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Qualifying pharmaceutical excipient suppliers: The role of EXCiPACT™

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Regulatory authorities expect excipient suppliers the world over to be audited regardless of whether they supply innovative, generic or OTC pharmaceutical companies. These expectations place a greater audit burden on all parties concerned. And what can be done when the supplier indicates they cannot or will not accept an audit?

The session will highlight the core features of a credible 3rd party audit scheme and compare the EXCiPACT™ Certification Scheme against them. The use of a risk assessment to determine an excipient supplier's GMP/GDP suitability and the use of a suitable 3rd party audit report like those from EXCiPACT™ Certified Suppliers will be demonstrated. The initial experiences of excipient suppliers holding EXCiPACT™ Certificates will also be shared.

If you manage a supplier audit program, or are an auditor, or host GMP audits then the session will explain how the EXCiPACT™ Certification Scheme can help you maximise the benefits of a high quality, 3rd party audit whilst minimising the risks. The session will be equally interesting to excipient suppliers, pharmaceutical manufacturers and those Certifying Bodies intending to offer EXCiPACT™ Certification as it will show how the Certificates and Audit reports can be used to best effect by pharmaceutical excipient users.

Biography

Allan Whiston is a professionally qualified Quality Practitioner (CQP) and Chartered Engineer (CEng) with 40 years' experience in the Pharmaceutical Industry. His later years in the industry were at Director level in global positions based in Germany. As a past Chair and current member of the IPEC Europe GDP Committee, he has developed and co-authored publications such as The IPEC Good Distribution Practices Guide (2006) and The IPEC Good Distribution Practices Audit Guideline (2008). Allan was part of the EXCiPACT standard development team and now sits on the Board of EXCiPACT asbl.

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