

Bretta Lichtenhan Abstract

The excipient supply chain, appropriate GMPs and excipient qualification are three tightly aligned topics. In this presentation we will cover the IPEC Federation's recent position paper on the excipient supply chain, and how the supply chain should be controlled from the excipient manufacturer to the final product manufacturer. In addition, we will discuss the current state of excipient GMP by reviewing the current documents that guide the industry such as the IPEC guides, EXCiPACT™ and NSF/IPEC/ANSI 363 standards. The presentation will aim to explain the differences and how each would be applied and used by the excipient maker and user. Lastly the presentation will cover the importance of excipient qualification by highlighting IPEC's Qualification of Excipients for Use in Pharmaceuticals guide.