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## ANTIBODIES, BIO THERAPEUTICS & B2B & GENETIC AND PROTEIN ENGINEERING

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## Developing and manufacturing the next generation of bioconjugates

**Thomas Rohrer** 

Lonza Pharma & Biotech, USA

Advances in the coupling of antibodies to potent cytotoxic drugs have resulted in stable delivery platforms with improved pharmacokinetics, which spares patients from the debilitating systemic toxicity observed with traditional chemotherapy. Two ADCs Adcetris\* (brentuximab vedotin) and Kadcyla (trastuzumab emtansine) are currently approved for difficult -to-treat therapeutic indications. Currently three more ADCs, Inotuzumab ozogamicin (Pfizer), Vadastuximab talirane (Seattle Genetics) and Depatuxizumab mafodotin (AbbVie) are undergoing regulatory review or completing Phase III clinical studies. In all, more than 60 ADCs are in clinical trails with over 100 more in the pipeline. In addition to ADCs the multi-faceted field of bioconjugates also extends to coupling targeting agents to non-cytotoxic payloads. Perserving the targeting ability of antibody and the effector function of the payloads require that process R&D find the intersection of reaction parameters which preserve the integrity of both molities. Case studies will be presented which discuss the development and manufacturing of several next generation bioconjugates.

## **Biography**

Thomas Rohrer is Associate Director of Bioconjugate Commercial Development at Lonza and has over 30 years of experience in biotherapeutic process development, scale-up and manufacturing. He holds a BS in Biochemistry and MS in Chemical Engineering. He established process development and clinical manufacturing of ADC(s) at Cambrex Biopharma in 2005. After Cambrex Biopharma was acquired by Lonza in 2007 he joined the Lonza Exclusive Synthesis ADC business team in Visp, Switzerland. Prior to joining Lonza he held senior positions in biotherapeutics process development and manufacturing at Human Genome Sciences, Otsuka Pharmaceutical and the National Cancer Institute (NCI) - Frederick Cancer Research Facility.

tom.rohrer@lonza.com

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