



IPEC Europe Task Force acts to help industry meet EU risk assessment guidelines for excipients

23 July 2015: IPEC Europe's recently-formed Risk Assessment Task Force is preparing a document to help pharmaceutical manufacturers comply with the EU Guidelines on risk assessment for excipients (2015/C 95/02).

At its inaugural face-to-face meeting on 1 July in Brussels, the Task Force agreed that a 'how-to' document will help drugmakers establish the appropriate GMP for excipients used in their products. The need is urgent as risk assessments for all excipients must be completed before the deadline of 21 March, 2016.

The compliance guide will draw on the experiences of both excipient suppliers and pharmaceutical manufacturers, according to the Task Force. It will cover the scope of the guideline, emphasise the new requirements that will come into play and detail the responsibilities of excipient manufacturers, distributors and users.

The document will also identify risk-mitigation activities and provide advice on how to resolve any conflicts that may emerge during the process, amongst other aspects. Practical examples will be included.

In May, the IPEC Federation* published a [position statement](#) noting that considerable effort will be required by the industry in order to complete all excipients risk assessments by the deadline.

"The implementation of appropriate excipient GMPs by suppliers will require more than a year, and may be difficult to achieve for manufacturers of certain substances not typically produced as pharmaceutical excipients," says the statement.

"Incomplete assessments may jeopardize the availability of high quality excipients that have been in use for many years."

Stakeholders who would be interested in taking part in the preparation of the new compliance guide - which is scheduled for publication in October - are invited to contact the IPEC Europe Secretariat.

The IPEC Europe Risk Assessment Task Force includes representation from leading suppliers and users of pharmaceutical excipients.

** The IPEC Federation represents the four existing regional International Pharmaceutical Excipient Councils: IPEC-Americas, IPEC Europe, IPEC Japan and IPEC China.*

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