Press Release

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The International Pharmaceutical Excipients Council Federation, (IPEC Federation) announces the availability of a new guide: Incorporation of Pharmaceutical Excipients into Product Development using Quality-by-Design (QbD guide).

The primary goal of the QbD guide is to:

- introduce Quality-by-Design (QbD) and pharmaceutical formulation development concepts to **excipient** manufacturers and suppliers,
- explain how changes in pharmaceutical formulation practices, due to the introduction of QbD, impact excipient manufacturers and suppliers,
- help excipient manufacturers and suppliers understand what excipient **users** will likely require when applying QbD principles during product development, and
- explain to excipient users and regulatory agencies what may or may not be possible when considering the impact of excipient variability in the application of QbD principles during product development.

This Guide includes some recommendations related to the impact of excipient variability on drug product quality during development and how excipient variability can be managed 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 Council on Harmonization (ICH) Q8 as well as other applicable ICH Guidelines such as ICH Q9, Q10, Q11, and Q12.

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 general public.

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