



Press Release

Brussels (Belgium), 6 May 2025

The International Pharmaceutical Excipients Council Federation, (**IPEC Federation**) announces the availability of the IPEC Risk Assessment Guide for Pharmaceutical Excipients – Risk Assessment for Excipient Manufacturers (Version 1, 2025). First published as a joint IPEC-Americas and IPEC Europe Guide in 2017, it is now issued as an IPEC Federation document. Widely applicable globally, it has been updated to reflect current practices and streamlined by removing duplicated content from referenced materials.

The IPEC Risk Assessment Guide provides detailed guidance on evaluating risks to excipient quality, supporting excipient manufacturers and distributors in making consistent, risk-based decisions, and serves as a resource for excipient users assessing their suppliers' risk strategies.

Key Risk Assessment methodologies and tools for identifying and mitigating quality-related risks are outlined; this document is essential to understand and apply effectively the risk assessment principles referenced in the IPEC-PQG GMP (Good Manufacturing Practices) and IPEC GDP (Good Distribution Practices) Guides for Pharmaceutical Excipients.

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.

For further information, please contact the IPEC Federation Secretariat at:
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