



Press Release

Brussels, Belgium, 30 April 2020

The International Pharmaceutical Excipients Council Federation, (IPEC Federation) announces the availability of a new position paper on Data Integrity for Pharmaceutical Grade Excipients.

This paper was developed to supplement published regulatory guidance defining data integrity requirements for drug substances and medicinal products, some of which are not easily adaptable to the manufacture of excipients.

Data integrity, the extent to which data are complete, consistent, accurate and maintained as such throughout the data lifecycle, is fundamental to the application of GMPs. Based on this, data integrity is clearly relevant to excipient manufacturing; however, data integrity controls for excipients may be different from controls used for manufacturing of drug substances and medicinal products.

IPEC believes that data integrity controls for excipient manufacturing and distribution processes should be commensurate with risks. Where the loss of data integrity would potentially jeopardize compliance with excipient GMPs/GDPs, impact confidence in excipient quality, pose potential harm to the patient, or cause the failure or rejection of the medicinal product, a higher level of controls would be necessary.

In addition to providing IPEC's position and recommendations on how to apply data integrity to excipient manufacturing and distribution, this paper provides references to where data integrity concepts and definitions have recently been incorporated into the various excipient GMP Standards and Guides.

The position paper will be available for download immediately via this website: ipec-federation.org

For further information contact the IPEC Federation Secretariat at:
+32 2 213 74 40 / info@ipec-federation.org

The International Pharmaceutical Excipients Council – Federation (IPEC Federation) asbl

Rue Marie de Bourgogne 52 - 1000, Brussels, Belgium

W: ipec-federation.org T: +32 2 210 74 40 E: info@ipec-federation.org.

VAT: BE 08239313 61 - IBAN: BE73 3630 6812 5160 - RPM Brussels Capital Region