

**NEW ITEMS on SoftwareCPR.com are listed below**  
**RECENTLY ADDED or UPDATED ITEMS ONLY - BROWSE OR SEARCH THE WEBSITE NEWS, LIBRARY or TOPICS PAGES for detailed information on THESE AND MANY OTHERS. Items denoted with \$ are only available to paid subscribers using their login.**

### SoftwareCPR April 2017 Services Spotlight

#### Automate Your Integration and System Level Testing

Have you considered automating your testing or considered using a different test automation tool that requires less maintenance? For a limited time, you can setup an appointment with our partner, Paul Felten, and he will remotely work with you and your team to demonstrate the simplicity and speed that automated tests can be setup using Ranorex directly on your product (assuming you can provide remote access)! Automated test development no longer requires software engineering skills and can now be managed by the software quality assurance team. Don't miss out on this opportunity. Email Paul directly at [pfelten@softwarecpr.com](mailto:pfelten@softwarecpr.com).

#### Legacy Software and Compliance with 60601-1 3rd Edition

Are you facing a new technical file assessment to the 3rd edition of 60601-1 for a legacy product? Does your legacy product lack the required documentation for 62304 compliance? Let us help you navigate a strategy that leverages the Amendment 1 update to 62304. Our support could save your company a tremendous amount of time and money. Contact Brian at [brian@softwarecpr.com](mailto:brian@softwarecpr.com) for more information and to receive our updated 62304 checklist.

#### New SoftwareCPR.com Subscription Add-on

An Add-on for access to our Standards Landscape and quarterly standards updates from Sherman Eagles is available to paid subscribers to our basic subscription for an additional \$200, \$400, and \$750/year respectively based on type of license. If you would like a free sample of this new service leave a message on our website or email [alan@softwarecpr.com](mailto:alan@softwarecpr.com).

### Regulatory News - Added since last newsletter. Details for each are on website.

4/24/2017 FDA Guidances Interoperability Final & Cybersecurity Revision expected this summer	1/21/2017 FDA Draft Medical Device product Communications
3/22/2017 FDA Experiential Learning Program Applications FDA Webinar on De Novo for Neurological Devices	1/18/2017 SoftwareCPR IEC 82304-1: Health software Checklist
3/21/2017 FDA Draft Class II Device 510(k) exemptions	1/13/2017 FDA FINAL Guidance Benefit-Risk IDE Devices Ranorex Automated Test Tool1
3/4/2017 FDA Presentation on Benefit-Risk IDE Devices	1/10/2017 21st Century Cures Act - SCPR SW Impact Analysis Implantable Device FDA Cybersecurity Notice
2/16/2017 82304 published, 80002-2, 80001-2-9 SW Stds Update	1/4/2017 21st Century Cures Act - Medical Device Summary 21st Century Cures Act - Standalone SW Summary FDA Device Recall Summary Page
2/15/2017 U.S. Bill to Modernize FDA Device Inspections	12/30/2016 FDA Accessories Classification Webinar FDA Device Accessories Classification Guidance
2/10/2017 Chinese FDA English Website	12/29/2016 FDA Final Postmarket Cybersecurity Guidance FDA Postmarket Cybersecurity Blog
2/8/2017 FDA Safety Alert - Alaris Pump Alarm	12/27/2016 FDA FINAL Guidance Benefit-Risk in Medical Devices
1/29/2017 US ONC Health IT Certification	
1/24/2017 FDA Postmarket Cybersecurity Guidance Webinar	

## [Conferences and Training](#)

### **24-April-2017 \*AAMI Regulatory Requirements for SW Validation\***

Brian Pate will be the lead faculty for the "Regulatory Requirements for Software Validation in the Medical Device Industry" training course on April 24 - 26, 2017. This three day course focuses on the requirements contained in the Quality System regulation specific to software validation. It is likely one or more FDA software stff will co-instruct. Contact Brian for more information on how to register at [brian@SoftwareCPR.com](mailto:brian@SoftwareCPR.com).

SoftwareCPR® can also provide more tailored training at your facility in these important areas:

- FDA Design Control and Software Regulation
- ISO 14971 Risk Management and Software Risk management
- IEC 62304 Software Development Processes including Agile Methods
- IEC 62366 Usability and Human Factors Engineering with Risk Focus
- ISO 13485 and FDA Quality Management Systems

Our onsite courses can be provided using a general approach to teach the standards and regulations course or tailored to your products and risk levels. Each course can be offered in 1, 2, or 3 day formats depending on the number of exercises provided. All our courses can typically be used to satisfy your training requirements. We have provided training to regulatory authorities such as the US FDA, Taiwan FDA, and Health Canada. For more information leave a message on our website [www.softwarecpr.com](http://www.softwarecpr.com) or email Brian at [brian@softwarecpr.com](mailto:brian@softwarecpr.com).

FDA Sponsored Workshops and Conferences - see the FDA webpage at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>

### [SoftwareCPR® Educational Material](#)

4/24/17  
\$SCPR SW Development Environment Information Worksheet\$

4/18/2017  
\$All Recall Excerpts from Jan 2015 - present\$

\$Warning Letter Excerpts- Jan 2014 - present\$

\$All Recall Excerpts from Jan 2012 thru 2014\$

\$Warning Letter Excerpts- Jan 2012 thru 2013\$

1/18/2017  
\$SoftwareCPR 82304 Health Software Checklist\$

Brian Pate's Twitter Feed <https://twitter.com/BPateCPR>

### [FDA SW Warning Letters](#)

4/3/2017 Mylan Pharmaceuticals, Inc.

3/10/2017 USV Private Limited

2/23/2017 Denttio, Inc.

2/17/2017 Morton Grove Pharmaceuticals, Inc.

1/13/2017 FACTA Farmaceutici S.p.A Ltd.

1/6/2017 Sato Yakuhin Kogyo Co., Ltd.

**Software SW Recalls**-New ones since last newsletter. Details for each are on website.

4/12/2017 eCare Coordinator, CI II Philips IntelliVue Patient Wearable Monitor, CI II	MEVION S250-Proton Radiation Therapy, CI II Siemens Mammomat Inspiration, CI II SiemensSyngo.plaza, CI II
4/5/2017 Hospira Plum 360 Infusion Pump, CI II Merge iConnect Enterprise Archive software, CI II MergeiConnect Enterprise Archive (ICEA) sw CI II Philips V60 Ventilator, CI II Siemens Syngo.via, CI II Siemens Syngo.x, CI II SynchroMed II implantable drug infusion pump CI II	2/1/2017 Merge Hemo software CI II Roche Accu-Chek App, CI II Roche Cobas b 123 POC system, CI II SCC Soft Computer Softbank II software, CI II SCC Soft Computer Softbank software, CI II
3/29/2017 Alaris System PC unit, CI II Ariol Wireless Water-Resistant Call Pendant, CI II EyeSuite i.8.2.1.0 Software, CI II Hitachi Echelon MRI System, CI II Hitachi Oasis MRI System, CI II Merge Cardio software with PID CI II Merge Cardio software., CI II Merge Cardio software., CI II Merge Eye Station Import Utility CI II Nidek Final Fit Software, CI II ONCOR" Expression,Impression,Impression Plus CI II Siemens ADVIA Centaur XPT System, CI II Siemens ARTISTE" MV System, CI II Siemens ONCOR" Avant-garde, CI II Siemens Syngo.plaza., CI II Zimmer Biomet Orthosize Templating, CI II	1/25/2017 Merge Cardio software CI II Alaris Syringe Pump Module Class I Ambra PACS UDI, CI II AutoMate System Series CI III Blood Bank Control System (BBCS) CI II Carestream Touch Prime, CI II Digital RID Plate Reader CI II Elekta Monaco RTP System, CI II Fresenius 2008 Series Hemodialysis Systems CI II
3/22/2017 Merge Hemo software CI II CADD Solis VIP Ambulatory Infusion Pump CI II Merge iConnect Enterprise Archive CI II Philips BrightView X CI II Philips BrightView XCT 882454 CI II PhilipsBrightView CI II	1/18/2017 Eclipse Treatment Planning System CI II Elekta Monaco RTP System, CI II Elekta Oncentra External Beam, CI II Philips IQon Spectral CT CI II Siemens Artis zee/zeego CI II Toshiba Kalare DREX-KL80, CI II Toshiba Ultimax DREX-ULT80,0, CI II
3/15/2017 Merge Cardio software CI II LIFEPAK 1000 defibrillator Class I Merge Cardio software using EchoIMS CI II	1/11/2017 Merge DR Systems Unity CI II 1/11/2017 Merge Eye Station CI II 1/10/2017 Implantable Device FDA Cybersecurity Notice
3/8/2017 McKesson Radiology 12.2 - PACS CI II	12/28/2016 Medtronic SynchroMed II CI II AQUIRE System Software Version 2.2 CI II Merge OrthoCase software CI II
3/1/2017 Keyspan High-High Speed USB to Serial Adap CI II Merge Eye Station Import Utility (ESIU) CI II Philips Efficia CMS200 CI II	12/21/2016 Merge Cardio Software. CI II Merge Cardio Software. CI II MicroScan LabPro CI II Olympus HF Cable WA00014A CI II
2/22/2017 Siemens CentraLink Data Management System SW CI II VIDAS 3 software v. 1.1.4 CI II	12/14/2016 Medtronic 37751 Recharger CI II RaySearch Radiation Treatment Planning CI II Merge eFilm, eFilm Lite Workstation CI II Merge PACS software CI II
2/15/2017 Boston Scientific, EMBLEM S-ICD Programmer CI II LIFEPAK 12 Defibrillator/Monitor CI II LIFEPAK 15 Monitor/Defibrillator CI II Merge Eye Station CI II Merge PACS software. CI II Merge RadSuite software CI II	Philips Brilliance 64 728231, CI II Philips Brilliance 64 728232 , CI II Philips Ingenuity Core 128 728323, CI II Philips Ingenuity Core 728321, CI II Philips Ingenuity CT 728326 CI II RayStation 4.0, 4.5, 4.7 and 5.0 CI II Siemens ADVIA 560, CI II Siemens SOMATOM Force: CI II SynCardia 5000 Series Freedom Drivers CI II
2/8/2017 FDA Safety Alert - Alaris Pump Alarm	

**More detailed information on the items listed above and many others is available on our website at <http://www.softwarecpr.com>**

### **Website Tips**

The **NEW** items listed above are organized according to their location in the **REFERENCE** section of <http://www.softwarecpr.com>. If you have trouble finding an item of interest, send email to [office@softwarecpr.com](mailto: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, click [Subscription Page](#) here or from the menu bar. Our annual subscriptions start at \$250 and provide access to a large volume of materials include sample procedures, documents, and checklists.

**Please be sure to check out our “topic” pages.** Try these out by clicking [Topics](#). Paid subscribers should log in and then will have access to all educational documents while others will have only limited access. Remember that additional documents are available by browsing or searching the library.

### **SoftwareCPR® News:**

Brian Pate is now General Manager of SoftwareCPR®. Alan Kusinitz continues his involvement as Founder providing strategic and tactical regulatory and compliance advice.

We have expanded our services in the area Cybersecurity to include technical threat assessment and our services related to **IEC 62366** and human factors in general now provides end-to-end support including summative usability testing and participant recruiting.

In addition to our comprehensive **regulatory and compliance services** we have specialized software compliance and safety services **including hands-on ValidationCPR services and automated testing.**

**We perform FDA Quality System compliance audits and inspection preparation including on-site support during inspections. We also prepare premarket submissions** as well as device classification analysis including for grey area Health IT applications.

We continue to perform **IEC 62304** assessments and assist in developing efficient methods of conformance with these important standards as well as Agile methods compliance.

We also provide a service to help you develop **Risk analyses** and **Safety/Assurance Cases** including use of your existing risk management documentation. We continue to expand our risk based technical design and code review service.

For more information on our subscriptions click [standard low cost subscription](#) (as low as \$250/year, \$500/site, \$1000/division or small company). An Add-on for access to our Standards Landscape and quarterly standards updates from Sherman Eagles is available for \$200, \$400, and \$750/year respectively based on type of license We also have a premium subscription service called **Software STANDARDS NAVIGATOR led by Sherman Eagles**. This provides real time insight, guidance, monthly reports, and access to public draft standards as well as some consulting or training time each year. Click [TOPICS](#) and then click the Standards Navigator topic to get further information.

