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EU biosimilar regulations: An analysis of the data which has underpinned the approval of biosimilars granted marketing authorizations in Europe

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The European Union has enacted a comprehensive legislative framework and associated regulatory provisions for the approval of biosimilar products. This has underpinned the approval in Europe of 14 such biosimilars since 2006. EU biosimilar regulations require the generation of comparative data between the proposed biosimilar product and its chosen reference product, i.e. the product to which it claims biosimilarity. The marketing authorization application for a biosimilar product must contain a full quality module as well as reduced clinical and non-clinical data modules. This presentation will provide an analysis of the main datasets (quality, non clinical & clinical) that underpinned regulatory approval of several biosimilars. The analysis seeks to illustrate key concepts enshrined in EU biosimilar regulations and to illustrate how European regulators are interpreting those concepts in practice.

Biography

Gary Walsh is an associate professor of biotechnology at the University of Limerick, Ireland. His research interests span various aspects of pharmaceutical biotechnology and his 220 publications include 9 authored books, 2 edited books, 12 book chapters and 70 journal articles. He has presented invited/keynote papers at 36 international conferences. He has served as editor, biotechnology section, of the European Journal of Pharmaceutics and Biopharmaceutics and as a member of the editorial boards of Biopharm. International, New Drugs and the Encyclopaedia of Industrial Biotechnology. He is a former scientific secretary and member of the board of governors of the European Association of Pharmaceutical Biotechnology.