

# THERE'S A SCIENCE TO SUCCESS.™

serán

STATE-OF-THE-ART LABORATORIES SUPPORTING EARLY DEVELOPMENT THROUGH COMMERCIAL

## Analytical Services & Support

Serán's analytical labs deploy a variety of techniques to assess the physical and chemical properties of drug substances and prototype formulations. Careful collection and evaluation of the right data enables rational scientific choices leading to optimized formulations.



**Pre-formulation  
assessment**



**Fundamental  
molecular  
characterization**



**Method  
development &  
validation**



**Finished product  
release testing**



## Quality Control & Quality Assurance

Serán's QC lab ensures that raw materials used in cGMP manufacturing, as well as intermediates and dosage forms manufactured at Serán, meet applicable quality standards. The QC lab also performs chemical and physical stability assessments of intermediates and drug product.

## EXPERIENCE COUNTS

**Industry Expertise** Our team of experienced scientists, analysts, specialists, and management professionals possess a wealth of knowledge and expertise in pharmaceutical development and manufacturing.

**Comprehensive Solutions:** We offer end-to-end analytical R&D and QC solutions tailored to meet the unique needs and requirements of CDMO clients across diverse therapeutic areas and dosage forms.

**Regulatory Excellence:** With a deep understanding of regulatory requirements and industry best practices, we help clients navigate complex regulatory landscapes and achieve regulatory approval efficiently.

Connect & Learn More

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# Comprehensive Analytical R&D and QC

## Designed to Uphold the Highest Levels of Product Quality and Compliance

### Unparalleled Analytical Support

#### Analytical Services

- Fundamental molecular characterization
- Pre-formulation assessment and formulation screening
- Advanced solid-state characterization
- Exploratory stability
- Dissolution assessment
- Modeling and predictions
- Method Transfer
- Method Development
- Method Optimization
- Method Qualification & Validation
- Development batch stability (IND-enabling)
- Onsite ICH Stability Chambers
- Data Trending & Predictive Modeling
- Cleaning method development and validation

### Quality Excellence in Every Step

#### Quality Control

- Raw material testing
- In-process testing
- Finished product testing
- Stability studies
- cGMP compliance
- Document control
- Regulatory Compliance
- Quality Assurance support - document review, audit preparation, and regulatory submission assistance

#### Equipment

- **Analytical Characterization:** mDSC, XRPD, TGA, DVS, SEM, HPLC, UPLC, HPLC-CAD, cKF, PION  $\mu$ Flux, Type I / Type II Dissolution, biorelevant dissolution
- **Physical Characterization:** Tablet hardness tester, disintegration (auto-endpoint), Geopyc, Accupyc, shear cell, FlowDex, sieve analysis, Texture Analyzer

