BJCP-EMA commentaries on the guideline on quality, non-clinical and clinical aspects of medicinal products containing genetically modified cells.

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Abstract

Great advances have been made in the knowledge of development and regulatory approval of medicinal product containing genetically Modified cells. Although a guideline has been available in the EU since 2012, the current updated version provides a useful guide to developers and professionals involved in the regulatory process of these medicines. This article presents the main issues communicated in that guidance, the regulators' insights and a commentary from the academic developers' point of view.

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