SVAr
Answers in Life Science

POTENCY BY DESIGN:

A stage-by-stage guide to potency strategy in biologics development

Potency testing is an integral part of biologics development, evolving as your therapy progresses from discovery to commercialization and beyond. A successful potency strategy starts early, with assays that reflect your therapy's mechanism of action (MoA) and provide meaningful insights into its biological activity.

Understanding what role potency testing plays at every stage can help you design a strategy that will stand the test of product development, regulatory scrutiny, and lifecycle management.

Start with the right strategy. Build robust evidence. Maintain confidence throughout development, regulatory approval, and lifecycle management.

Learn more about potency across development
svarlifescience.com

DISCOVERY
Laying the foundations for potency strategy

- Identify promising candidates through MoA-relevant activity.
- Link biological activity to therapeutic potential.
- Establish a foundation for future consistent potency assays.

PRE-CLINICAL RESEARCH
Establishing proof of concept through MoA-reflective assays

- Develop an understanding of product biology, safety and efficacy.
- Identify critical factors influencing biological activity.
- Build assay robustness for downstream development.

CLINICAL DEVELOPMENT
Demonstrating stability, safety and efficacy

- Ensure consistent potency across clinical batches.
- Support comparability, stability and lot release.
- Qualify assays and reference standards for reliable testing.

REGULATORY SUBMISSION
Building confidence in the product's therapeutic performance

- Confirm safety, efficacy, batch-to-batch consistency and product quality.
- Provide robust potency data for regulatory approval.
- Demonstrate consistent biological activity and product quality.

POST-APPROVAL
Ensuring potency throughout the product lifecycle

- Verify potency against predefined release specifications.
- Monitor biological activity throughout shelf life.
- Support comparability following manufacturing changes.

Doc. No. S-241-GB00, Nov 2026