



International Alliance for
Biological Standardization

10th Annual Statistics Workshop: Science & Statistics – Elevating CMC through Partnership

November 12-14, 2024
IBBR, Rockville, USA

Session II: Stability Innovations in Manufacturing Biologics

Monitoring products on stability is critical to determine how long they will remain safe and efficacious, and a major area where statistics are used in manufacturing biologics. Traditional stability studies for biologics take years to complete, but work is being done to use accelerated studies to determine or estimate shelf life more quickly. This session will have two presentations on estimating shelf life more quickly, one for mRNA vaccines and therapies, and one for biologics in general. Although regulatory guidance specifies one statistical method that can be used to determine shelf life, other methods are frequently used because of limitations with that method. One presentation in this session will discuss a novel method of using tolerance intervals to estimate shelf life, and discuss a method for estimating tolerance intervals for linear mixed models with unbalanced data, which can also be applicable for other stability analyses.

