Announcing the publication and availability of the revised IPEC-PQG GMP Guide in May 2017

The IPEC – PQG Good Manufacturing Practices (GMP) for Pharmaceutical Excipients 2017

The IPEC Federation and PQG have updated the IPEC-PQG GMP Guide, bringing the document in line with the latest thinking on Good Manufacturing Practice requirements for pharmaceutical excipients.

The revised guide will be officially available to download on 16 May 2017 from the following websites:

IPEC Federation: www.ipec.org
IPEC-Americas: http://ipecamericas.org
IPEC China: www.ipec-china.org/info/cn
IPEC Europe: www.ipec-europe.org
IPEC Japan: www.jpec.gr.jp/english/index.html
PQG: www.pqg.org

The quality of excipients is critical to assure the safety, quality and efficacy of medicines. Excipients have a wide range of applications and are essential components of the drug product formulation. Characteristics that excipients impart to formulated drug products include cosmetic appearance, stability and delivery of the active ingredient making the application of appropriate GMP principles essential.
The 2017 version of the IPEC-PQG GMP Guide replaces the 2006 edition. While the fundamental principles of GMP remain, there have been important changes in the way adherence to GMP should be achieved.

There is now an increased regulatory emphasis on risk-assessment. The EU Directive on Falsified Medicines (2011/62/EU) sets out a requirement for pharmaceutical manufacturers to carry out a risk-assessment for excipients used in medicines to determine the appropriate level of GMP used to produce them. This led to the publication of the EU Guidelines on risk assessment for excipients (2015/C 95/02) effective since 21 March 2016. While it applies to pharmaceutical manufacturers this same risk assessment thinking should also be applied by excipient manufacturers as they implement GMP.

The Guide needed to be updated to take into account the EXCiPACT and ANSI standards, against which excipient suppliers can be certified to provide assurance that they are operating in conformance with excipient GMP.

Third-party certification referencing EXCiPACT, ANSI and Japan's GAB is increasingly being adopted by excipient producers and sought by pharmaceutical manufacturers.

"We needed to bring the guidance up to date with new requirements such as risk assessment, and also make sure that it is fully aligned with standards such as EXCiPACT and ANSI," said Kevin McGlue, the Revision Task Force Leader for the Guide. "Users of the new version will be brought fully up-to-date with the latest GMP thinking for excipients."

Other updates to the Guide include the provision of greater detail on documentation – taking into account the shift to from paper to electronic record-keeping over the last decade – as well as refined and expanded guidance about corrective actions, sample retention, and packaging.

The Guide is an important accompaniment to EXCiPACT's international standard as well as NSF/IPEC/ANSI 363 standard, according to McGlue. It provides guidance for groups just starting with GMP, as well as for those who may not want to go down the certification route. It also gives initial assistance for those just starting to think about standards and certification in the context of pharmaceutical excipients.

*The **IPEC Federation** is a global organization that promotes quality in pharmaceutical excipients. The IPEC Federation represents the five current regional International Pharmaceutical Excipient Councils (IPECs) - IPEC-Americas, IPEC Europe, IPEC Japan, IPEC China and IPEC India - and which provides a unified voice to promote the best use of pharmaceutical excipients in medicines as a means of improving patient treatment and safety.*
(www.ipec.org).

*The **Pharmaceutical Quality Group (PQG)** was formed in 1977 to promote development of a consistent approach to pharmaceutical quality and good manufacturing practice. The group has since expanded, and in 1990 the PQG published three codes of practice to cover pharmaceutical raw materials, printed and contact packaging materials. In 1995 the codes were revised and were integrated with ISO 9002:1994. The code for raw materials was revised and reissued as PS 9100:2002 Pharmaceutical excipients, an application standard and GMP guide for pharmaceutical excipients.*
(www.pqg.org)