

Compliance enforcement trends for the health care industry

Serialization on Schedule?

It's hard to say because its implementation is still on the horizon. Serialization of drug products and the associated 2D-barcodes in the US have the first deadline (for manufacturers) on Nov 2017, and the final date in the EU is Feb 2019. The EU issued [unique identifier requirements](#) in the form of a regulation, which introduces the technical problems to overcome.

An interesting EU requirement in the regulation is (7): "In order to have a negligible probability that a serial number can be guessed by falsifiers, the serial number should be generated according to specific randomisation rules." Together with the requirement for uniqueness, i.e. "the combination of the product code and the serial number sequence should be unique to a given pack of a medicinal product until at least one year after the expiry date of that pack or five years after the product has been released for sale or distribution in accordance with Article 51(3) of Directive 2001/83/EC, whichever is the longer period" as well as (39), "no unique identifiers having the same product code and serial number should be present in the repositories system at the same time." could result in some challenging algorithms and/or database designs. There is still time to work this out, but maybe not enough to implement it.

Currently required, at least in the US, is recordkeeping of all drug transactions by all players in the drug supply chain. Recently, the Code of Federal Regulations was amended to include this recordkeeping requirement for wholesalers, ([21CFR205.50f](#)). There is fortunately [guidance for this documentation](#), and it appears to include the classic documentation, such as delivery slips, also in paper form. The classic burden of keeping these records has simply been extended to the other players in the supply chain.

ISO IDMP Standards (Identification of Medicinal Products)

A shorter timeline is given in the EU for implementing the [IDMP Standards](#), and its deadline is July 2016. The EMA will begin providing data management services so that the ISO standards for maintaining the SPOR data, (substance, product, organization, referential), are followed. This information will subsequently be used in the tracing and tracking schemes.

Corporate Fraud at Philips Respironics

It may seem like splitting hairs to consider providing free call center services to suppliers a kickback scheme, but the suppliers then logically push the Respironics sleep-aid products. The attorneys for the US Dept. of Health & Human Services consider it a [Violation of the False Claims Act](#), since funds from government programs were used to buy these sleep-aid products. The competitive advantage must have been significant, in light of the agreed settlement to pay \$34.8 million. Besides the fine, Respironics has been forced into a [Corporate Integrity Agreement](#), which may be even more unpleasant, i.e. bureaucracy costs time and money.

Warning Letters of Interest

The FDA has made a slow start posting WLs for 2016, but 2 were posted for finished pharmaceutical manufacturers in India. Also 2 American compounding facilities came under fire.

The [WL to Indian Emcure Pharmaceuticals](#) gives a lesson in Sterility Unassurance. The inspectors were not happy observing aseptic filling operators crawling on their hands and knees as part of the apparently normal operations, which also involved filling water, (WFI?), in a jug placed on the flow. Also the inspectors were able to determine that the operators conducting visual inspections were not identifying defects.

Again this finding, typical for India was made: "During our inspection, we observed multiple examples of incomplete, inaccurate, or falsified laboratory records."

The [WL to Ipca Laboratories](#) was focused upon data integrity, particularly regarding lab testing records, "Our investigators observed systemic data manipulation and other CGMP violations and deviations at three separate sites. Your quality system does not adequately ensure the accuracy and integrity of the data generated and available at your facilities to support the safety, effectiveness, and quality of your drugs."

With such strong evidence of noncompliance, it is hard to rationalize why it took 1 – 2 years to issue WLs to these firms. Apparently, some Emcure products are barred entry to the US market, but none yet from Ipca. The following standardized text gives some insight here:

"If, as a result of receiving this warning letter or for other reasons, you are considering a decision that could reduce the number of finished drug products produced by your manufacturing facility, FDA requests that you contact CDER's Drug Shortages Staff immediately, as you begin your internal discussions, at drugshortages@fda.hhs.gov so that we can work with you on the most effective way to bring your operations into compliance with the law..... In appropriate cases, you may be able to take corrective action without interrupting supply, or to shorten any interruption, thereby avoiding or limiting drug shortages."

The US has apparently become so dependent upon offshore suppliers of drugs, that they cannot simply ban the import of substandard drugs. There is also the political aspect of fostering trade with India to consider. Global manufacturing is not a level playing field.

"Right-sizing" Corporate Compliance?

Contact msg industry advisors to perform your individual compliance fitness check.