

# Development and Testing Overview

The Analytical Testing Laboratory at Singota Solutions offers formulation assistance and technical services to clients in the pharmaceutical, animal health, and biotechnology industries.

## Development and Analytical Services

- Pre-clinical development services include:
  - Pre-formulation, excipient and formulation studies of parenteral and lyophilized formulations
    - Solubility, degradation, potency, thermal analysis
    - Non-clinical reference standard hand fills
- Process development:
  - Lyophilization cycle development/optimization
  - Particle/droplet size reduction
  - Technology transfer
- Analytical method work:
  - Method transfer/validation
  - Method development/optimization
  - Examples include: (U)HPLC, UV-Vis, CE, moisture, endotoxin, particulate matter, etc.



## GMP Testing Services

- GMP testing services include:
  - ICH thermal stability test programs
  - Compendial testing (USP/EP)
  - Raw material testing for manufacturing use
  - Release and certificate of analysis generation
  - Trials for solubility, pH, degradation, potency, purity, reconstitution
  - Testing of cytotoxic compounds
  - Thermal cycling and excursion testing
  - Materials compatibility testing (e.g.: infusion sets, IV bags, stoppers, etc.)
- Microbiology:
  - Microbial enumeration tests
  - Tests for specified microorganisms
  - Bacterial endotoxin
  - Sterility

*Focused on Faster*