

SINGLE-USE EQUIPMENT FOR HANDLING AND MANUFACTURING OF HIGHLY POTENT APIS

Diego R. Schmidhalter, Director, Lonza AG, Visp, Switzerland
diego.schmidhalter@lonza.com

The industry embraced single-use technology early on after first off the shelf solutions were brought to the market. Initially focused on cell cultures and cell culture products, the use of single-use production solutions expanded over the last decade into other selected technology areas.

The bioconjugates custom manufacturing offering of Lonza has about a 10 years history. While glass and stainless steel based manufacturing equipment dominated in the beginning, the face of bioconjugates manufacture changed in the meantime quite dramatically. Only 7 years after launch of the new market offering, we achieved first successful end-to-end production out of single-use equipment.

Handling of bioconjugates and especially the toxin payload poses a major challenge. The concept of product (patient) safety, a focus in biopharmaceuticals production, is to be amended by the containment and safe working environment aspect. Advantages, caveats and remaining challenges will be discussed.