



# Press Release

Brussels Belgium 20 January 2015:

The International Pharmaceutical Excipient Council Federation, (IPEC Federation) announces the availability of the IPEC Significant Change Guide for Pharmaceutical Excipients. The purpose of the guide is to establish a uniform approach to the evaluation of the significance of changes involving the manufacture and distribution of pharmaceutical excipients. The purpose of the evaluation is to consider the impact of the change on the excipient and to determine whether or not the excipient user and/or regulatory authority should be informed.

This is the first guide that has been published by the IPEC Federation, a global organization consisting of four regional associations (Americas, China, Europe, and Japan) organized to promote standard harmonization, quality and safety of pharmaceutical excipients.

A major revision to the guide is the modification from three levels of change to only two levels of change. Therefore changes have become either significant or not significant. This will allow for a much clearer distinction for when customer notification will be required, as some confusion has been perceived in the past. The guide will be available for download by IPEC members immediately and a hard copy may be purchased from the IPEC Europe website.

Presentations relating to the updated guide will be provided at the following two events:

IPEC Europe Excipients Forum, Feb. 5, Nice, France:

[http://ipec-europe.org/UPLOADS/Preliminary\\_program\\_Nice\\_web4.pdf](http://ipec-europe.org/UPLOADS/Preliminary_program_Nice_web4.pdf)

ExcipientFest Americas, April 28-29, San Juan, Puerto Rico <http://www.excipientfest.com/>

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