



International Excipients Certification Project: minimize risks – maximize benefits

The safety of medicines for patients is paramount to all; the pharmaceutical industry, suppliers of raw materials, 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.

In addition to active pharmaceutical ingredients, excipients are present and used in the formulation of pharmaceutical finished dosage forms. They serve many purposes in dosage forms, from aiding in the manufacture of the pharmaceutical product to influencing the bioavailability of the active ingredient. Thousands of different excipients are used in medicines and make up, on average, about 90 % of each product. They represent a market value of € 3 bn., accounting for 0.5 % of the total pharmaceutical market according to industry experts.

Whereas the supply, distribution and use of active ingredients are regulated internationally, no such schemes exist for excipients. Nevertheless, excipient suppliers, distributors and the pharmaceutical industry are committed to use quality raw materials throughout the supply chain and control this by self regulation.

A group of industry experts from European Fine Chemical Group (EFCG), International Pharmaceutical Excipients Council (IPEC) Europe, IPEC Americas, European Association of Chemical Distributors (FECC), and Pharmaceutical Quality Group (PQG) have worked together on the development of a certification scheme for excipients suppliers. All parties are in agreement that an international pharmaceutical excipient good manufacturing practise (GMP) and good distribution practice (GDP) certification scheme will ensure the safety of these key ingredients of drug products throughout the supply chain.

The scheme proposes an independent certification of manufacturers including a classification of excipients based on risk. This is a means of ensuring patient safety, improving assurance of supplier quality, while minimising the overall supply chain costs.

The key project principles are:

- “International”: an excipient manufacturer’s certification should have the same acceptance and value anywhere in the world.
- “Inclusivity”: The scheme should provide quality standards and be applicable to as many excipients as possible.
- “Accessibility”: The scheme should be accessible from as many 3rd party organizations as possible.
- “Evolution not revolution”: Existing best practices, guides and standards should be utilised and adapted wherever possible.
- “Simplicity”: The overall scheme should be as simple as possible.

To fulfil these principles, the project has been set-up by an international group of organizations broadly representing excipient manufacturers, distributors and users. The project steering committee has, and will, consult stakeholders such as national regulators and trade associations, throughout the duration of the project.

Key deliverables are:

- Classification system for excipients in relation to patient risk
- Revision of the established IPEC-PQG GMP Guide to cover manufacturing of excipients for enhanced risk classes
- GMP and GDP standards suitable for 3rd party auditing
- Auditor competency schemes
- Certification scheme rules for 3rd party audit organisations
- Publication, communication and ongoing maintenance of the schemes, standards and guides developed

The project team will deliver these schemes by end of 2010. Starting from December, 2009 draft documents for the schemes will be sent out to key stakeholders for review. A public review of all schemes will follow from spring 2010.

This project does not envisage mandatory certification of excipients nor additional legislative or regulatory burden. However, should regulatory agencies require third party certification or a mandatory GMP for excipients, industry will be ready with a consistent, harmonised science and risk based approach to the subject.

To read more:

http://efcg.cefic.org/downloads/excipients_stakeholder_meeting_PR_090621.pdf