Current European regulatory expectations for synthetic peptides

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The number of clinical trial applications for human products and marketing authorisation applications for synthetic peptides significantly increased over the last few years. From an analytical and regulatory perspective, peptides are interesting since they present a link between products derived from biotechnology and small molecular chemical compounds. The European Medicines Agency (EMA) is currently drafting a guideline on the development and manufacture of synthetic peptides.

A summary on the development and approval process for medicinal products will be provided. More specifically current European regulatory expectations for synthetic peptides will be outlined.

[1] Concept Paper on the Establishment of a Guideline on the Development and Manufacture of Synthetic Peptides, September 2022, EMA/CHMP/QWP/735422/2022