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EXCiPACT™ - International Pharmaceutical Excipients Certification Project Update

Minimize risks – maximize benefits

The safety of medicines for patients is paramount to all; the pharmaceutical industry, suppliers of excipients, national and regional health care agencies and regulators. To assure the quality of medicines produced, risks in the supply chain need to be evaluated and minimized.

Thousands of different excipients are used in medicines and make up, on average, about 90% of the volume or weight of each product. They represent a market value of approximately €3 billion, accounting for 0.5% of the total pharmaceutical market according to industry experts. However, only few excipients are manufactured solely for pharmaceutical use.

With proposed legislation requiring cGMP and cGDP for excipients in Europe and the USA, excipient suppliers will be faced with an avalanche of quality audits and related requests to ensure their facilities and products meet these new requirements.

Excipient suppliers, distributors and the pharmaceutical industry are fully committed to control the use of high quality excipients throughout the supply chain, and ensure this by self-regulation. As a result, a group of industry experts from the European Fine Chemicals Group (EFCG), the International Pharmaceuticals Excipients Council (IPEC) Europe, IPEC Americas, the European Association of Chemicals Distributors (FECC), and the Pharmaceutical Quality Group (PQG), have worked together on the development of a certification scheme for pharmaceutical excipient suppliers – called EXCiPACT™.

All these parties are in agreement that an international pharmaceutical excipient current good manufacturing practice (cGMP) and current good distribution practice (cGDP) certification scheme is one of the tools which help to ensure the quality and reliability of these key ingredients for medicinal products throughout the supply chain.

The EXCiPACT™ scheme provides independent certification of manufacturers and suppliers of pharmaceutical excipients as a means of ensuring patient safety, through supplier quality, while minimising the overall supply chain costs.

Key project principles:

- “International”: a pharmaceutical excipient manufacturer’s certification should have the same acceptance and value anywhere in the world

- “Inclusivity”: the scheme will provide quality standards and be applicable to all pharmaceutical excipients
- “Accessibility”: the scheme should be accessible from as many 3rd party auditing organisations as possible
- “Evolution not revolution”: builds upon existing best practices, guides and standards
- “Simplicity”: the overall scheme should be as simple as possible.

Key deliverables:

- cGMP and cGDP standards suitable for 3rd party auditing
- Definition of auditor competency
- Definition of training requirements for auditors
- Certification scheme rules for 3rd party audit organisations resulting in an EXCiPACT™ certificate

EXCiPACT™ Project update

The EXCiPACT™ cGMP and cGDP standards Version 2 was made available for public and stakeholder review between March and June 2011. All submitted comments have been reviewed and amendments made to create the official Issue 1, which is being prepared for publication later in 2011. A pilot study will follow to complement the overall launch process.

As the EXCiPACT™ standards act as Annexes to ISO standards 9001, 19011 and 17021, organisations already ISO certified will find it very effective to extend their ISO certification to the EXCiPACT™ standards. Alternatively, suppliers who do not hold ISO 9001 certification will be able to obtain an equivalent certificate through the forthcoming US national standard (ANSI-NSF 363), which also uses the EXCiPACT™ GMP standard. All suppliers will, therefore, have the choice of which certification route to follow. In either case, the requirements will be the same.

EXCiPACT™ is being planned for launch on 25th January 2012 in Barcelona.