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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 June 2018 Newsletter Highlights

Sherman Eagles of SoftwareCPR was given an award for his volunteer activities over the past 40 years and a proclamation was read by the mayor making July 4, 2018, Sherman Eagles Day in St. Paul. Please join us in congratulating Sherman and thanking him for giving so much to his community.

Reminder: we have provided a Mobile App containing key regulations and software guidance organized by section for handy reference for both Android and iPhone users -- just search for SoftwareCPR in the app stores.

IEC 62304 2nd edition failed balloting. It has gone back to committee to resolve issues which appear primarily to be related to the use of ISO 14971 and its applicability given the expanded scope of 62304 to include all healthcare software not just medical devices.

A short summary of FDA expectations for Benefit-Risk Analysis is posted in now posted in our library.

We are happy to announce that Ron Baerg, of Seminole, FL USA, is now a partner at SoftwareCPR. Ron has over twenty three years experience in medical device software development and management. His experience has been primarily focused on large, complex medical device systems with multiple computing systems containing all safety classes of software. His training has included risk management, software V&V, standards such as 62304, and he was a recipient of the Baxter Technical Award.

Our privacy policy continues to include that we do not retain paid subscribers credit card information and only use contact information for requested services. You can unsubscribe from our mailing list by sending an email to office@softwarecpr.com or leaving a message on the website. We never sell your contact information to outside organizations.

SoftwareCPR has expanded its **remediation services** including hands-on capabilities to retrospectively develop missing software design history elements in addition to regulatory and quality systems consulting and FDA submissions.

SystemsCPR services focused on EMI/EMS and wireless coexistence now has its own web page for more information at <http://www.systemscpr.com> as does ValidationCPR for our validation remediation services at <http://www.validationcpr.com> .

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

6/29/2018 FDA Benefit-Risk Analysis Summary FDA eSubmitter Download Webpage	4/14/2018 Ron Baerg now a Partner at SoftwareCPR
6/7/2018 FDA Q-Submission Program Draft Guidance	4/12/2018 FDA Draft Guidance Expansion of Abbreviated 510(k)
6/1/2018 FDA Proposed Reclassification of MIMS	4/6/2018 FDA Unique Device Identifier Webpage Status Update
5/10/2018 FDA Precertification Pilot Interactive Webinar	3/29/2018 SoftwareCPR March 2018 Newsletter
5/1/2018 FDA Draft MultiFunction Device Guidance	3/23/2018 Software Standards and FDA Guidance Visual Aide

6/29/2018
 \$All Recall Excerpts from Jan 2015 - present\$
 \$Warning Letter Excerpts- Jan 2014 - present\$

6/29/2018
 FDA Benefit-Risk Analysis Summary

3/23/2018
 Software Standards and FDA Guidance Visual Aide

5/23/2018
 IDT Australia Ltd.

5/9/2018
 Nox Bellcow Cosmetics Co., Ltd.

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

FDA Documents

6/29/2018
 FDA eSubmitter Download Webpage

6/7/2018
 FDA Q-Submission Program Draft Guidance

6/1/2018
 FDA Proposed Reclassification of MIMS

FDA Documents

5/1/2018
 FDA Draft MultiFunction Device Guidance

4/12/2018
 FDA Draft Guidance Expansion of Abbreviated 510(k)

4/6/2018
 FDA Unique Device Identifier Webpage Status Update

Conferences and Training

5/10/2018
 FDA Precertification Pilot Interactive Webinar

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
- Agile Methods Efficient Compliance -NEW
- 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 or email Brian at brian@softwarecpr.com.

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

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.

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

6/29/2018 \$All Recall Excerpts from Jan 2015 - present\$ 6/27/2018 Apollo Anesthesia Machine, CI II CARESCAPE R860 ventilators CI II Criticore Automated Urine Monitor, CI II Cyberonics VNS Therapy Programmer, CI II Fabius GS MRI Anesthesia Machine; CI II Fabius GS Premium Anesthesia Machine; CI II Fabius GS Tiro Anesthesia Machine; CI II Perseus A500 Anesthesia Machine, CI II 6/20/2018 CellaVision DM Software, CI II Sonialvision Safire II, CI II 6/13/2018 AdaPTinsight software: CI II Draeger Jaundice Meter JM-103, Class I Draeger Jaundice Meter JM-105, Class I GE Centricity Universal Viewer, CI II nordicBrainEx 2.0 CI II nordicICE v 2.3.14, CI II Xper Flex Cardio Physiomonitring System: CI II 6/6/2018 nordicBrainEx CI II nordicICE 2.3.14 image processing software, CI II nordicTumorEx 1.0 CI II Siemens SOMATOM go.Now CI II Siemens SOMATOM Go.Up CI II 5/30/2018 Baxter Prismaflex 7.20 US CI II Baxter Prismaflex 7.XX ROW CI II Baxter Prismaflex System CI II Siemens Biograph Horizon, PET/CT System CI II 5/23/2018 Draeger Infinity Acute Care System, CI II PHILIPS Xper Flex CI II Siemens SOMATOM Definition AS; CI II Siemens SOMATOM Force CT diagnostic system CI II 5/16/2018 FlexLab Laboratory Automation System CI II Siemens ACUSON SC2000 Ultrasound CI II Siemens Syngo.plaza software : CI II Siemens Syngo.plaza software VB10A : CI II 5/9/2018 AQUIRE system CI II 5/9/2018 cobas b 221<2>Roche OMNI S2 system CI II Cobas b 221<4>Roche OMNI S4 system CI II Cobas b 221<6>Roche OMNI S4 system CI II Hitachi MHI-TM2000 Linear Accelerator System CI II PerkenElmer Specimen Gate Screening Center, CI II	Philips Allura Xper R8.x.25.5 and UNIZ , CI II Siemens Perspective 16 : CI II Siemens Biograph Horizon - PET/CT, PET : CI II Siemens Perspective : CI II Siemens SOMATOM Emotion (2003) : CI II Siemens SOMATOM Emotion 16 : CI II Siemens SOMATOM Emotion 6 : CI II Siemens SOMATOM Perspective 16 : CI II Siemens SOMATOM Scope : CI II Siemens SOMATOM Scope Power : CI II Siemens SOMATOM Sensation 16 : CI II Siemens SOMATOM Sensation 40 : CI II Siemens SOMATOM Sensation 64 : CI II Siemens SOMATOM Sensation Cardiac : CI II Siemens SOMATOM Sensation Emotion Duo (: CI II Siemens SOMATOM Sensation Open : CI II Siemens SOMATOM Spirit : CI II Siemens SOMATOMSensation 10 : CI II 4/25/2018 GE Healthcare Lunar: CI II GE Healthcare Prodigy: CI II Ingenuity TF PET/CT, CI II Siemens MEVATRON M2 / PRIMUS: CI II Siemens ONCOR Avant-garde: CI II Siemens ONCOR Expression: CI II Siemens ONCOR Impression Plus : CI II Siemens ONCOR Impression: CI II Siemens PRIMUS HI : CI II 4/18/2018 AQUIOS CL Flow Cytometer System CI II Fresenius Liberty Select Cycler (SW v.2.8.7) CI II HomeSafe AutoAlert Pendant CI II IntelliVue X3 Patient Monitor., CI II iQ200 Series Urine Microscopy Analyzer ; CI II iQ200 Series Urine Microscopy Analyzer CI II 4/11/2018 DynaCad software, CI II 4/11/2018 Fresenius 2008 K2 Hemodialysis Machine CI II GE Healthcare Centricity PACS-IW CI II Phadia Prime software CI II Prismaflex Control Unit CI II Siemens Syngo.via. Medical Device Software CI II 4/4/2018 Ray Station 4.9, 5, 6, 7 Software CI II Siemens ACUSON SC2000 CI II Siemens Syngo.via software CI II St. Jude Proclaim DRG Implantable Pulse Gen. CI II 3/28/2018 Medfusion Syringe Pumps CI II
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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. **Note: Items with the H3 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 Services Update:

We have expanded our services in the area of 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 remediation and 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.