



USP's complimentary web-based interactive tool for choosing monoclonal antibody (mAb) quality and safety resources.

Monitoring quality and safety throughout the product development and manufacturing process

Extended Characterization

Thoroughly understand the biophysical and biochemical properties of the product.

In-Process Testing

Monitor product quality during the various steps of the manufacturing process.

Release & Stability

A broad array of analytical methods to test for purity, potency and safety.



To access the **USP Monoclonal Antibody Analytical Guide**, scan the code or visit: <https://go.usp.org/register-mab-analytical-guide>

Find what you need to assess the quality & safety of mAbs



Analytical assays & methods created before and during clinical development play a significant role in any regulatory filing. Well-characterized and reproducible analytical methods can accelerate product and process development, which can lead to faster submissions for regulatory approval, and eventual product launch.

It may be hard to find reliable methods and controls that can help you accelerate your work with confidence.

A wealth of mAb resources at your fingertips.

Working with global scientific and regulatory experts, USP has developed a suite of mAb resources including:

- Relevant documentary standards found in the USP–National Formulary (USP–NF) compendium recognized by the US FDA and many regulatory bodies around the world
- USP Education courses
- Physical reference standards
- Peer-reviewed publications, conference presentations, posters, and technical notes

