January 17th Webinar: Supplier Qualification for Excipient Makers and Users

Date: Wednesday, January 17, 2018 - 11:00am to 1:00pm EST

Featuring Irwin B. Silverstein – Lead Trainer and Consultant, IPEC-Americas

Description:
This webinar is an overview of the IPEC guide Qualification of Excipients for Use in Pharmaceuticals. It reviews the general guidance section with emphasis on the regulatory assessment, manufacturing and packaging, and excipient specifications. The webinar also provides an overview of the users’ assessment, selection and specification process; concluding with pitfalls that arise from negotiation of excipient specifications between supplier and customer.

Webinar Objectives for Excipient Makers:
● Identify regulatory considerations to be addressed
● Identify user requirements
● Learn how to develop excipient specifications
● Understand how to market your excipient

Webinar Objectives for Excipient Users:
● Understand the impact of the uniqueness of excipient manufacture
● Recognize steps for the selection of an excipient
● Understand how to select a supplier
● Learn the pitfalls of the various options for negotiating the excipient specification

Who Should Attend:
Employees from; Quality, Regulatory Affairs, Supplier Qualification/Management, Purchasing

Presenter
Irwin B. Silverstein: Irwin is a consultant to IPEC and the excipient industry specializing in quality assurance and regulatory compliance for pharmaceutical excipient ingredients. He also has experience in areas of quality assurance for API, medical device and drug products.

For 17 years, he was Corporate Director of Quality Assurance for International Specialty Products (ISP) with responsibility for their excipient, API, and medical device products. He has worked since 1991 with the International Pharmaceutical Excipients Council (IPEC) developing guidelines for excipient GMP compliance and has represented IPEC at various conferences and at the Food & Drug Administration. Dr. Silverstein established an excipient GMP certification program that was accredited by the American National Standards Institute (ANSI) and ran the program from 2001 till sale of IPEA in 2014.
His recent consulting has broadened to include pharmaceutical firms where he assesses conformance to site requirements. As an experienced GMP auditor, with American Society for Quality (ASQ) Certified Quality Auditor (CQA) status as well as ISO 9000 Certified Lead Auditor training, he has developed the IPEC-Americas auditor training, and GMP eLearning programs.