

Implementing the ANSI NSF-IPEC 363 Standard on Excipient GMPs Will Help Ensure Compliance with FDASIA, FMD and EU's New Excipient Risk Assessment Guideline

Implementation of the ANSI NSF-IPEC 363 standard on GMPs for excipients by pharma and excipient manufacturers will help ensure that they are compliant with the supply chain mandates of the FDA Safety and Innovation Act (FDASIA), the EU Falsified Medicines Directive (FMD), and the newly-completed EU excipient risk assessment guideline.

At the International Pharmaceutical Excipient Council (IPEC)/ExcipientFest conference in late April in San Juan, Puerto Rico, IPEC Federation President Janeen Skutnik-Wilkinson discussed the import of the new ANSI NSF-IPEC 363 standard and how its implementation will help prepare both pharma and excipient manufacturers for meeting the FDASIA, FMD, and EU guideline expectations.

Skutnik-Wilkinson was heavily involved in the development of the standard and the 2006 IPEC/Pharmaceutical Quality Group (PQG) GMP guide out of which the standard grew. Currently a Compliance & Standards Staff Associate at Biogen in addition to being President of the IPEC Federation – which includes regional councils in the US, Europe, Japan, and China – she was previously NSF Health Sciences Pharma-Biotech VP, and is a past chair of IPEC-Americas.

The most salient change in the consensus standard from the IPEC/PQG guide was incorporation of a more clearly-delineated risk-based approach to assuring the needed quality of pharmaceutical excipients ([*IPQ August 20, 2013*](#)). The standard, completed in late 2014, provides a stand-alone, quality system-based GMP standard that industry and regulatory agencies can use in evaluating, auditing, and certifying excipient manufacturing and quality.

NSF is one of a select number of organizations accredited by the American National Standards Institute (ANSI) to develop “national consensus standards” – standards that can be adopted and used by US government agencies such as FDA when the agency has not developed its own standard.

Participation of industry suppliers and users, FDA, and academia in developing the excipient GMP standard – along with a public comment process – means that the standard was fully vetted prior to its adoption.

Meeting the 363 standard “should make the implementation of the expectations” in FDASIA, the FMD, and the EU risk assessment guideline “much easier,” Skutnik-Wilkinson explained.

At the ExcipientFest/IPEC meeting, she explained how implementing the standard enables the needed excipient quality assurance and what is involved in doing so.

Included in the implementation challenges are: ● development by pharma firms of an overall supplier qualification and monitoring program ● variability in processes across suppliers and sites, and ● creating an implementation plan for each supplier site that addresses the resources needed, prioritization of activities, timelines, and management buy-in.

Skutnik-Wilkinson noted that IPEC is developing a risk assessment guideline to help in the implementation of the standard.

Her comprehensive presentation on the 363 standard encompassed: • why the standard was developed • how the standard, IPEC's GMPs, and EXCiPACT are related • the implementation benefits and process for excipient suppliers, distributors, and pharma manufacturers • the importance of a risk-based approach and quality systems for excipient suppliers and pharma manufacturers, and • how EXCiPACT fits in. *[Skutnik-Wilkinson's complete remarks at the ExcipientFest/IPEC conference will be provided in the next IPQ "Monthly Update."]*

The EU excipient risk assessment guideline provides expectations for a formalized risk assessment of "appropriate GMP for excipients of medicinal products for human use" [link provided below]. The guideline was approved in March 2015 with a one-year implementation deadline.

The "scope" section broadly defines an excipient as "any constituent of a medicinal product other than the active substance and the packaging material." The guideline focuses on "determination of appropriate GMP based on the type and use of excipient," with references to the tools and methodologies presented in ICH Q9 on quality risk management.

The phrase "appropriate GMP" for each excipient opens the door to having different levels of GMP for different excipients manufactured in the same plant – an approach that Skutnik-Wilkinson warned is not viable. Use of the standard, she stressed, will help provide "consistency" in how the EU guide is interpreted.

IPEC will be hosting a webinar on excipient GMPs and the 363 standard on June 3. [Click here](#) for more information.

LINK:

[EU Excipient Risk Assessment Guideline](#)

[A full review of Skutnik-Wilkinson's presentation and the discussions that ensued at Excipientfest will be provided in the next IPQ Monthly Update. By special arrangement with IPEC, excipient suppliers who are members can receive a company-wide license for the normal price of the subscription for an individual user. The license allows everyone in a company to access all of IPQ's coverage of the key drug/biotech CMC and GMP issues globally and the full searchable archives. Contact Wayne Rhodes (rhodes@IPQPubs.com, (202) 841-9720) for more information. IPQ will be providing in-depth coverage of a key excipient regulatory issue in each of its Monthly Updates, with an excerpt included in IPEC's Insider.]

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