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Cork Region - Evening Lecture

Revised FDA Guidelines for Process Validation Impact on C & Q Programmes

Speaker: Alice Redmond, BSc, PhD, MBs
CQ Technical Director, PM Group

The FDA published its draft Guidance for Industry 'Process Validation: General Principles and Practices' in November 2008. This set out the general principles and approaches that the FDA consider appropriate for process validation for the manufacture of Human and Veterinary drugs including Biologicals and API's.

This lecture will discuss the three stages of Process Validation outlined, i.e. Process Design, Process Qualification and Continued Process Verification. It will review the guidance with particular emphasis on its impact on the current industry approaches to science and risk-based design and qualification.


Alice Redmond has more than 20 years of experience in the R&D, Pharma and BioPharm industry. Current responsibilities include oversight of regulatory compliance, GEP, quality, C&Q and validation strategies for PM Group.

Date: Tuesday 9th March 2010 @ 8.00pm.
Venue: Rochestown Park Hotel, Cork

All are Welcome

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