Simtra
BioPharma Solutions

Made for this

Development Services and Clinical Manufacturing

Where your product & our expertise go further.

At Simtra, we're made for this. With 65+ years of sterile injectable manufacturing experience, we bring precision and transparency to every step of the production process, from product development through commercial fill and finish. As a premier independent CDMO, we partner with pharmaceutical and biotech companies to help realize their commercialization objectives for sterile injectables. Whether you are looking to launch your innovation globally, improve your formulation, or proactively mitigate risk, Simtra can help you deliver on your commitments to patients.

Simtra
BioPharma Solutions

Made for this

Why Choose Simtra?

65+ years of sterile injectable manufacturing experience.

We bring **precision** and **transparency** to every step of the production process, from development through commercial fill/finish.

Over **20 scientists** with an average of nearly **18 years'** experience.

Renowned, **widely published leaders** with scientific expertise in parenteral science.

Leaders in **USP** and **AAPS**

Formulation & Lyophilization Optimization

Simtra's **Lyophilization Center of Exellence (LCOE)** has extensive experience in developing lyophilized products as well as performing lyo cycle optimization.

We specialize in establishing design space for primary drying, which results in:

- Risk reduction in development and production
- Minimal cycle time
- Cycle optimization
- Simplification of the process transfer
- Acceleration of process development, including the edges of failure
- Facilitation of deviation handling during production

Putting It All Together: Development Process – Lyophilized Final Product

CONTAINER SELECTION

ANALYTICAL METHOD DEVELOPMENT

FORMULATION STUDIES

- Biophysical Characterization
- Effect of pH, Ionic Strength, Surfactants
- Screening Study

LYO FORM DEVELOPMENT

- Thermal Characterization
- Trial runs to induce failure during primary drying

CYCLE DEVELOPMENT

- Primary Drying — Design Space
- Secondary Drying — Effect of Residual Moisture Study
- Confirmation Batch and Long-Term Stability

ANALYTICAL SUPPORT

PROCESS TRANSFER

Formulation Development

Simtra has extensive expertise in developing formulations for a wide variety of molecule types, including: Small and Large molecules, Antibody Drug Conjugates (ADCs), Proteins, Vaccines (including adjuvants), mAbs, Biosimilars, and Peptides.

Specialties Include:

- Process development
- Container closure selection
- Materials compatibility
- Stability studies (ICH, IND, all zones)
- Freeze/thaw studies
- Filling/shear studies
- Syringe/vial retention studies

Equipment:

- Six research freeze dryers
- MicroFD with LyoPAT
- DSC (modulated and nano)
- Peristaltic and piston pumps available for lab-scale filling and studies
- TGA
- XRPD
- Freeze-dry microscopy (FDM)
- KF & NIR for moisture analysis

Analytical Services

What We Offer:

- Analytical method development, transfer, and validation
- Residue detection method development and validation
- Forced degradation studies
- Characterization studies, including: RLD comparison, in-use solution and particle ID
- A broad range of analytical techniques, including:
  - Dot Blot, ELISA, icIEF, cIEF, CE, SDS-PAGE, SDS-cGE
  - GC, GC-MS; HPLC, HPLC-MS, UPLC
  - FTIR microscopy, SEM-EDXS
  - Cell-based bioassays
  - FlowCAM , HIAC, DLS
  - ICP-MS, ICP-OES
  - UV-VIS, SoloVPE
  - FT-IR, NIR
  - qPCR
  - TLC
  - TOC

Analytical Capabilities:

- Aggregation
- Binding/Potency
- Carbohydrate Analysis
- Chemical Degradation
- Chromatography
- Compendia
- Concentration
- Electrophoresis
- Elemental Analysis
- ELISA and other plate-based methods
- Fragmentation
- Identity
- Light Scattering
- Particle Identification
- Particulate Matter
- Spectroscopy
- Structural Analysis
- Thermal Analysis
- Water Content

Clinical Manufacturing Services

- Vials (2R – 50R) Liquid and Lyo
- Syringes (1 mL -3 mL)
- Compounding 5L up to 350L
- Annex I compliant
- Automated processing of nested vials & syringes
- 100% IPC
- Rotary piston or peristaltic filling options
- Flexible compounding areas
- Viable and non-viable environmental monitoring
- Automated loading and unloading for lyophilization
- Flammable solvent handling
- Isolator technology for highly potent molecules
- SafeBridge Certified

For more information:

Visit us at
Simtra.com

Follow us on **LinkedIn**
for the latest updates

Simtra
BioPharma Solutions

Made for this