Enterprise Archive Cl II
10/28/09 - Siemens ARTISTE MV Systems , Cl II
10/21/2009 - BrainLab Radiotherapy Treatment Planning SW, Cl II
10/21/09 - Clinac with Version 7.x Software, Cl II
10/21/09 - Eclipse Proton Convolution Superposition DC, Cl II
10/21/09 - Neuro Kinetics SW, Cl II
10/21/09 - Oridion Medical Capnostream20 , Cl II
10/21/09 - Pyxis Anesthesia System 3500, Cl II
10/21/09 - Roche AMPLILINK Software, Cl II
10/21/09 - Varis, Aria Radiation Oncology, Cl II
10/14/2009 - Ortho ProVue, Cl II
10/7/2009 - AGFA NX 2008 Central Monitoring System, Cl II
10/7/2009 - Carl Zeiss Stratus OCT Model 3000 , Cl II
10/7/2009 - Hologic Bone Densitometer Systems, Cl II
10/7/2009 - Toshiba Infinix, Cl II
9/30/2009 - Hitachi DICOM Ultrasound Scanner, Cl II
9/30/09 - Perkin Elmer,Specimen Gate Lab, Cl II
9/16/2009 - American Optisurgical , Cl II
9/4/2009 - Haemonetics Corp., Cl Ill
9/4/09 - Haemonetics Donor Management System (DMS), Cl Ill
9/4/09 - Hospira Phoenix Infusion System, Cl II
8/27/2009 - Cardinal Health Alaris, Cl I
8/27/09 - CellTracks AutoPrep System , Cl II
8/27/ 09 - GE Healthcare, CT Perfusion 4, Cl II
8/6/2009 - Hitachi Computed Tomography (CT) Scanners, Cl II
8/6/09 - Philips IntelliVue , Cl II
8/6/09 - Welch Allyn AED 10, Cl II
7/31/2009 - TumorLoc software application, Cl II
7/22/2009 - GE Centricity PACS RA1000 Workstation SW , Cl II
7/22/2009 - Gendex VixWin Platinum Imaging Software, Cl II
7/22/2009 - TumorLoc software , Cl II
7/8/2009 - Brilliance iCT software v2.5.0 , Cl II
7/8/09 - GE Centricity PACS , Cl II
6/19/2009 - CareVue Chart Release, Cl II
6/12/2009 - Terumo Advanced Perfusion System 1 , Cl II
6/5/2009 - Cell-Dyn Ruby Hematology Analyzer Cl II
6/5/09 - Panorama Patient Monitoring Network , Cl II
5/20/2009 - Bio-Rad Variant II Hemoglobin Testing System Cl II
5/20/2009 - Carina Home Ventilator, Cl II
5/20/2009 - Centricity TriWin Laboratory Info System, Cl II
5/13/2009 - GE Healthcare CIC Pro" Software , Cl II
5/6/2009 - Alaris Patient-Controlled Analgesia Module, Cl II
5/6/2009 - Cerner Corp , Cl II
5/6/2009 - syngo Imaging , Cl II
4/22/2009 - Deltec Cozmo Insulin Pump , Cl II
4/22/09 - GE Healthcare Infinia , Cl II
4/15/2009 - CELL-Dyn Ruby Hematology Analyzer , Cl II
4/15/2009 - Medtronic RV Lead Integrity Alert , Cl Ill
4/15/2009 - Roche/Hitachi Modular Analytics System , Cl II
4/15/2009 - Sonora Transcranial Doppler (TCD) System , Cl II
4/8/2009 - Cerner HNA Classic PathNet Blood Bank Donor, Cl II
4/8/09 - GE HealthcareS/5 iCentral & iCentral Client, Cl II
4/1/2009 - Bio-Rad Variant II TURBO , Cl II
4/1/09 - Leica Microsystems QCA and iQCA software, Cl II

20 Berkshire Drive Winchester, MA 01890 USA
Telephone (781) 721-2921
email: office@softwarecpr.com

Industry Papers/Presentations

(complete index, new items added are in ***red italics***)

11/11/2009 - SEI article on Medical Device Assurance Cases
11/8/2009 - 62304 CMMi Comparison Article
2/4/2009 - SEI Safety Assurance Cases for Medical Devices
12/13/2008 - Reprint of "Where Testing Fails" Articles
12/13/2008 Reprint of AAMI IT Horizons IEC 80001 article
12/13/2008 Reprint of Sensible Testing Article
8/14/2008 - Usability and Risk Management Slides
3/9/2008 - Presentation on Records Management Standards
1/22/2008 - Safety Modeling Articles related to JPL mission
10/2/2007 - Risk Management for Language Translations – UL
9/30/07 DHS Software Security Information
9/30/07 Article on why Windows is less Secure then Linux
9/6/2007 - Reprint AAMI BIT Journal Mulilingual Risk Article
1/30/2007 - Reprint of AAMI BIT Journal Probability Article
11/20/2006 - International Software Standards Update Nov 2006.
3/25/2006 - Guidant Independent Panel Report Issued.
1/28/2006 - Attorney Presentation on FDA loss of Utah Med Case
11/2/05 - Beckman Design Tool Validation Slides
11/2/05 - Beckman Software Maintenance Presentation Slides
6/16/2005 – SCPR ASQ Cybersecurity & SW Submission Guidance slides
4/7/2005 - SCPR BOSCON Software Risk Management Slides
3/30/2005 - AAMI Stds. Conference Software Session 2005 – FDA and SCPR slides
12/13/2004 - RAPS Presentations on Electronic Submissions
6/18/2004 - Reprint of BIT Journal Software CAPA Article
5/13/2003 - EU Medical Device Software Regulation Proposal
9/9/2003 - Reprint of AAMI BIT Journal Test Coverage Article
5/13/2003 - EU Medical Device Software Regulation Proposal
4/1/2003 - EU Medical Device Software Regulation Article
3/11/2003 - Part 11 Redirection Presentations at AAMI Conf.$
3/11/2003 - Software Standards Presentations at AAMI Conf.
2/5/2003 - ISPE Part 11 Risk Paper
1/14/2001 - Part 11 Industry Coalition Update
10/16/2000 - GAMP Part 11 Draft Guidance Issued for Review
3/16/2000 - AAMI Standards Conference Software Session
7/1/1994 - Comparison of ISO 9001 to the CMM
3/11/2003 - Part 11 Redirection Presentations at AAMI Conf.
3/11/2003 - Software Standards Presentations at AAMI Conf.
2/5/2003 - ISPE Part 11 Risk Paper
1/25/2003 - ADVAMED Part 11 Risk Paper
1/25/2003 - EWICS TC7 Medical Devices Subgroup Risk Paper
4/7/2002 - Article: Methodology for Safety Case Development
10/16/2000 - GAMP Part 11 Draft Guidance Issued for Review
6/13/2002 - NEMA comments on FDA Draft Part 11 Guidance
4/23/2002 - NEMA HIPAA Medical Device Issues Presentation
4/23/2002 - NEMA HIPAA Medical Device Remote Service
4/23/2002 - NEMA HIPAA Privacy and Security Introduction
4/7/2002 - Article: Methodology for Safety Case Development
3/2/2002 - NIST Article on Medical Device Software Safety
09/06/01 - Safety Model Article - FDA co-author
05/30/01 - Update on Part 11 in "Validation Times"
01/14/01 - Part 11 Industry Coalition Update
10/16/00 - GAMP Part 11 Draft Guidance Issued for Review
06/24/00 - BOSCON QSIT Presentation
04/01/00 - AAMI Newsletter Standards Conference SW Summary
03/16/00 - AAMI Standards Conference Software Session

Standards and Non-US Regulations

(partial index, new items added or updated are in ***red italics***)

- ***11/8/2009 - SOFTWARE SAFETY NASA Guidebook - 2004 update***
- ***9/27/2009 - IEC 80002-1 Software Risk TR Published***
- ***9/8/2009 - FDA Updates Standards Recognition list***
- FDA Recognizes 4 Additional Software Standards.
- IEC 80001 and 80002 renumbered
- Korean KFDA Draft Software Guidelines
- EU harmonizes IEC 62304 and 60601-1 3rd edition
- China adopts IEC 62304 software standard
- UL 1998 Software Standard reaffirmed
- FDA changes 62304 Recognition.
- FDA changes UL 1998 Recognition
- GHTF Supplier Management Draft.
- AAMI TIR 36 Released
- CENELEC to include IVDD for 62304 Harmonization
- ISO14971 Revision Transition Period
- MISRA C Coding Standard
- IEC 601-1-4 withdrawal Risk Management for Language Translations – UL
- EU Parliament Report on MDD Changes
- FDA Recognizes ISO 62304 .
- UL 1998 renewed as ANSI National Standard
- ISBT Blood Bank Automation Validation Guidelines
- FDA CDRH standards recognition NCCLS GP-19-A2
- Comparison of ISO 9001 to the CMM
- ***EWICS TC7 Medical Devices Subgroup Risk Paper***
- FDA Issues Checklist for Standards Conformance
- FDA CDRH Recognition of ISO 14971
- FDA CDRH Standards Recognition Guidance
- Good Automated Manufacturing Practices 4 (GAMP)
- Nuclear Regulatory Commission Coding Standards
- IVT Proposed Computer Validation Std. VS-2
- UK Software Safety Standard Part 1
- UK Software Safety Standard Part 2
- Military Software Safety Handbook
- Nuclear Regulatory Commission Software Reviews
- FDA Software Standards Recognition
- IEC 61713 Software Dependability Guide Issued
- AAMI Software Standard Comment Resolutions
- Public Comment Draft AAMI Software Std.
- IEEE 1073 Standard - free software available
- NIST Guidance on Errors in C++

20 Berkshire Drive Winchester, MA 01890 USA
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- GHTF approves a new study group on software
- FDA IVD Computer related standards
- GHTF Quality System Risk Management Guidance
- EU MDD Revision Ready - New Software Clauses
- AAMI Issues TIR32 Software Risk Management Report
- NIST Statistical Data Sets Useful for Validation
- Nuclear Regulatory Commission Coding Standards

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