July 2018 - October 2018 **SoftwareCPR.com Newsletter**

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 October 2018 Newsletter Highlights

COMING SOON: REDESIGNED WEBSITE AND INTEGRATED BLOG – This should make finding things on our website a lot easier. It will also allow us to post more of our regulatory and standards insights and explanations from all of our experts.

News Highlights
Webinars were held in early October on 62304 second edition. These were aimed at the IEC & ISO national groups that will be voting on the next draft.

A new draft of the Manufacturer Disclosure Statement for Medical Device Security (MDS2) developed by the HIMMS and NEMA industry groups was released. MDS2 will be used by hospitals to gather cybersecurity information from manufacturers.

FDA issued notices about 2 pilot programs one for Special 510(k)s and one for the Quik Review Pilot Program and issues its 2019 New Guidance Plan. It also issued a final risk guidance related to premarket review of devices with similar intended use but different technologies.

2019 Private, in-house training slots are available! We are currently planning our training courses for 2019 - now is a good time to reserve a course for your company. Our most popular courses are: 1) 3-day 62304 and emerging software standards course (includes FDA); 2) 2-day Software Risk Management; 3) 2 or 3 day Being Agile and Compliant with IEC 62304 and FDA Expectations for Medical Device Software

Right sizing tool validation - Validating the tools we use for quality system and production processes is important. We want to know that we can trust the software to automate the processes consistently and repeatably. However, the methods and process we use for tool validations should be commensurate with the risk associated with any software failures. Many manufacturers can drift toward wasteful and non-value added activity in this area.

Out-sourcing tool validation - Did you know that SoftwareCPR offers fast (1-2 weeks) fixed price tool validations for many common quality system tools such as JIRA, SVN, Git, DataGrip, Microsoft(R) Visual Studio, Apple(R) Xcode, and others. Call 781-721-2921 or email Brian Pate (office@softwarecpr.com) today for more information.

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

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 service**s including hands-on capabilities to retrospectively develop missing software design history elements in addition to regulatory and quality systems consulting and FDA submissions.

SCROLL DOWN TO SEE NEW ITEMS POSTED ON THE WEBSITE SINCE THE LAST NEWSLETTER INCLUDING WARNING LETTERS AND RECALLS

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

11/15/18
FDA CDRH Special 510(k) Pilot Program
10/15/18
AAMI FDA Agile Methods Compliance Course*
10/10/18
FDA Quik Review Pilot Program and Webinar
10/9/18
FDA Final Risk Guidance different technologies
10/6/18
FDA CDRH 2019 New Guidance Plan
10/2/18
IEC 62304 Edition 2 Issues Status Webinar
10/1/18
FDA Biologics Assistance Branch (MATTB)
FDA CDRH Updates SW Precert Pilot

FDA Device Center Patient Advisory Committee
FDA Reflects on National Cybersecurity Month
9/26/18
FDA CBER Secure Email Webinar
9/24/18
FDA CBER Blood establishment Reg and Listing
9/20/18
UL 5500 - Safety for Remote SW Updates Approved
8/1/18
FDA Raises User fees Oct 1, 2018
7/27/18
FDA Clears Home Urinalysis using smartphones
FDA Software Precertification News
FDA webpage of examples of cleared apps
7/17/18
JAMA Article by FDA Staff - Summary

SoftwareCPR Educational Material

9/26/18
$All Recall Excerpts from Jan 2015 - present$
$Warning Letter Excerpts- Jan 2014 - present$
7/27/18
FDA Software Precertification News
7/17/18
JAMA Article by FDA Staff - Summary.
7/9/18
SoftwareCPR June 2018 Newsletter

FDA SW Warning Letters

10/2/18
Datascope purchasing controls
9/26/18
$Warning Letter Excerpts- Jan 2014 - present$
8/29/18
Pharmaceutical Laboratories and Consultants, Inc.
8/10/18
Kyowa Hakko Bio Co., Ltd
7/17/18
Yuki Gosei Kogyo Co., Ltd.
7/5/18
Baxter (Claris Injectables Ltd.)

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

11/15/18
FDA CDRH Paitent Advisory Committee Public Meeting
11/12/18
Medica, Nov 12-15, 2018
11/8/18
FDA CDRH Special 510(k) Program Pilot Webinar
11/6/18
High Integrity Software Conference, Nov 6, 2018
10/15/18
AAMI FDA Agile Methods Compliance Course*
10/10/18
FDA Quik Review Pilot Program and Webinar
10/2/18
IEC 62304 Edition 2 Issues Status Webinar
10/1/18
RAPS Regulatory Convergence, Oct 1-4, 2018
9/26/18
FDA CBER Secure Email Webinar
9/24/18
FDA CBER Blood establishment Reg and Listing
The MedTech Conference, Sep 24-26, 2018

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 or email Brian at office@softwareCPR.com.

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

For more information on our subscriptions (as low as $250/year, $500/site, $1000/division or small company) check our webiste . 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.

10/10/18
CAPNOSTREAM 20 (US, CPM,COV, INTL) N, Cl II
Integrated Gate Controller PCB, Cl II
OptiMedica Catalys Precision Laser System, Cl II
TrueBeam Radiotherapy Delivery System, Cl II
VitalBeam Radiotherapy Delivery System Vers, Cl II
10/3/18
ABL90 FLEX Analyzer, Cl II
ddR Formula B X-ray System, ddR Formula B, Cl II
G8 Automated HPLC Analyzer-723G8, Cl II
Hoffmann LRF Hexapod Software, Cl II
Model 3300 LATITUDE(TM) Programming System, Cl II
VISUALASE THERMAL THERAPY SYSTEM, Cl II
9/26/18
2008T HEMODIALYSIS SYSTEM W/BIBAG, Cl II
$All Recall Excerpts from Jan 2015 - present$
2008T HEMODIALYSIS SYS, WITH CDX Cl II
AIRO Mobile CT System , Cl II
Makoplasty RIO Standard System Cl II
9/12/18
Canon DRAD-3000E (Radrex-i) TFP-4336W Cl II
McKesson Cardiology Hemo, Cl II
VidiStar(TM) PACS & DICOM Viewer SW system Cl II
8/29/18
Liebel-Flarsheim Digital Imaging System Cl II
Liebel-Flarsheim Hydra Vision Urology X-Ray Cl II
Ortho Kinematics Vertebral Motion Analyzer Cl II
8/22/18
Arkon Anesthesia Delivery System Cl II
G8 Automated HPLC Analyzer, Cl II
8/10/18
Arkon Anesthesia Delivery System Class I
8/8/18
ENVOY 500 ISE CALIBRATOR Kit, Cl II
NS Therapy Programming System, Cl II
Siemens SOMATOM Emotion 16 (10165977) Cl II
Siemens SOMATOM Emotion 6 Model 10165888 Cl II
Siemens SOMATOM Perspective (10495568) Cl II
Siemens SOMATOM Perspective 16 Cl II
Siemens SOMATOM Scope Power, Cl II
Siemens SOMATOM Scope, Cl II
Siemens SOMATOM Spirit, Cl II
8/1/18
CardioMEMS HF, Cl II
Forte Automation Patient Positioning System Cl II

RayStation Treatment Planning System; Cl II
Vivo 65, Continuous Ventilator, Cl III
7/25/18
Disinfection unit for Celldiscoverer 7, Cl II
Health Harmony Mobile application software, Cl II
RayStation stand-alone sw treatment planning Cl II
T2100 Micro flex Drive Treadmill, Cl II
Tandem Diabetes Care t:slim G4 Insulin Pump, Cl II
7/18/18
Proteus 235, Cl II
Reliance 1227 Cart & Utensil Washer/Disinfec Cl II
7/11/18
GE Healthcare CARESCAPE Monitor B650, Cl II
Medtronic MiniMed Paradigm Vea Insulin Pump, Cl II
7/4/18
Proteus Plus and Proteus ONE, Cl II
RayStation Radiation Treatment Planning Sys, Cl II
Siemens Artis Q biplane, Cl II
Siemens Artis Q ceiling, Cl II
Siemens Artis Q zeego, Cl II
Siemens Artis Q zen biplane, Cl II
Siemens Artis Q zen floor, Cl II
Siemens Artis zee biplane MN, Cl II
Siemens Artis zee biplane, Cl II
Siemens Artis zee ceiling; Cl II
Siemens Artis zee floor MN; Cl II
Siemens Artis zee floor; Cl II
Siemens Artis zee MP; Cl II
Siemens Artis zeego, Material no. 10280959; Cl II

More detailed information on the items listed above and many others is available on our website

Website Tips

The **NEW** items listed above are organized according to their category on our website . 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 the items in the Educational Documents category are only accessible to those with valid logins**. If you are not a paid subscriber, and would like more information on becoming one, information is on our website. Our annual subscriptions start at $250 and provide access to a large volume of materials include sample procedures, documents, and checklists.