It is now 12 years since the regulatory framework for biosimilar medicines was established in the EU and ten years since the overarching guideline on biosimilar medicines, prepared by the Committee for Medicinal Products for Human Use (CHMP), came into force. Since that time, biosimilar products of increasing complexity, from both a molecular and a clinical perspective, have received a marketing authorisation. Both the overarching biosimilar guideline and its sister guidelines covering quality and nonclinical and clinical issues have been updated in the past 12 months, reflecting the increasing experience regulators now have with biosimilars and the maturation of expectations for their development.

In the US, the regulatory pathway for biosimilars is newer than that in the EU. Nevertheless, the FDA has been heavily engaged in guiding biosimilar development and providing advice to stakeholders, with the first biosimilar medicine approved in the US in March 2015 (filgrastim biosimilar: Zarzio). Globally speaking, the regulation of biosimilar medicines has advanced considerably in recent years; the publication of biosimilars guidance by the World Health Organisation in 2010 represented an important milestone and has supported developing economies in creating robust regulatory mechanisms for biosimilars, and to distinguish them from generic or “non-similar” medicines.

As we look to the future, many complex issues surrounding the development and clinical use of biosimilars remain. For example, assigning appropriate invented and non-proprietary names for biosimilars, or extrapolation of safety and efficacy across multiple indications, continue to be contentious, hotly debated issues. Concerns surrounding the clinical use of approved biosimilars, particularly when they are to be substituted for – or used interchangeably with – innovator medicines, remain largely unanswered. With several biosimilar products expected to receive marketing authorisation in the next few years, we can expect answers to many of these currently unresolved questions, as the biosimilars industry matures and experience increases.

This edition of Regulatory Rapporteur contains a number of insightful articles discussing both the present and future of biosimilars regulation. We have an interview with Dr Christian Schneider, Chair of the EMA’s Biosimilar Medicinal Products Working Party, who shares his thoughts on the development and evolution of biosimilars regulation in the EU over the past ten years as experience and understanding has grown.

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Some of the challenges emerging from the successful development and registration of the current crop of biosimilars are quite thought-provoking; stakeholders will be required to work together to define appropriate pathways going forward to fulfil the potential of biosimilars. Our first focus article discusses the challenges surrounding biosimilars in the future, including whether complex biologics, such as vaccines and advanced therapies, could be developed in this way.

Similarly, increasingly complex molecules such as monoclonal antibodies place a heavy burden on analytics. The development of state-of-the-art analytical methods to characterise the physico-chemical-biological characteristics of protein products such as antibodies has been central to the progression of the biosimilars industry. Our second focus article discusses the importance of critical quality attributes (CQAs) in demonstrating biosimilarity, including an overview of the FDA’s recent CQA classification system.

Aside from the above-mentioned focus features, we have standalone articles covering the topics of medical device risk management and pharmaceutical impurities, in addition to a report on the joint TOPRA/RPIF meeting discussing key topics in education for regulatory professionals.

Finally, we have an interview with Karl Broich, President of the Federal Institute for Drugs and Medical Devices (BfArM), Germany, as a prelude to TOPRA’s 2015 Annual Symposium, which this year is being organised in collaboration with the BfArM and will be held on 12–14 October in Berlin. We hope you’ll be able to join us there.