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Biosimilars regulations: Updates from Canada

Biosimilars is still a relatively new and rapidly developing area of biologics; as such there are ongoing changes in regulatory requirements for biosimilars in different countries across the globe. Recent changes in regulatory requirements in USA and EU have definitely attracted much attention and sparked many comments and discussions. In light of changes in these two jurisdictions, the regulatory landscape in Canada is somewhat overlooked. However, a few interesting and exciting changes in regulatory requirements for Subsequent Entry Biologics (SEBs) have occured in Canada in the last year. Examples include the revision of the guidance document "Information and Submission Requirements for Subsequent Entry Biologics (SEBs)" and the SEB Scientific Advice Meeting Pilot project. This presentation will address the following questions: Are there more differences than similarities between Health Canada, FDA and EMA regulatory requirements, and what is the future perspective?

Biography

Oxana Iliach is a Senior Director Regulatory Affairs at the Biosimilar Center of Excellence, Quintiles. She has more than 15 years of experience in healthcare industry, including the last 10 years in regulatory affairs at pharmaceutical and biotechnology industries. Her expertise lies in the development of global regulatory strategy for biosimilars with the focus on overall quality and CMC compliance. She has a PhD in Pharmaceutical Science from St. Petersburg Chemical and Pharmaceutical Academy, Russia. She is a Professor at Seneca College of Applied Arts and Technology, Toronto, Canada and a member of CAPRA (Canadian Association of Professionals in Regulatory Affairs) and RAPS.

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