FROM

# Lab THROUGH Launch

## YOUR PARTNER AT EVERY STEP

As a leading contract development and manufacturing organization (CDMO) with a singular focus on sterile injectables, Simtra BioPharma Solutions provides customized end-to-end services that meet the unique challenges of manufacturing injectables, from product development to clinical and commercial production at any scale.

Simtra
BioPharma Solutions

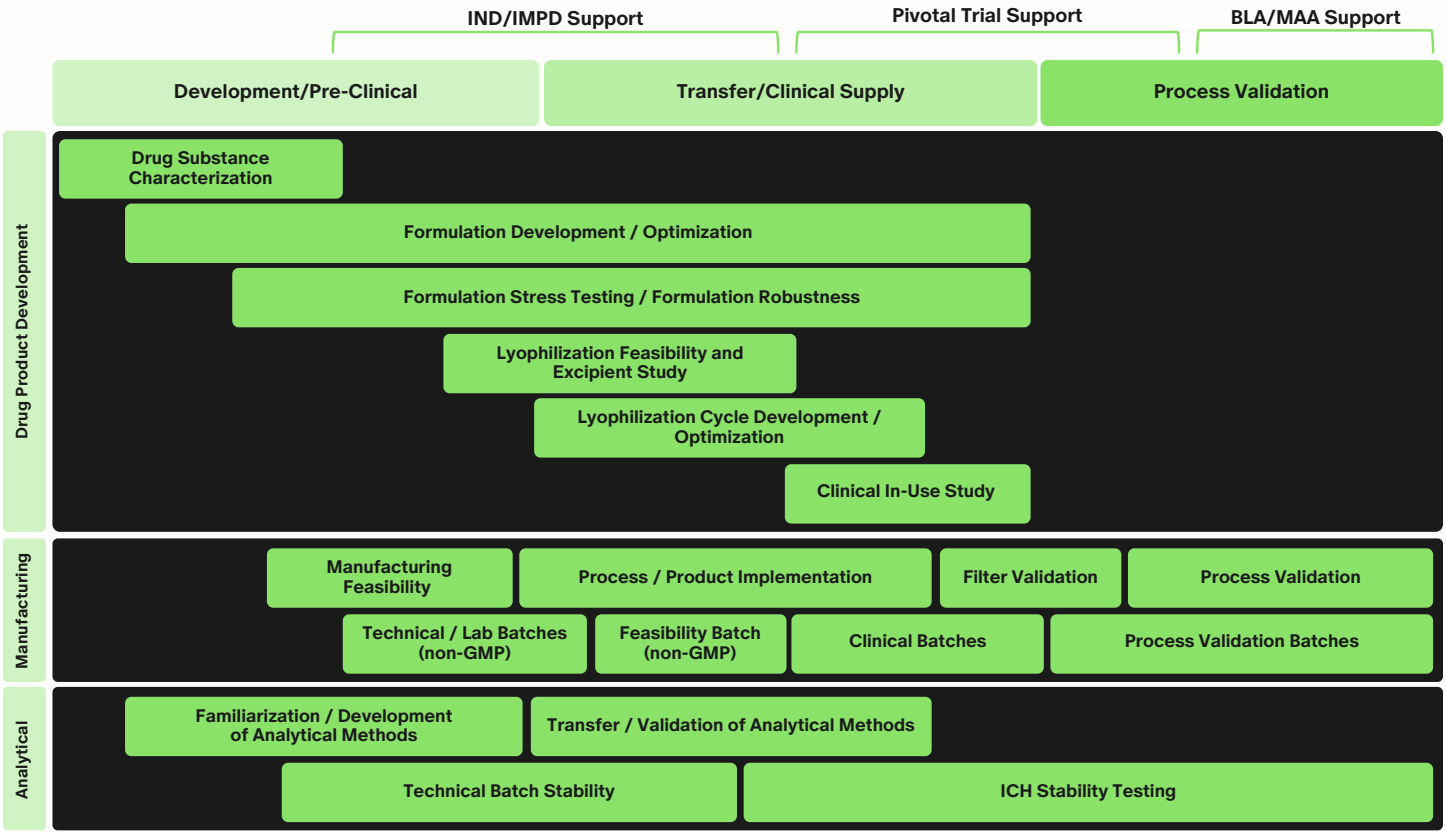
**Made for this**

## Unlock Efficiencies **With Simtra**

Our development and pre-commercial services team streamlines transitions, maximizes yield, minimizes loss and reduces risk, accelerating products' speed to market. Our quality-driven, full-service approach is **made for this**.

- Product design with the end in mind
- The right partner
- Integrated expertise under one roof
- Proven methodologies, expertly implemented
- Commitment to excellence

# A Full-Service Continuum




# Why Simtra for Development & Pre-Commercial Services?

## Development & Pre-Clinical

**We develop robust formulations designed for manufacturability, minimizing the risk of late-stage setbacks and enabling smooth progression into clinical studies.**

Early-stage formulation design, feasibility assessments and analytical method support establish a strong foundation for clinical success.

- Solve challenges in solubility, stability and robustness through development, stress testing and excipient screening.
- Industry-leading Lyophilization Center of Excellence supports feasibility studies and cycle optimization.
- In-use studies and manufacturability assessments ensure products meet patient, regulatory and manufacturing requirements.
- Integrated analytical services provide precise chemical, microbiological and stability testing.

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## Transfer & Clinical Supply

**De-risk clinical supply, shorten time to trial readiness and ensure compliance with global regulatory expectations for commercial readiness.**

Production and supply of non-GMP feasibility batches, full clinical trial material and stability-tested formulations for efficient scaling.

- Clinical batch manufacturing in flexible vial and syringe formats, with compounding ranges from small (5 L) to large (350 L).
- Multiple fill/finish formats, including liquid vials, lyophilized vials and prefilled syringes.
- Lyophilization cycle development and optimization using a “design space” approach to reduce time and improve reliability.
- Rigorous ICH stability testing programs.

## Process Validation

Comprehensive process validation and analytics to confirm reproducibility, compliance and readiness to ensure products set for commercial-scale manufacturing and regulatory approval.

- Validation batches executed under stringent quality and sterility controls.
- Robust analytical method transfer and validation, leveraging state-of-the-art testing capabilities.
- SafeBridge-certified facility in Halle/ Westfalen, Germany, for highly potent/ complex molecules.

**Improve compliance, reduce risk of production delays and provide a strong foundation for regulatory submission and commercialization.**

WHY SIMTRA?

## Experience, Innovation & Expertise

Continuously investing in industry-leading technology and leveraging proven processes to offer efficient, cost-effective and innovative solutions for even the most complex products.

**65+** **years dedicated to sterile injectables**

**100+** **products manufactured annually**

**20+** **years of experience in lyophilization development/optimization**

- ✓ Successful clinic entry for all Simtra-developed formulations
- ✓ Industry-leading Lyophilization Center of Excellence in U.S. and Europe
- ✓ Track record of developing, transferring and manufacturing complex modalities, such as cytotoxics (including ADCs), highly potent compounds (including hormones), small-molecule drugs and biologics (including vaccines)

WHY SIMTRA?

## Commitment to Excellence

We seek to exceed industry standards with every project by being relentlessly focused on quality and performance.

- Annex 1-compliant facilities
- Strong global audit and inspection record
- SafeBridge-certified in Germany
- Quality focus apparent in sterility record
- Diligent focus on continuous process improvement
- End-to-end analytical services supporting compliance and quality assurance

Simtra BioPharma Solutions is your dedicated partner at every step from development through commercialization. **We are made for this.**

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