



Compliance enforcement trends for the health care industry

Breaking News

The recent FDA draft Guideline, [“Postmarket Management of Cybersecurity in Medical Devices”](#), defines cybersecurity routine updates and patches as “updates or patches to a device to increase device security and/or remediate vulnerabilities associated with controlled risk and not to reduce a risk to health or correct a violation of the FD&C Act”. The recent legal battle between Apple and the FBI regarding cracking the iPhone of a dead terrorist has implications for how the healthcare sector manages such updates. Such updates can also be used to decrease device security by essentially disabling it. The IT industry is just starting to consider how this potential risk can be managed.

The widespread Zika virus outbreak has broad implications for blood and tissue banks, fertility clinics, and organ transplantation. A large number of people have become ineligible as donors, as captured in the [FDA Press Release](#). The affected institutions have to scramble now with their donor lists and screening. In Europe there has been a more muted response to the developing situation.

The [FDA is covering its --s](#) with regards to Bayer’s Essure contraceptive device, which has come into the

news regarding patient injuries. This is not the first time that Bayer has gotten this kind of media attention. It is ordered now to start a new post-market study. Negative findings could result in recalls and liability claims.

The FDA just submitted its budget für FY2017, which in sum is an 8% increase. Included in the budget is financing for the [“National Cancer Moonshot Initiative”](#) which probably belongs to the “21st Century Cures”. There is a lot at stake, (ca. \$1 billion) with this upcoming election.

E Health Initiative

The Moonshot initiative i.e. 21st Century Cures shows the direction, in which at least government policy is pointed - away from blockbuster drugs and towards more data acquisition, analysis and personalized medicine. In tandem the German authorities have started their [E Health Initiative](#), in which the first goal appears to be establishment and expansion of a national portal for “Telemedizin”. Check out the [“Kriterienkatalog Telemedizin”](#), which reads like a User Requirements Specification composed by lawyers. Such initiatives are good for IT firms, but not a replacement for past lucrative blockbuster drugs of the departed 20th Century real economy.

Warning Letters of Interest

Recently on German public television, there was a muck-raking story about defective implanted medical devices, "[Schrott im Koerper](#)", which highlighted the high risks of such devices and the relatively low government oversight of this industry in Europe. A quick look for Warning Letters to a big industrial name in implantables, Medtronic, revealed no shortage of WLs, and here is a link to the [most recent WL](#). The FDA expects for this industry robust CAPA and complaint handling systems, so that problems can be quickly analysed and addressed. Although there is no close-out to this older WL, Medtronic certainly put energy into attempting to placate the FDA.

The [WL to Repr-Med Systems](#) is not just another example of poor quality control of infusion pumps. This one gives insight in how the design of such products should be verified (& validated). Verifying the design of medical devices is required for all class II & III devices, per Quality System Regulation 21CFR820.30(f). When changes are made to product specifications, e.g. flow rates, maximum pressure, the design must be verified as appropriate for the new specifications. A statistically representative number of units must be tested, and not just 2 units. Tests must encompass the anticipated operating space, (tubing variations, syringe variations). This WL is quite extensive and covers other interesting topics as well, such as off-label advertising, reworking, etc. Regarding reworking, replacing parts and retesting must be documented in the DHR. One pump was tested 5 times before passing, which gives the impression that a test-until-passing regime was followed.

There have been so many problems associated with infusion pumps over the years, (Baxter could write a book about it from past experience), that the FDA finally released a [Guidance Document for Infusion Pump Manufacturers](#). You will find here plenty of guidance about verification and validation, and there is a quite an extensive listing of potential hazards which can be used for risk analyses, (also for other products).

The [WL to Lucy's Weight Loss System](#) illustrates that the FDA will investigate dietary supplements for undeclared ingredients when there is reason. Diet pills cannot be claimed to be dietary supplements, as this firm has tried, especially when they contain registered drugs which have been deemed unsafe.

The [Civic Center Pharmacy](#) appears to not fit into the compounding pharmacy loophole to the GMPs, and is being threatened to comply with the full GMPs for sterile drug manufacturers. The FDA was able to determine that not all of its product is devoted to patient prescriptions, but rather some was prepared for "doctor's offices for doctor's use". Compounders cannot supply such products.

[Argo Medical Technologies](#) demonstrates that you can put the FDA on a long leash via lengthy communications with appropriate gaps in availability. They were supposed to start a post-marketing study of its ReWalk device back in June 2014. Argo stretched the study plan to the date of this WL, Sept 30, 2015, (which was just posted), and there is no close-out yet for this WL. Soon it will be 2 years since the device was licensed. Apparently there have been no reported injuries.