



Press Release

Brussels (Belgium), 13 January 2021

The International Pharmaceutical Excipients Council Federation, (IPEC Federation) announces the availability of the new International Pharmaceutical Excipient Council Validation Guide for Pharmaceutical Excipients. This guide is applicable globally.

The guide was developed to help describe activities taken by excipient manufacturers to test and evaluate their systems, processes and methods in order to provide a high degree of assurance that they consistently produce results meeting predetermined acceptance criteria. It recognizes that an excipient manufacturer often does not perform “validation” activities in the same manner or to the same extent as the pharmaceutical industry, however, many activities that they do perform leads to the same degree of assurance. In addition, the guide attempts to address how to document the activities that are currently used by an excipient manufacturer to successfully produce excipients in a manner that meets the excipient user’s expectations.

The guide will be available, initially exclusively to IPEC members for a three-month period, on the [IPEC Federation](http://www.ipec-federation.org) and national/regional members’ websites. Thereafter, the guide will be made available to the general public.

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