Release Testing

Rapid, high-quality, cGMP-compliant

Release testing is a critical aspect of drug development, ensuring the safety, identity, purity, and potency of raw materials, drug substances (DS), and drug products (DP). From preclinical stages to commercial lot release, rigorous testing protocols with phase-appropriate validation must be employed to safeguard patient health and uphold confidence in the pharmaceutical supply chain:

Preclinical

- Assess identity, purity, and potency of the DS and the DP
- Evaluate stability of the formulation under various storage conditions

Clinical

- Ensure methods are validated and phase-appropriate
- Analyze CQAs for DS and DP under cGMPs
- Conduct stability studies and ensure proper storage

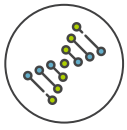
Commercial

- Confirm safety, efficacy, purity, and quality in final product
- Monitor stability of DP over shelf life
- Preserve retains for future testing requirements

Solvias has decades of experience performing excipient & raw materials, DS, and DP release testing for small molecules, biologics, and cell and gene therapies. We can help establish your CQAs and devise the right and minimum combination of tests to deliver the phase-appropriate results you need for release.

Small Molecules
Full service with 10- to 15-day turnaround: identity, purity, impurities, potency, particulates, dissolution, bioavailability, and DS-excipients interactions.

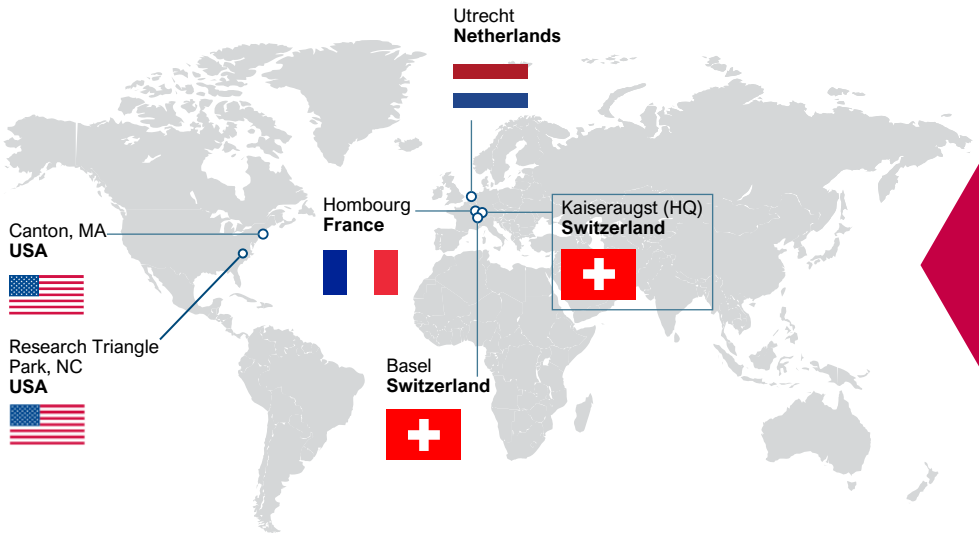
Biologics
Comprehensive solution for DS and DP batch release testing for monoclonal antibodies (mAb), bispecific antibodies, ADCs and other recombinant proteins.



Cell & Gene Therapies
Release testing for viral vectors, from biophysical characterization of capsid proteins and stability testing, to potency and sterility testing for both *in vivo* and *ex vivo* CGTs.

Why partner with us?

- CDMO/CRO
- Founded in 1999
- 800+ team members
- 175+ PhD-level scientists
- GMP, GLP, ISO9001 certified
- 22.5K sqm of lab capacity
- 700+ customers worldwide
- 6 centers of excellence



Contact us to speak with an expert: info@solvias.com

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