Press release

Brussels, March 2018

IPEC Federation joins forces with the Parenteral Drug Association (PDA) to help industry to meet EU risk assessment guidelines for pharmaceutical excipients

IPEC Federation is pleased to announce the first joint initiative with the Parenteral Drug Association (PDA). Both associations signed a memorandum of understanding to collaborate on the development of a joint technical report on excipient GMP risk assessment in response to input from their respective memberships.

In March 2016 IPEC Europe published an "how-to" document to help pharmaceutical manufacturers comply with the European Commission Guidelines on risk assessment for excipients (2015/C 95/02).

In May 2017 a joint IPEC-Americas and IPEC Europe Guide on risk assessment for excipient manufacturers followed. This guide provides excipient suppliers with an overview of risk assessment tools, and resources that they can use, when conducting risk assessments required by both NSF/IPEC/ANSI 3631 and EXCiPACT™ excipient GMP standards.

Both PDA and IPEC Federation believe that presenting a common approach to the legal, regulatory and related issues concerning excipients is best presented as "one voice", and so this joint initiative will deliver one technical document addressing the complex challenges of implementing risk assessment in this context. IPEC Federation sees much benefit in this collaboration bringing in IPEC's excipient expertise from one side, and the drug product manufacturer perspectives through PDA.

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Joint PDA, IPEC Task Force to Work on Excipients TR
by: Michael Schousboe, Novo Nordisk, and Eva Urban, Celgene | Jan 29, 2018

Excipients serve a critical role in the production of final dosage forms for drug products and biologics as they help the product fulfil its purpose *(1)*. Recognizing this critical role, recent EU regulations require manufacturers to ensure appropriate levels of GMP for excipients by using formalized risk assessments *(2,3)*. As of March 21, 2016, excipient users/drug product manufacturers in the European Union are legally mandated to have performed the needed assessments of excipient use and function throughout the entire supply chain.

In 2016, following an initial webinar, a team under the PDA Quality Risk Management Interest Group exchanged their experiences on meeting this requirement. The group then surveyed other companies, finding that these companies have comparable questions. Different solutions have been found in different companies, but similar principles apply.

The group has joined forces with IPEC, who in 2016 published a guide for excipient users on the subject *(4)*. Now, this group and IPEC will work together to produce a joint technical report. The group will form

subteams for different specific topics. Volunteers working within these subgroups will consist of representatives from both PDA and IPEC, and reflect manufacturers and suppliers. Volunteers interested in sharing their company experience and working on the TR are welcome to join the group. Please contact PDA's Volunteer Coordinator.

The technical report will provide examples of industry practices, and propose a generic solution. The document will serve as practical guidance intended for use along with existing regulatory and industry standards. The technical report team expects that the document will enable manufacturers and CMOs to either set up or benchmark their systems, and further establish collaboration with excipient suppliers and distributors.

About

The ***Parenteral Drug Association (PDA)*** is the leading global provider of science, technology and regulatory information and education for the pharmaceutical and biopharmaceutical community. Founded in 1946 as a nonprofit organization, PDA is committed to developing scientifically sound, practical technical information and resources to advance science and regulation through the expertise of its nearly 10,000 members worldwide. PDAs mission is to advance pharmaceutical / biopharmaceutical manufacturing science and regulation so members can better serve patients.

The ***IPEC Federation (IPEC)*** is a global organization that promotes quality in pharmaceutical excipients. The IPEC Federation represents the five existing regional International Pharmaceutical Excipient Councils (IPECs) - IPEC-Americas, IPEC Europe, IPEC Japan, IPEC China and IPEC India - and provides a unified voice to promote the best use of excipients in medicines as a means of improving patient treatment and safety. IPEC's objectives are to contribute to the development and harmonization of international excipient standards, the introduction of useful new excipients to the marketplace and the development of good manufacturing and good distribution practice for excipients.

References

1. Holtz, F. "Establishing a Formalized Risk Assessment for Excipients." *PDA Letter* (January 2017) 53: 40–43.
2. "Directive 2011/62/EU." *Official Journal of the European Union* 54 (2011): 74-87.
3. Guidelines of 19 March 2015 on the formalised risk assessment for ascertaining the appropriate good manufacturing practice for excipients of medicinal products for human use (2015/C 95/02)
4. March 18 2016, IPEC Europe "How-to" document related to Guidelines of 19 March 2015 on the formalized risk assessment for ascertaining the appropriate good manufacturing practice for excipients of medicinal products for human use (OJ 2015/C 95/02)