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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 March 2018 Newsletter Highlights

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.

We have posted an updated list of software related FDA recalls to include 2017. The total in 2017 was approximately 176 while in 2016 there were 346 that we could identify.

The International Medical Device Forum which FDA participates in released a draft for comment entitled: "Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices". This guidance document describes fundamental design and manufacturing requirements, referred to as 'Essential Principles of Safety and Performance' that, when met, indicate a medical device is safe and performs as intended. A draft for comment is at the link provided on our website.

IEC 62304 2nd edition is went out for committee vote. This edition expands its scope beyond medical device software to Health Software. Work continues on a variety of cybersecurity guidances.

FDA has issued a number of new guidances including for Clinical Data, Revised Refuse to Accept 510(k)s, UDI for unclassified devices, Accessory Classification and others. FDA has continued work on its Digital Health innovation action plan and precertification pilot.

SoftwareCPR offers comprehensive **remediation service**s including hands-on capabilities to retrospectively develop missing software design history elements.

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.

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

3/10/2018
FDA Software Recall Summary-2017

3/3/2018
IEC 62304 2nd Edition draft for Committee Vote
IMDRF Safety/Performance of Medical Devices/IVDs
SoftwareCPR Mobile App with Regs and Guidance

2/22/2018
FDA Premarket Clinical Data FAQ Guidance

1/30/2018
FDA Final Revised Refuse to Accept Policy

1/16/2018
FDA UDI Class I and Unclassified Policy Guidance

12/20/2017
FDA Device Accessories Classification Guidance
NIST_cybersecurity_framework-v1-1

12/14/2017
FDA CDRH 2018 Proposed Guidance Development
FDA Least Burdensome Principles Draft Guidance

12/11/2017
FDA Changes to Medical SW Policies Draft Guidance
FDA Clinical Decision Support SW Draft Guidance
FDA SAMD Clinical Evaluation Final Guidance

12/9/2017
FDA new Digital Health Policy Statement

12/8/2017
FDADigital Health Innovation Action Plan

12/26/2017
FDA Voluntary Device Malfunction Summary Reporting

12/1/2017
FDA Digital Health Webpage

SoftwareCPR Educational Material

3/23/2018
SoftwareCPR Standards and FDA Visual Aide

3/22/2018
$All Recall Excerpts from Jan 2015 - present$
$Warning Letter Excerpts- Jan 2014 - present$

3/3/2018
SoftwareCPR Mobile App with Regs and Guidance
11/16/2017
SoftwareCPR Nov 2017 Newsletter

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

FDA SW Warning Letters

3/22/2018
$Warning Letter Excerpts- Jan 2014 - present$
2/2/2018
Cosmecca Korea Co., Ltd.
12/18/2017
Prosana Distribuciones S.A. de C.V.

FDA Documents

3/3/2018
IMDRF Safety/Performance of Medical Devices/IVDs
2/22/2018
FDA Premarket Clinical Data FAQ Guidance
1/30/2018
FDA Final Revised Refuse to Accept Policy
1/16/2018
FDA UDI Class I and Unclassified Policy Guidance
12/26/2017
FDA Voluntary Device Malfunction Summary Reporting
12/20/2017
FDA Device Accessories Classification Guidance.
12/14/2017
FDA CDRH 2018 Proposed Guidance Development
FDA Least Burdensome Principles Draft Guidance
12/11/2017
FDA Changes to Medical SW Policies Draft Guidance
FDA Clinical Decision Support SW Draft Guidance
FDA SAMD Clinical Evaluation Final Guidance
12/9/2017
FDA new Digital Health Policy Statement
12/8/2017
FDADigital Health Innovation Action Plan
12/1/2017
FDA Digital Health Webpage
Medical Device Section 21st Century Cures Act
11/16/2017
FDA Approves Digital Pill

Standards and Industry Papers

3/23/2018
SoftwareCPR Standards and FDA Visual Aide
3/3/2018
IMDRF Safety/Performance of Medical Devices/IVDs
12/20/2017
NIST_cybersecurity_framework-v1-1

SCROLL DOWN FOR TRAINING AND RECALLS

Conferences and Training

3/22/2018 AAMI 2018 International Standards Conference

24-26 January 2018 SoftwareCPR Public 62304, SW/HIT stds and regulations training Sunnyvale, CA
This course will focus on 62304 (2015 Amendment) and 80002-1 with some comparison to FDA, and with some overview of new topics related to 82304 for HealthIT software, 62304 2nd edition planned changes, human factors 62366, and regulation of standalone software. More information is at **http://alturl.com/bbgyc**

11/17/2017 FDA Digital Health Precertification Pilot Webinar
Following the webinar a written transcript, audio recording and slides available at: http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm411063.htm

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 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

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

3/22/2018
$All Recall Excerpts from Jan 2015 - present$
3/21/2018
Brainlab ExacTracCl II
Philips HeartStart XL+ Defibrillator/Monitor Cl II
Siemens ACUSON SC2000 Ultrasound System Cl II
3/14/2018
i-STAT DE handheld module, Cl II
Medtronic Navigation O-arm Imaging Cl II
Mindray Anesthesia Delivery Systems, Cl II
Philips Network Firewall, Cl II
3/7/2018
Fresenius 2008T, Hemodialysis Delivery Syst, Cl II
Philips All PIIC iX Surveillance stations, Cl II
Philips digital x-ray detectorProGrade R1, Cl II
Zoll 731 Series Ventilators , Cl II
2/28/2018
Fuji Computed Radiography Mammography Suite Cl II
Fujifilm Medical Aspire Systems Cl II
OCULUS Pentacam AXL, Model 70100, software Cl II
Protura Software with Eleckta interface Cl II
Roche Cobas 8000 Modular Series, Cl II
ROSA Brain 3.0 Cl II
ROSA Spine 1.0.2 Cl II
2/21/2018
Accu-Chek Connect Diabetes Management App, Cl II
Philips Ingenuity TF PET/CT Cl II
Roche cobas e 411 Immunoassay Analyze, Cl II
Syngo.plaza PACS, Cl II
1/31/2018
Brilliance iCT - Model 728306, Cl II
Brilliance iCT SP systems, Cl II
MyCareLink Patient Monitors, Cl II
MyCareLink Smart Patient Monitors, Cl II
Siemens Syngo Imaging version V31 , Cl II
1/24/2018
Cobas c 6000 MODULAR Series System, Cl II
Phadia 1000 Instrument,, Cl II
RayStation Product Usage, Cl II
1/17/2018
Orthoscan Mobile Mini C-arm system, Cl II
12/27/2017
Xper Flex Cardio Physiomonitoring system, Cl II
12/20/2017
enGen Track System, Cl II
Radiometer ABL800 analyzer with FLEXQ module Cl II
Remisol Advance Software, Cl II
12/13/2017
Accu-Chek Connect App, Cl II
CARESCAPE Patient Data Module , Cl II
ICU Mednet(TM) Medication Management Suites, Cl II
12/6/2017
BRAINLAB EXACTRAC VERO, Cl II
ROSA Surgical Device 2.5.8. Cl II

2/14/2018	Rosa Spine 1.0.2 Cl II
Philips Brilliance 64 Ct xray system Cl II	Volcano Imaging Systems, Cl II
Philips Ingenuity Core 128 CT xray system Cl II	11/29/2017
Philips Ingenuity Core CT xray, Cl II	3M Bair Hugger(TM) Normothermia System, Cl II
Philips Ingenuity CT xray system Cl II	Arkon Anesthesia Delivery System, Class I
Spacelabs Healthcare Xhibit Telemetry Receiv Cl II	ROSA Brain 3.0.0. Cl II
Syngo.plaza systems with SW VB20A, Cl II	ROSA Surgical Device 2.5.8., Cl II
2/7/2018	Siemens Syngo.plaza PACS Cl II
Edwards Hemosphere System, Cl II	11/22/2017
GE HEALTHCARE CARESCAPE software, Cl II	Plum 360 Infusion System, Cl II
Metrotom 800 (130kV CT scanner) Industrial C Cl II	ROSA Surgical Device 2.5.8. Cl II
Roche / Hitachi MODULAR Analyzer Systems, Cl II	Symbia Intevo 16, SPECT/CT System Cl II
	Symbia Intevo 16, SPECT/CT, Cl II

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 H3symbol 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 Цopic3pages. 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 and Subscriptions 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.

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.