Regulatory Update – The New European Peptide Quality Guideline

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The presentation will provide an overview on current European regulatory expectations in light of the EMA Guideline on the development and manufacture of synthetic peptides published in December 2025. The presentation will outline key regulatory principles governing quality, characterization, and control strategies for these complex active substances. Particular emphasis will be placed on the unique position of synthetic peptides, which bridge the gap between traditional small molecules and recombinantly expressed proteins and therefore raise specific analytical and regulatory challenges. The talk will highlight how the new guideline addresses these challenges and clarifies expectations for applicants developing synthetic peptide medicines.