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PRESENTATION ABSTRACT

Title: Excipient Certification and Supply Chain Security

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Abstract: Excipients form a critical part of the Drug Product and are just as important in assuring patient safety as the Active Ingredient. In this respect users of excipients need a high degree of assurance about how the Excipient is manufactured and how it was shipped to them. From the users perspective the number of excipients in use and the number of suppliers of those excipients means that gaining this assurance first hand through audits and other direct means is both challenging and expensive in terms of resources and time. Yet from an excipient supplier's perspective the situation could be quite extreme with some suppliers receiving 100 audits or more a year. In some cases just managing these audits can be a full time job.

A solution to these armies of auditors is to use 3rd party certification processes. These can provide the necessary assurance of the excipient origin in terms of GMP and GDP. The European Fine Chemicals Group (EFCG) and the International Pharmaceutical Excipients Council (IPEC) have joined forces with the UK Pharmaceutical Quality Group (PQG) and the Federation of European Chemical Distributors (FECC) to develop an excipient GMP and GDP certification scheme. The GMP certification will be based on the well known and accepted Joint IPEC-PQG GMP Guide for Pharmaceutical Excipients (2006) and the IPEC GDP Guide (2006).

The presentation will explain the current status in the development of the scheme, and how it can be used by suppliers and users to improve the security of excipient supply chains.