

CDMO







Your drug development partner



CHEMICAL ENTITIES

PRECLINICAL

CLINICAL PHASES I & II

CLINICAL PHASE III, COMMERCIAL & LIFE CYCLE MANAGEMENT

- Development of new, scalable API route options
- Synthetic route scouting/design
- Process safety and hazards assessment
- Synthetic route redesign
- Process step redesign/redevelopment
- High-throughput screening
- Physicochemical characterization of API's and advanced intermediates
- Process mapping (Design of Experiments)
- Lifecycle optimization
- Impurity synthesis/characterization

- Preformulation/formulation screening
- Formulation development and manufacturing
- Analytical method development
- Stability studies
- GLP analysis of non clinical formulations

- Formulation and process development
- Process confirmation run, production of reference material
- Clinical trial manufacturing
- Analytical method development
- Analytical method qualification/ validation
- QC testing and batch release
- Stability studies

- Commercial manufacturing (small commercial batches and orphan drugs)
- Process validation
- Release testing
- Analytical method update
- Analytical method validation
- Stability studies
- Life cycle management of mature products and analytical methods

- Pharmacology (Proof of concept)
- Pharmacokinetics
- Bioanalysis for toxicology studies
- ADME studies
- Clinical PK: development, validation and assay of samples
- Quality Control of raw materials
- Clinical packaging and logistics
- Quality control of raw materials and drug products
- Clinical PK: development, validation of bioanalytical method and assay of samples
- Clinical packaging and logistics

DRUG SUBSTANCE



CDMO







Your drug development partner **PORTFOLIO**



BIOLOGICAL ENTITIES

PRECLINICAL

CLINICAL PHASES I & II

CLINICAL PHASE III & COMMERCIAL

- Microbial strains and cell lines
- Upstream and downstream process development
- Analytical method development
- Manufacturing

JRUG SUBSTANCE

DRUG PRODUCT

JTHER SERVICES

Stability studies

- Bioprocess development
- Process confirmation run, production of reference material
- Analytical method development
- Analytical method qualification/ validation
- Clinical trial manufacturing
- Stability studies

- Process upscaling and validation
- Analytical method update
- Analytical method validation
- Manufacturing of commercial batches
- Stability studies

- Preformulation/formulation screening
- Formulation development and manufacturing
- Analytical method development
- Stability studies

- Formulation and process development
- Process confirmation run, production of reference material
- Clinical trial manufacturing
- Analytical method development
- Analytical method qualification/ validation
- QC testing and batch release
- Stability studies

- Process upscaling and validation
- Analytical method update
- Analytical method validation
- Commercial manufacturing
- Stability studies

Pharmacokinetics

- Bioanalysis for toxicology studies
- Quality Control testing of raw materials
- Transfer
- Consultancy

ADME studies

- Clinical PK: development, validation and assay of samples
- Quality Control testing of raw materials
- Process transfer
- Clinical packaging and logistics
- Quality control testing of raw materials
- Process transfer
- Clinical packaging and logistics

