Impact of Variability of Excipient Properties on Drug Product Manufacturing and Performance

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A brief, selective history of the focus on excipient quality and functionality…

1974 – OTA's ***Drug Bioequivalence Study Report***

1974 – ***Katalog Pharmazeutische Hilfstoffe*** – published under the collaborative auspices of Hoffmann-La Roche, Ciba-Geigy, and Sandoz

ca. 1976 – ***Handbook of Pharmaceutical Excipients*** – Academy of Pharmaceutical Sciences of APhA; Pharmaceutical Society of Great Britain — **1st edition, 1986**

> *The **HPE** comprises practical compilations of technical data, test methods, and relevant literature…*

Contemporaneous developments…

- 1976 – *Pharmaceutical Technology*
- 1987 – Pharmacopeial Discussion Group (**PDG**)
  [USP, EP, JP]
- 1991 – International Pharmaceutical Excipients Council of the Americas (**IPEC**)
- 1992 – Land-o-Lakes Conference on “Pharmaceutical Excipients: Characterization, Functionality, and Harmonization”

Nonetheless, limited information has been available up until now, in the public domain, regarding objectionable and unexpected variations in drug product manufacturing and performance that can be attributed to variations in excipient properties.

The intended function of the excipient, the nature and robustness of the formulation, the unit operations comprising the product manufacturing process, can all potentially be affected by the excipient properties.

Primary Objective

To survey the pharmaceutical industry and establish the collective knowledge of excipients known to have caused problems in the course of drug product manufacturing or in finished drug product quality issues…

Secondary Objective

To enable generalizations to be made regarding source-to-source, grade-to-grade, and lot-to-lot critical excipient functionality-related properties that relate to drug product manufacturing and/or performance

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THE INITIAL SURVEY IS ANTICIPATED TO BE CONDUCTED *VIA* SURVEY MONKEY® TO MEMBERS OF AAPS, IPEC, etc.

THE RESULTS WILL BE ANALYZED & USED TO CONSTRUCT A SECOND, MORE SPECIFIC SURVEY…