



Press Release

Brussels (Belgium), 25 February 2025

The International Pharmaceutical Excipients Council Federation, (**IPEC Federation**) announces the availability of the revised IPEC Incorporation of Pharmaceutical Excipients into Product Development using Quality-by-Design (QbD) (Version 2, 2025). The guide was first published as an IPEC Federation guide in 2020; however, with this revision, the guide has been updated to include an annex incorporating contents from the 2016 IPEC-Americas QbD Sampling Guide. This guide is widely applicable globally.

The primary goal of the QbD guide is to

- introduce Quality-by-Design (QbD) and pharmaceutical formulation development concepts to excipient manufacturers and suppliers,
 - provide an explanation of how changes in pharmaceutical formulation practices, due to the introduction of QbD, impact excipient manufacturers and suppliers,
 - provide understanding for excipient manufacturers and suppliers as to what excipient users will likely require when applying QbD principles during product development, and
 - provide understanding to excipient users and regulatory agencies regarding what may or may not be possible when considering the impact of excipient variability in the application of QbD principles during product development.
- include an Annex to address the provision of samples to support QbD studies.

This Guide includes recommendations related to the impact of excipient variability on drug product quality during development and to justify management of excipient variability in the control strategy. It contains useful explanations and suggestions for pharmaceutical excipient makers and users.

The Guide is applicable to excipient use throughout the pharmaceutical product development process using a Quality by Design (QbD) approach described by the International Conference on Harmonization (ICH) Q8 as well as other applicable ICH Guidelines such as ICH Q9, Q10, Q11, Q12 and Q13.

The guide will be available, initially exclusively to IPEC members for a three-month period, on the [IPEC Federation](#) and national/regional members' websites.

Thereafter, the guide will be made available to the public.

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