

## **USP Compendial Standards for Biologics- Current Opportunities**

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In this presentation, we will discuss the importance of public standards and the need for applicable and relevant reference materials as a means of advancing access to good quality, safe and effective biological medicines. The scope of USP's public standards encompasses product specific monographs as well as general chapters with associated reference standards. The USP process is public and open to participation and collaboration with stakeholders from industry, academia, regulatory agencies, and other standard setting organizations. USP's current approaches to developing standards for biologics will be presented, with emphasis on cell- and tissue-based therapies.