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CMC consideration for biosimilar drug development and manufacturing process

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As more and more blockbuster biologics loose patent protection, hundreds of biosimilar/follow-on biologics developments have been started by multiple companies internationally and more will follow next years. Matching biosimilarity is the key for these projects giving a high priority on CMC consideration with new aspects compared to NBE developments like Originator Monitoring to define the QTPP for the upcoming biosimilar and for the subsequent pool and clone selection phase. The analytical characterization and monitoring is crucial to make a quality driven development and to select the most promising candidate on top of aspects productivity, stability and upscaling possibility. Depending on the molecule complex structural characterization, glycosylation and physicochemical analysis with orthogonal techniques is required to demonstrate the biosimilarity to the originator molecule. The presentation will focus on the CMC requirements needed in the different steps of biosimilar development. In addition, different examples will highlight the analytical modules used in each development stage and how they align in a multidisciplinary overall bio-similar development project.

Biography

Marcus Mreyen is an Expert for peptide and protein analysis with a focus on mass spectrometric techniques. He holds a PhD in Chemistry and spent two years in Australia were he worked in the protein analytical field at Macquarie University and the Australian Proteome Facility (APAF). Starting at Protagen in 2000, he successfully worked as a Project Manager and supported customer projects in the various protein fields. He transferred and deepened his technical understanding during a time working for Shimadzu, one of the worldwide leading analytical instrument providers, as a Product Manager for the Mass Spectrometry and Life Science products. During this time, he supported customer in pharma and biotech in Europe and Russia, before returning to Protagen´s Protein Services Unit as a Director Business Development, a company serving now over 180 international clients as CRO to support the development of new protein therapeutics and biosimilars from early phases of discovery, production to GMP release testing.

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