Crystal Pharmatech

Crystal Pharmatech is a leading CRO/CDMO specializing in solid-state research, pre-formulation, and formulation, advancing your preclinical candidates to Phase I and beyond with a first-time-right approach.

2025 Capabilities & Services Overview

Crystal Pharmatech Overview

Specialized in API solid state research, pre-formulation, formulation development & GMP manufacturing

Worked with over **1,000** clients worldwide since 2010, including **8/10** of the largest multinational pharmaceutical companies.

Supported pharmaceutical development of over **2,000** drug molecules.

Leadership team with experience developing over **100** NCEs and commercialization of **15** drug products.

519,090 ft² total research and manufacturing facility space throughout USA, Canada, and China.

You have challenges?

Polymorph/Salt/Co-Crystal Selection

- *“My molecule has multiple crystal forms — how do I know which one is best?”*
- *“I’ve chosen a polymorph, but what if a more stable one appears later?”*
- *“I’m not sure how many polymorphs exist — what risks does that create?”*
- *“How can I be confident I’ve identified the most stable crystal form?”*
- *“My compound forms an amorphous solid — should I stick with it or pursue a crystal form?”*
- *“Would a co-crystal strategy improve solubility, stability, or IP positioning for my compound?”*
- *“When timelines are tight, how do I balance speed with thoroughness in polymorph or salt screening?”*

We provide solutions!

Crystallization

- *“I scaled up crystallization and got a new form — what is the root cause?”*
- *“Company X is making our GMP API — how do we ensure that we will always make the same crystalline form?”*
- *“We’re starting our GMP API campaign in a month — can you help, or is it too late?”*
- *“We’re close to NDA filing — is it too late to fix solid-form issues?”*
- *“Our lab process gives needle-like crystals that filter poorly — how do we shift morphology/PSD for manufacturability without creating a new form?”*
- *“How do we de-risk hydrate/solvate formation during drying, milling, and packaging so warehouse humidity swings don’t trigger form conversion?”*

You have challenges?

Preformulation

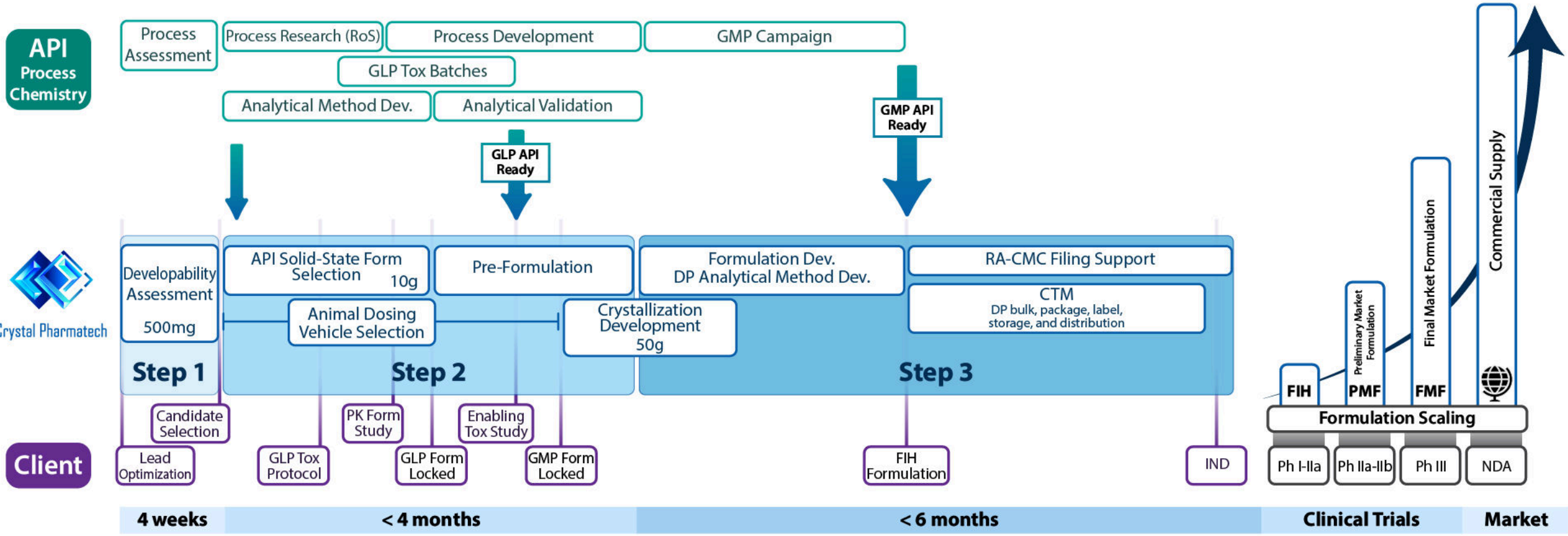
- *“I’m concerned about achieving tox exposures — why am I falling short?”*
- *“My in-vivo PK data doesn’t make sense. Could this be related to form or formulation?”*
- *“I’m not even sure what solid form was dosed in animals. What could go wrong later?”*
- *“We only have a few grams of API globally. How should we prioritize studies?”*
- *“Right now we’re using PEG and ethanol. Could that be a problem?”*
- *“We only have 50 mg of material. Can we still screen solid forms properly?”*
- *“I just want to get into GLP tox with an acceptable vehicle. What’s the fastest and most cost-effective way to do that?”*

We provide solutions!

Formulation Development

- *“My formulation works in vitro but fails in vivo — could this be polymorph related?”*
- *“How do you align formulation development with the target product profile (TPP) and clinical study design?”*
- *“My API degrades quickly. How can I address this?”*
- *“I want to move fast to first-in-human — what hidden risks should I watch for?”*
- *“I’m planning a powder-in-capsule (PIC) formulation for our SAD/MAD study — is this the best path forward? Would moving to a tablet or capsule add significant cost and time to development?”*
- *“My CDMO says my compound is solubility- and permeability-limited. Does that mean I need an amorphous solid dispersion?”*

Mol2Med™ : First-time-right to FIH and beyond

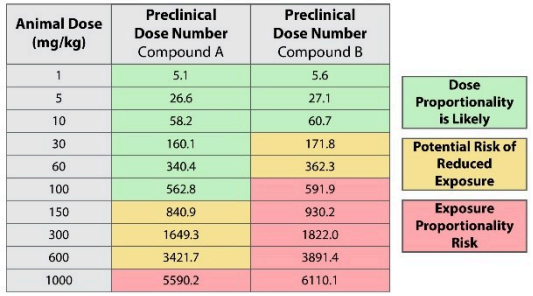


FIH – First In Human

Step 1: Developability Assessment

Solid State Research and Developability Assessment

- pKa, Log P/D with Pion material-sparing automation
- Solid-state characterization
  - XRPD, TGA, DSC, PLM, DVS, PSD, Surface Area, SEM, KF, HPLC
- Fit for purpose HPLC analytical method
- Solubility
  - Biorelevant
  - pH-dependent
- Chemical and physical stability
- Industry benchmarking
  - Predicted fraction absorbed
  - Dose proportionality
  - BCS/DCS Classification
  - Dataset formulation outputs
- PBPK modeling
  - Regional absorption
  - Parameter sensitivity
- Detailed guidance for API solid-state form selection and formulation design

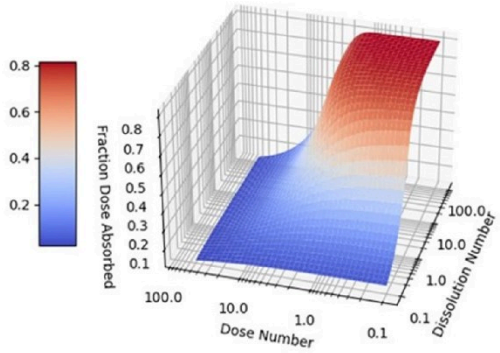


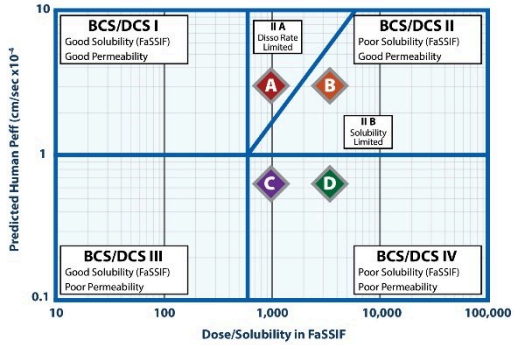
Animal Dose (mg/kg)	Preclinical Dose Number Compound A	Preclinical Dose Number Compound B
1	5.1	5.6
5	26.6	27.1
10	58.2	60.7
30	160.1	171.8
60	340.4	362.3
100	562.8	591.9
150	840.9	930.2
300	1649.3	1822.0
600	3421.7	3891.4
1000	5590.2	6110.1

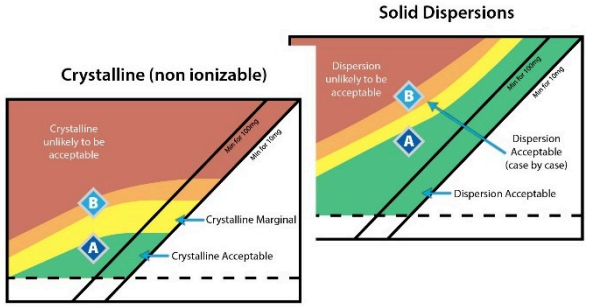
Dose Proportionality is Likely

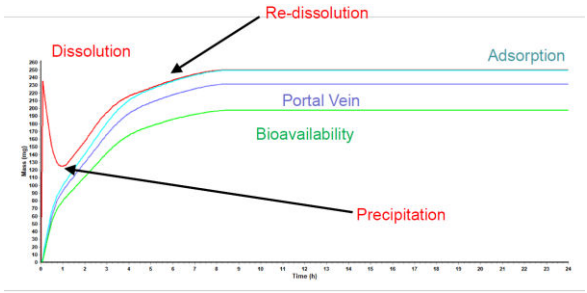
Potential Risk of Reduced Exposure

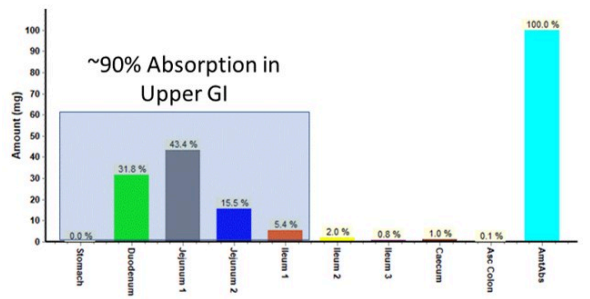
Exposure Proportionality Risk







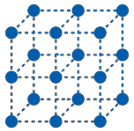




Step 2: Solid Form Screening, Crystallization and Pre-formulation

Solid Form Screening & Selection

- Solid form screening and selection
  - Polymorph/salt/co-crystal screening
  - Thermodynamic phase relationship
  - Stability and solubility evaluation
  - Optimal form recommendation
- Form identification and quantification
- Form de-risking
  - Crystal Structure Prediction, CCDC Snapshot
- Single crystal growth & structure determination
  - SXRD, Synchrotron, and MicroED



Crystallization Development

- Crystallization development
  - Purification
  - Particle attributes control
  - Polymorphic isolation
  - Chiral separation
- Intermediate crystallization process development
  - Purification (replace chromatography)
  - Increase process efficiency (less solvent, less time, increase scale)
- Milling evaluation

Pre-Formulation

- Analytical research
- Method development
- Comprehensive physicochemical property evaluation
- Drug-excipient compatibility
- Formulation development for PK/PD and GLP Tox studies
  - Solutions and suspensions
- Animal dosing vehicle selection (solubility, bioavailability and stability enhancement):
  - Gavageability
  - Redispersibility evaluation
- Amorphous solid dispersion

Step 3: Formulation Development, Manufacturing and Clinical Supply

Formulation Development

- Conventional formulation
  - Direct compression
  - Dry and wet granulation
  - Tablet, capsule, pellet, bilayer
  - IR, CR
  - Topical formulations
- Enabling formulation
  - Amorphous Solid Dispersion (ASD): spray drying, hot melt extrusion
  - SMEDDS*
  - Micronization and nanocrystals
  - Long-acting Injectables
- Pediatric formulation (mini-tablet)
- Oral peptide formulation
- Compaction simulation
- Process scale-up & optimization
- FIH to commercial development

Analytical Development

- Method development and validation
- Release testing for raw material and drug product
- cGMP QC release and stability study
- Formal stability study (FSS)
- Extractables and leachables

GMP Manufacturing & Clinical Supply

- Capacity and capability:
  - Current: 0.5-120kg, OEB 3 and below
  - Upcoming: > 300kg
- CTM manufacturing
- Registration batch manufacturing
- Process performance qualification (PPQ) batch manufacturing
- Commercial manufacturing
- Clinical stability study
- Packaging:
  - Primary: Blistering, bottling, over encapsulation, mini tablets stickpack packaging
  - Secondary: Label & packaging design, blinded packaging solution, carton, wallet, etc.
- Storage and distribution, import/export, return and destruction, comparator souring

Regulatory Support and Other Services

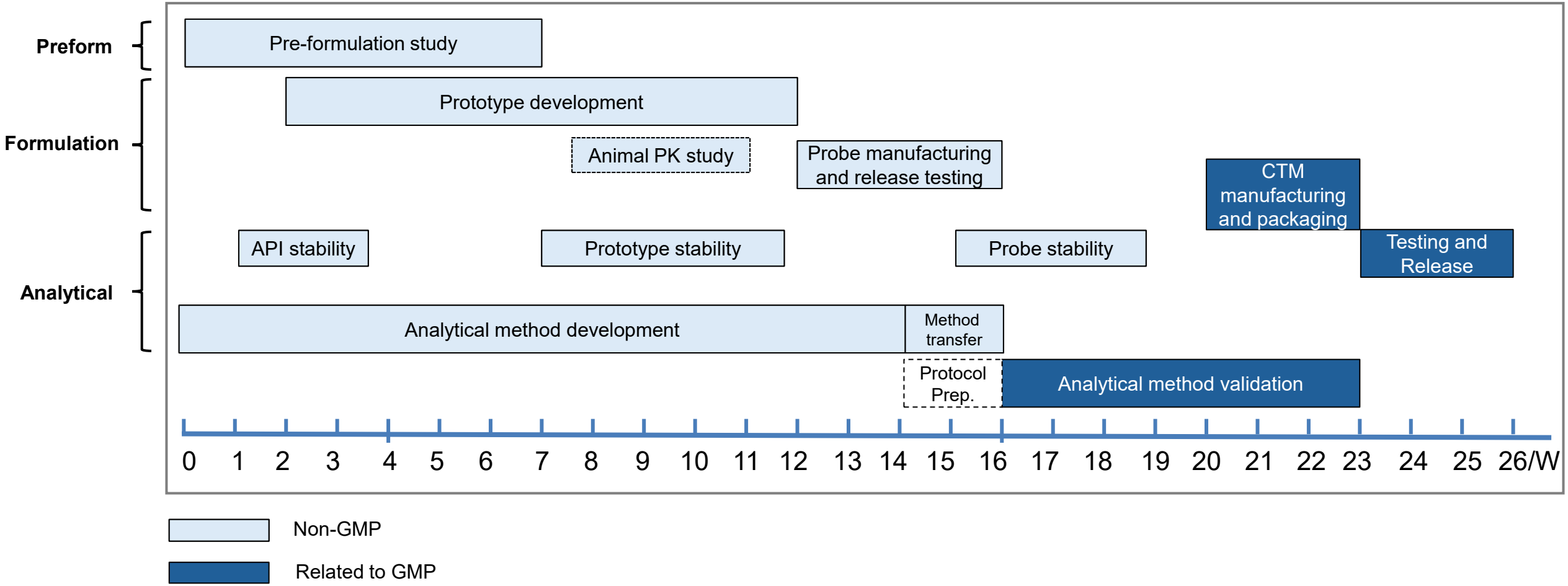
- Product Development Report
- Support CMC parts in IND, CTA and NDA authoring and Regulatory Support
- Technical consultancy on formulation development and feasibility

**SMEDDS – Self-Microemulsifying Drug Delivery System, FIH – First in Human*

Standard Timeline (for FIH Formulation Package)

Conventional Formulation or Mini-Tablet Package (Preform + Formulation Development + GMP Manufacturing): **~6** months

ASD Formulation Package (Preform + Formulation Development + GMP Manufacturing): **~7.5** months



Clinical Supply Service

- Supply planning
- Supply strategy
- End to end supply and inventory management
- IRT* integration

- Packaging design
- Label design
- Translation
- Randomization
- Comparator sourcing

- Global transportation
- Timely monitoring
- Cold chain capability
- Importation
- Exportation

Primary Packaging

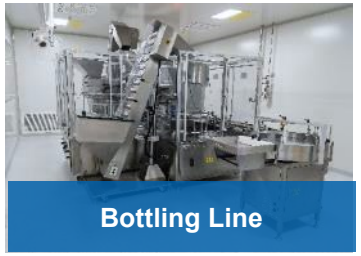
- GMP environment
- Blistering: alu-alu; alu-PVC
- Bottling
- Over encapsulation

Secondary Packaging

- Match with protocol
- Double blind & double dummy
- GMP compliance
- Patient compliance
- Cost saving
- Flexibility

Package and Label design:

- Labels design: single panel, dual panel, wrap around, booklet labels
- Package design: Carton; Bottle labelling; Wallet card
- Package material: Outer carton and tamper seals



** IRT - Interactive Response Technology*

Specialized Formulation Partner vs. One-Stop Shop CDMOs

Model	Pros	Cons
Specialized Formulation Partner (as CP)	• Direct access to leading formulation expertise • Equal or faster project timelines than one-stop shops • First-time-right formulations matching Target Product Profile • Senior experts with 20+ years' experience overseeing projects	• Requires coordination with a separate API vendor • Multiple vendor qualifications may be needed
One-Stop Shop CDMOs	• Maybe single project team for API and formulation • Only one vendor qualification required • Simplified communication between API and formulation teams • Potential pricing leverage through bundled services	• Few CDMOs excel equally in both API and formulation • Limited flexibility to select best-in-class partners • Formulations often designed only as "fit-for-purpose" for FIH, with weak late-stage path • Limited senior oversight; projects often handled by junior staff • Over-reliance on one CDMO for all CMC work

Solid-State Research Core Scientific Team

Alex M. Chen, Ph.D.

Co-Founder, Chairman &CEO

21 years of pharmaceutical research experience, including 8 years at Merck Research Laboratories and Merck Manufacturing Division. Obtained a B.S. in Chemistry from Peking University and a Ph.D. in Chemistry from Rutgers University

Expertise: Solid-state research, solid form screening, chiral resolution by crystallization, and nanoparticle delivery for gene therapy

Robert Wenslow, Ph.D.

Co-Founder, Chief Business Officer

26 years of experience in pharmaceutical development, including 14 years at Merck with various leadership positions. Headed the API group - Center for Materials Science and Engineering in Merck Manufacturing Division. Obtained a Ph.D. degree in Chemistry from Pennsylvania State University

Expertise: Solid-state NMR, drug characterization, crystallization development, IP protection; Expert witness on crystal form patent cases

Lianfeng Huang, Ph.D.

Chief Scientist

Over 30 years of experience in pharmaceutical development, including BMS, Celgene and J&J with various leadership positions in successfully leading pharmaceutical sciences departments and CMC project teams. Obtained a Ph.D. degree in Pharmaceutics from Iowa University

Expertise: Solid-state research, crystallization development, pre-formulation, formulation

Rositza Petrova, Ph.D.

Executive Scientific Director

15 years of working experience in Merck with various leadership positions including Leader of API Development Support Group - Center for Materials Science and Engineering in Merck Manufacturing Division, and Analytical Project Leader - Merck Animal Health. Obtained Ph.D. in Materials Science, Georgetown University

Expertise: API solid form screening/discovery, crystalline form selection, polymorphism, and chiral separations by crystallization

Combined Leadership: ***100+*** *years of pharmaceutical leadership,*
>60 *years at Big Pharmas, founded by scientific experts*

Formulation Core Scientific Team

Decheng Ma, Ph.D.

CEO – CDMO Business Unit, China

25 years pharmaceutical industry experience with 22 years formulation development and CRO/CDMO/CMO vendor management experience at Merck (US) and MSD (China). Expertise on oral solid formulation development, analytical and clinical supply. Responsible for or supported over 30 new drug development, 5 of which were commercialized. Trained as Chemical Engineer at Lehigh Univ. (Ph.D.) and Tsinghua Univ. (B.S.).

Expertise: Oral solid dosage, amorphous solid dispersion, controlled release, analytical and clinical supply

Feng Li, Ph.D.

CSO – CDMO Business Unit, China

23 years of Phase I-III and commercial formulation development experience at Merck (US). Involved in over 50 small molecule NCE drug product development, 15 of which were commercialized. Significant expertise on oral solid dosage, powder mechanics, dry granulation and pediatric formulation. Trained as an engineer (mechanical leaning) at Penn State Univ. (Ph.D.) and China Agricultural Univ. (B.S.).

Expertise: Oral solid dosage, preclinical formulation powder mechanics, amorphous solid dispersion, dry and wet granulation, oral peptide, controlled release/extended release, mini-tablet based pediatric formulation

Yongqiang Li, Ph.D.

CEO – CDMO Business Unit, Canada

23 years of formulation development and management experience in innovative and generic pharmaceutical industries. Developed more than 30 products for global markets including First-to-Files, NCE, 505 b (2) and First-to-Markets. Ph.D. degree in Pharmaceutics and Drug Delivery from Faculty of Pharmacy, University of Toronto, Canada.

Expertise: Complex oral delivery systems, solubility/permeability enhancement, peptide delivery, bioequivalence, and alignment of nonclinical and clinical formulations for NCE drugs

***Combined Leadership: 70+** years of pharmaceutical leadership, **>50** years at Big Pharmas*

*Over **100** NCEs and **15** commercial drug products developed*

Testimonials from U.S. Biotech & Pharma Clients

Los Angeles-Based CNS Biotech **Head of R&D**	*“I have to say that the gratitude goes from me to your group. The formulation group has done a phenomenal job. I always knew that *** is a very bright person but the work he has done and the way he evaluated the compound and created the approach, the dosage route, in my opinion is spectacular. I can't say enough good things about your group but they're just really really super and you can quote me on that any time.”*
Leading Drug Discovery Company **Director, Preclinical Development**	*"It was great working with the Crystal Pharmatech team on this project - we were very impressed with the speed, responsiveness and high quality of the data, project updates, and final report. We definitely look forward to working with you again in the future!"*
Small Pharmaceutical Company **Head of CMC**	*"For a small company, cost is always an issue, but so is the use of scarce materials from early-stage programs. Crystal Pharmatech has so far delivered a huge amount of work at a very competitive price, and at the same time, has been parsimonious with the supply of materials sent (API, standards, etc.). I look forward to working with you on our current and future projects."*
Small Drug Discovery Company **Senior Formulation Consultant**	*"Thanks to the Crystal Pharmatech team for this comprehensive write-up of the formulation studies with our compound and the very diligent work in running the studies under a compressed timeframe."*
Mid-sized Pharmaceutical Company **Senior Associate Scientist**	*"I had a great first experience with Crystal Pharmatech. Tasks were completed rapidly and completely, questions were answered rapidly, and data was presented clearly. It was exactly what I had hoped for and more than I expected based on the pricing. I have paid more and received less from many other companies conducting this kind of work. I was very satisfied and look forward to working with Crystal Pharmatech in the future."*
California-Based Biotech **CEO**	*"The formulation team's work, including compound evaluation, process development, and dose strategy selection and precise control, was outstanding, providing us with a perfect solution."*
San Diego-Based Biotech **Chief Development Officer**	*"Fabulous work and for the constant communication updates. Truly appreciate it. Huge thanks to your team!"*

Crystal Pharmatech

Solid-State & Pre-formulation Capabilities

CrystalFAST - Solid-State Research Technology Platforms

Focused Analytical Solids Testing (FAST) – Make Smarter Early Decisions with FAST

- Whether you're exploring multiple candidates or need early risk assessment without heavy investment, FAST offers **speed, confidence, clarity, and cost control**—all with minimal material.

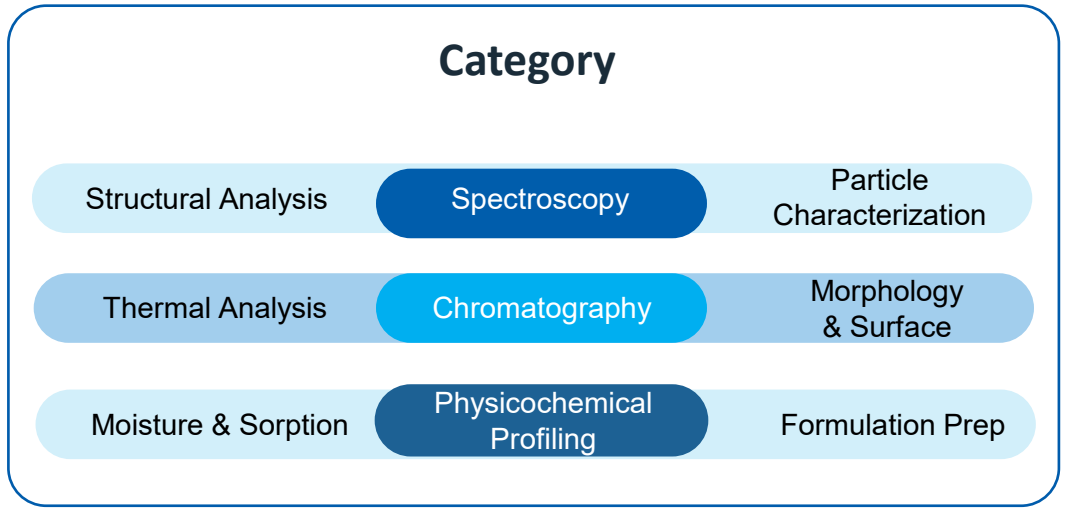
Requires as little as 2 mg of material

Results in 1-5 business days

Expandable to full CMC or development programs

Ideal for candidate ranking, risk assessment, and formulation guidance

FAST Service Test Menu



CrystalSCREEN - Solid Form Screening and Selection Platforms

Advanced Screening Platform – Data Driven, Built for Speed

Input Characterization → **Tailored Screening Matrix** → **Data-driven solid-form generation** → **Real-Time Solid-State Characterization** → **Form Optimization for Development**

- Approximate solubility
- Physicochemical properties

- Prediction (**CSP**) pinpoints stable forms and reduces polymorph "blind spot"
- Conformer-weighted targeting increases success of rare/low-energy forms
- Screening design based on:
  - Client's objective
  - Solvent
  - Temperature
  - 30+ crystallization methods

- Parallel solid-form generation
- Material-efficient workflow
- Rapid setup and execution

- XRPD, DSC, TGA, PLM, DVS, PSD, etc.
- Immediate solid-form ID and feedback

- Form stability & solubility profile
- Scalability assessment
- Input for pre-formulation and formulation

Solid-Form Generation Toolbox

Solvent-Based	Temperature-Based	Other Mechanisms	CP Applied Methods*
Slow evaporation	Slow cooling	Polymer induced crystallization	Capillary Crystallization
Fast evaporation	Crash cooling	Ionic liquid induced crystallization	Alternate Vial Screening
Slurry	Temperature cycling	Humidity induced phase transition	Gel Crystallization
Anti-/Reverse solvent addition	Crash cooling from a melt	Grinding	Slurry in bulky liquids

*15+ CP applied crystallization method.

Outcome for sponsors

- **Optimal solid form** — (polymorph, salt, cocrystal) selected for best balance of stability, solubility/bioavailability, and manufacturability
- **Accelerated screening** — key crystalline forms identified with minimal material in as little as **1–2 weeks**
- **Greater probability of success** — modeling-guided, property-driven design ensures efficient discovery of the most relevant forms
- **De-risked development** — fewer late-stage surprises and costly re-formulations
- **Stronger IP** — comprehensive crystalline form mapping secures maximum patent protection

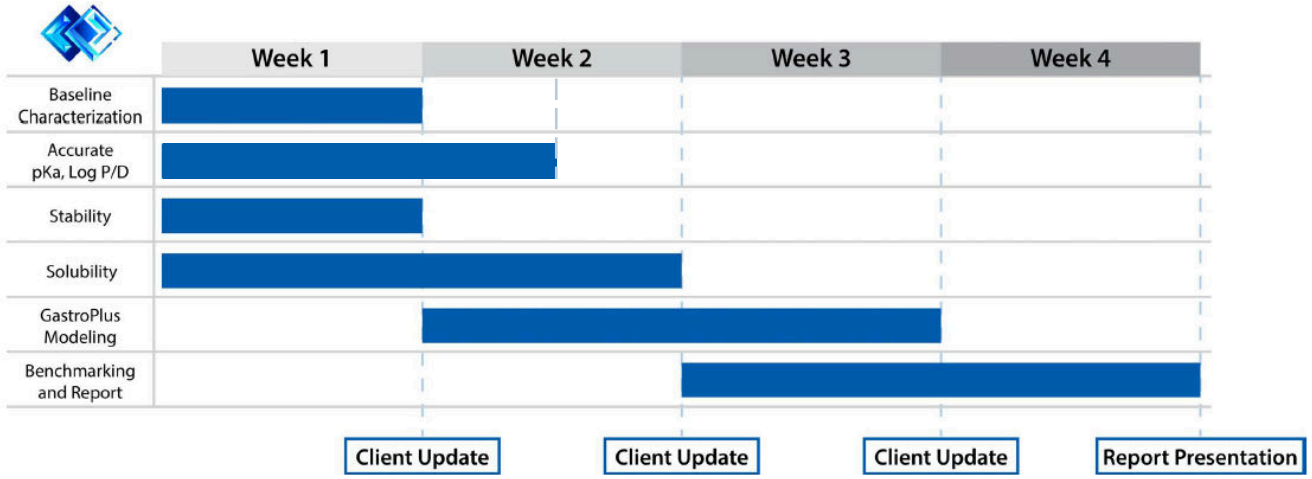
CrystalPATH - Developability and Pre-formulation Platforms

Our Technical Advantage

- Get a full pre-formulation profile with as little as 500 mg of API within 4 weeks
- PBPK + DCS/BCS modeling links lab data to human dose and exposure early
- Mol2Med™ benchmarking distills DCS class, solubility, dose numbers and a clear tox roadmap

Side-by-side comparison of all data results for Compound A and Compound B		
Parameter	**Data for Compound A**	**Data for Compound B**
Chemical Information		
PK Parameters and Calculations	Up to 14 vital data points	Dose, Dose Number, Absorption Number, PK Data, etc.
Solubility	Material-sparing solubility	pH-dependent and biorelevant comparisons
Characterization	Up to 14 different outputs to characterize and understand form	Accurate Log P/D, pKa, low energy form screening, etc.
Chemical and Physical Stability	Up to 9 different conditions	1 to 7-day stability studies

Preformulation Material Sparing Workflow



Outcome for Sponsors

- Go/no-go and formulation direction decided with milligrams, not grams
- Lower risk of late-stage reformulation or tox surprises
- Data-driven package ready for IND, fundraising and first-in-human dosing

CrystalVEHICLE - Vehicle Screening Platform for PK/Tox Animal Studies

Optimizing PK/Tox studies through data-driven vehicle selection for consistent, reproducible results.

Platform Strengths

- Comprehensive vehicle screening from compound profiling to in vivo readiness
- Rapid, material-sparing evaluation across aqueous and non-aqueous systems
- Integrated solubility, stability, and form analysis for confident selection
- Biorelevant media testing to ensure reliable GI tract performance

What Sets Us Apart

- Data-driven selection matrix — no guesswork, no wasted time
- Miniaturized workflows to maximize API efficiency
- In-house analytical suite for rapid turnaround and complete characterization
- Proven success in supporting consistent, reproducible PK/Tox studies

Value to Our Clients

- Shorter timelines from candidate profiling to study start
- Reduced risk of variability in PK/Tox data
- Lower API consumption for scarce or costly compounds
- Smoother transition from preclinical to clinical development

CrystalBOOST - ASD Screening Platform for Enhanced Bioavailability

- Rapidly develop optimal ASDs that boost bioavailability, save API, and ensure clinical translation.

Prototype Preparation → **Dissolution Testing** → **Suitability Testing** → **Stability Assessment**

Platform Strengths

- End-to-end ASD development — from API characterization to stability profiling
- Rapid material-sparing prototype generation with targeted polymer selection
- Integrated dissolution, suitability, and re-suspendability testing for go/no-go clarity
- Comprehensive solid and suspension stability assessment for reliable scale-up

What Sets Us Apart

- Predictive, data-driven design — avoiding costly trial-and-error
- Parallel prototype development for faster turnaround
- Fully integrated in-house analytical suite for rapid insight
- Proven track record in improving bioavailability for challenging molecules

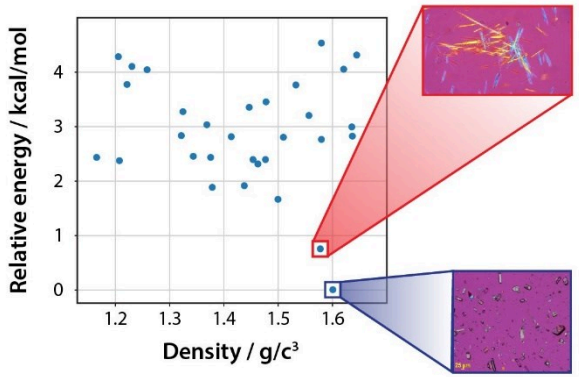
Value to Our Clients

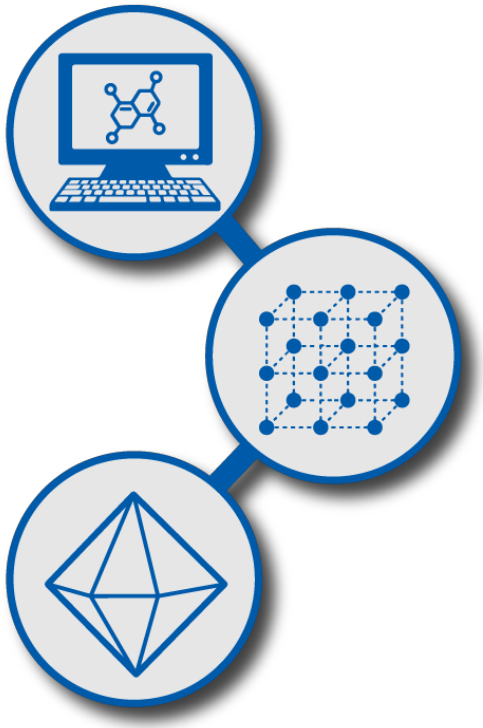
- Accelerated development timelines and faster path to clinic
- Reduced project risk with early go/no-go clarity
- Conserved API for other critical studies
- Greater confidence in clinical translation and scalability

CrystalAI - In-Silico Simulation Platforms

Crystal Form Prediction

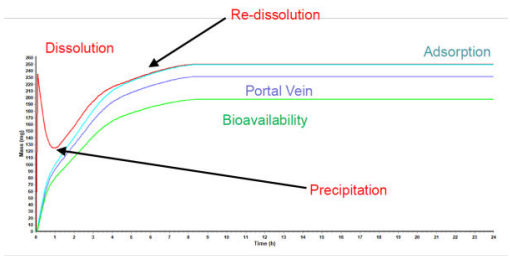
- Crystal Structure Prediction
- CCDC Solid Form Snapshot

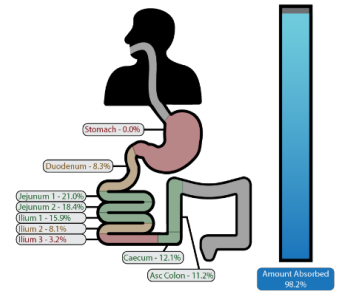




PBPK Modeling

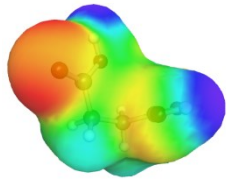
- Assess Drugability
- Model Human PK & Absorption
- Gain Regional Absorption Insights
- Guide Formulation Strategy
- De-risk Development Early





COSMOlogics

- Salt & Cocrystal Insights
- Solvate Risk Prediction
- Guided Crystal Form Screening
- Solubility Profiling
- Phase & Miscibility Maps



Crystallization

- Crystallization Process Modeling

CrystalSPECIAL - Controlled Substance and Potent Compound Lab

Facilities & Compliance

- Containment suites engineered for OEB 4–5 potency, with independent negative-pressure HVAC and HEPA filtration
- Licensed secure vaults for Schedule I–V controlled substances
- Validated containment workflows for milligram- to gram-scale solid-state studi

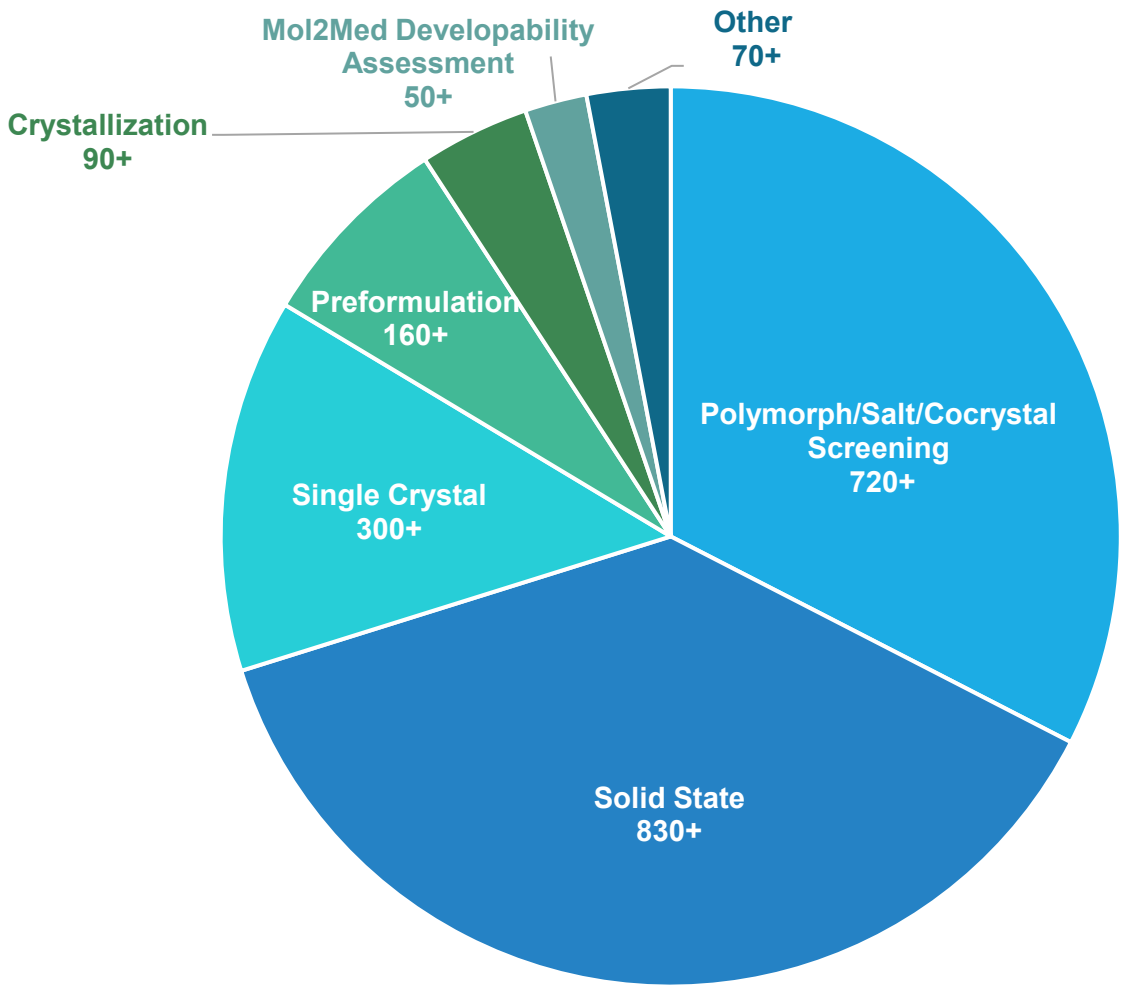
Operational Strengths

- Segregated equipment and HVAC systems to ensure no cross-contamination
- Rapid changeover, with study launches typically within 3 days of sample receipt
- Cross-trained team with integrated expertise in solid-state studies and HPAPI handling

Outcome for Sponsors

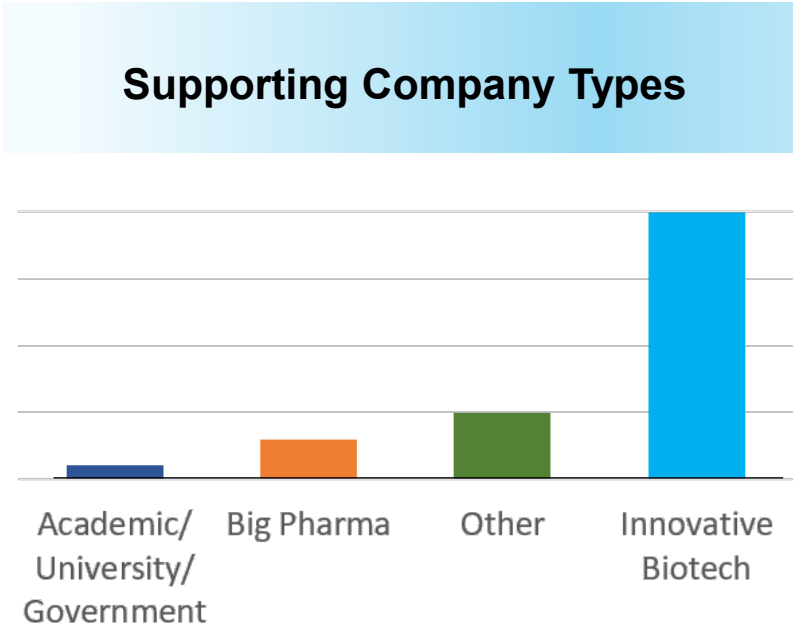
- Safe, compliant development of highly potent or controlled APIs
- First-time-right solid form before tox or GMP scale-up
- Fewer hand-offs, faster path to IND/IMPD

Driving Success Through Solid-State and Pre-formulation Expertise



2,220+ Projects

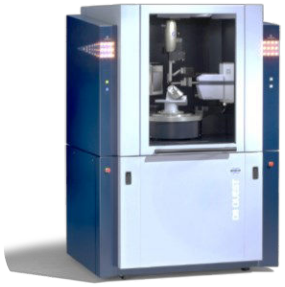
(Statistics Based on Selected Projects)



Solid State Research and Pre-formulation Instruments

Rigaku Smartlab 9kW
XRPD

Panalytical Empyrean
XRPD



Bruker D8
XRPD

Rigaku XtaLAB
Synergy-R SC-XRD

TA Instruments
TGA5500

TA Instruments
DSC2500

Renishaw inVia
Raman Microscope

SMS DVS Intrinsic
Plus

SMS DVS
Resolution

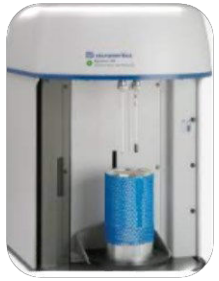
Carl Zeiss Axio Lab.A1
PLM with Hot Stage

JEOL Scanning Electron
Microscope

Malvern Panalytical
Mastersizer 3000/Hydro
EV Particle Size Analyzer

Solid State Research and Pre-formulation Instruments

CM Protégé PharmD High-throughput Screening System



Micromeritics Surface Area Analyzer

Pion Sirius T3 pKa/LogD/LogP Measurement

Pion MicroDiss/MicroFlux

Freeze Dryer

Metrohm Potentiometric Titrator

Mettler Toledo pH/Ion Meter

Mettler Toledo Volumetric KF

Mettler Toledo Coulometric KF

Buchi B-290 Spray Dryer

KW 4A Spin Coater

Crystallization Development & Milling Instruments

Crystal 16

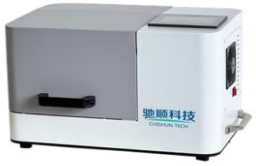
ReactIR 45m

FBRM G400

OptiMax

EasyMax

ChemRxnHub
Crystallization System



PULVERIZER 80
Planetary ball mill

SPEX SamplePrep 8000D
Mixer/Mill

Bench Top Mini High Energy
Vertical Planetary Ball Mill

Quadro Comill

Micron GMP01
Jet Mill

Jet Miller Model 00
Jet-O-Mizer System

Crystal Pharmatech

Formulation Development & Manufacturing Capabilities

Formulation CDMO Sites

Crystal Pharmatech (CDMO Site in China, Crystal Formulation Services)

located in Suzhou, China, our 50,590 sq. ft. facility is designed to support pharmaceutical and manufacturing needs:

- **R&D Facility (11,840 sq. ft.)** - Dedicated to research and development projects.
- **GMP Facility (17,250 sq. ft.)** - Equipped to handle batch sizes up to 120 kg.
- **Clinical Supply Depot (21,500 sq. ft.)** - Provides packaging, labeling, storage and distribution, with extended support through a partnered U.S. depot.

Crystal Pharmatech (CDMO Site in Canada, Candoo Pharmatech)

located in Toronto, Canada, our 12,500 sq. ft. facilities are designed to meet your pharmaceutical and manufacturing needs:

- **R&D Facility (3,500 sq. ft.)** - Dedicated to research and development projects.
- **GMP Facility (9,000 sq. ft.)** - Equipped to handle batch sizes up to 100 kg.

140+

Clients Worldwide

280+

Projects

Quality management system (QMS) in accordance with cGMP standards by FDA, EMA, Health Canada, and the NMPA

Our Formulation Development Philosophy - The M3 Core

Molecule

Material

Medicine

- Clinical info and needs
- DMPK understanding
- Pharmacodynamics
- Safety information
- Molecular profile

- API Solid Form
- API physiochemical, biopharmaceutical, mechanical properties and stability
- Excipient functionality, physical attributes, compatibility
- Properties of composition tailored for process

- Target product profile (TPP) /label as driver for design
- Interaction of composition and process
- Impact of API and excipient properties and composition on CQAs
- Impact of CPP on CQAs
- Control strategy for drug product

Formulation Novel Technology Platforms

Conventional Formulation Platforms

- Compaction simulation to guide OSD formulation development (roller compaction, tableting, bilayer, sticking and over-lubrication risk assessment.)
- Dry coating approach for unstable amorphous API formulation
- ER, Gastric-retentive, and bimodal release for API with short half-life, narrow absorption window, fast onset
- Polymer-surfactant combination to keep long supersaturation for weak base with dramatic pH-dependent solubilities

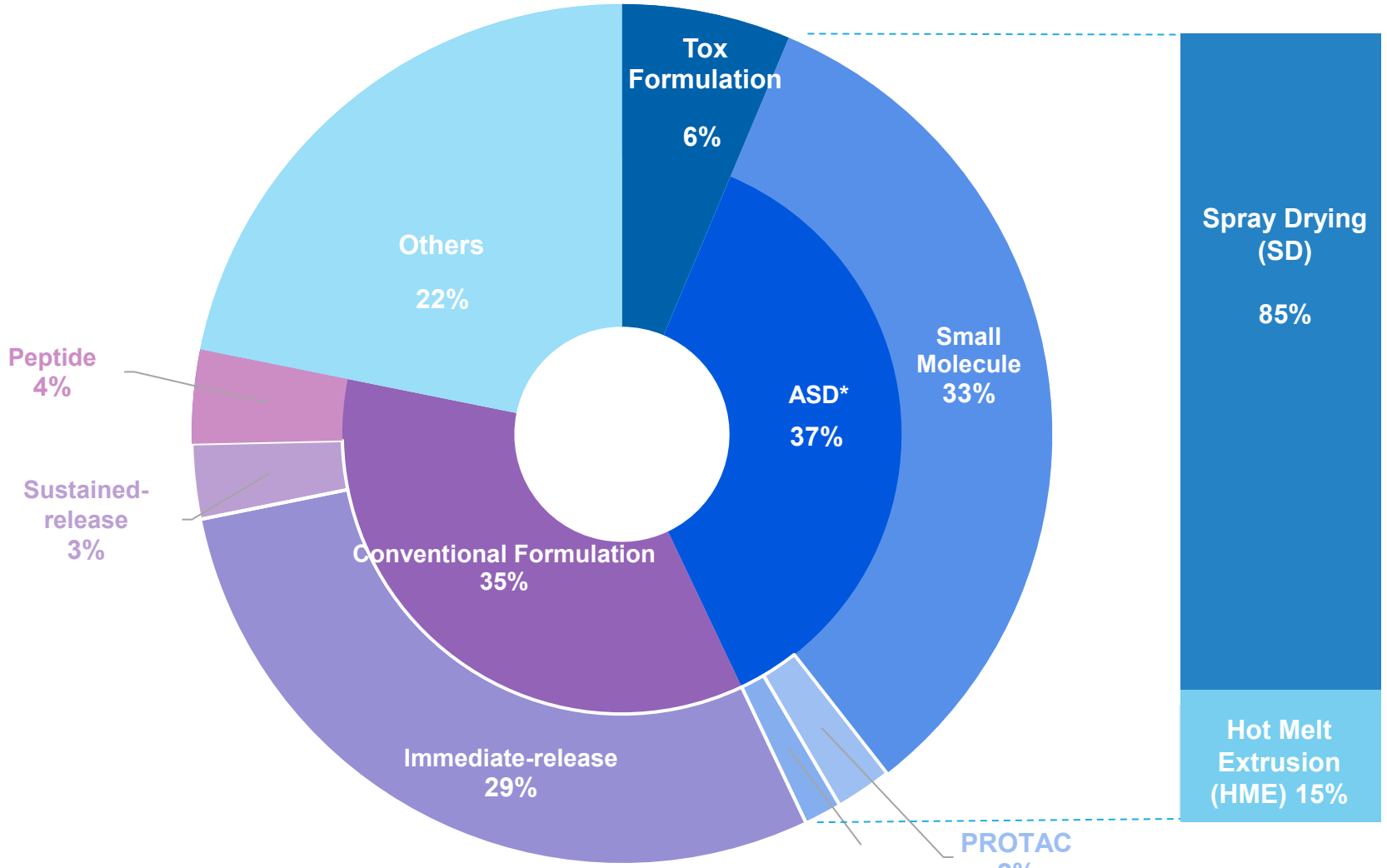
Enabling Technology for Insoluble Compounds and PROTACS

- **Comprehensive ASD Platform:** From composition screening to tablet formulation
- **Spray Drying Workflow:** Film casting → Lab-scale → PSD-1 scale-up (API-polymer-surfactant analytics)
- **Rheology-guided HME:** 12mm lab → 18mm extrusion (polymer rheology-driven)
- **SMEDDS for low solubility but with High logP, or Low Permeability**: Solution in liquid-filled capsules or tablet dosage forms
- **Protein Degrader Platform:** ASD & Permeability Enhancement (PE) for low solubility/permeability (high Mw)
- **Oral Peptide Platform:** PE, stabilization & release profiling

Mini-tablet Based Pediatric Formulation

- 2mm in diameter, 7-8mg image
- Drug load as low as 0.7% with 7.5% RSD for individual tablet
- Encapsulation achieved 4 tablets/capsules with 100% accuracy

Driving Success Through Formulation Expertise



Quality Management System China Site

NMPA

December 2022

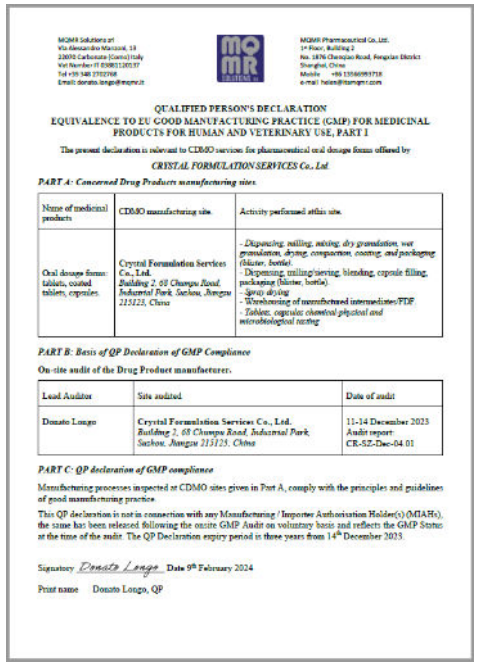
New production site added for US customers with signed contracts.

FDA

Expected in 1Q2026

EU QP

December 2023



QUALIFIED PERSON'S DECLARATION
EQUIVALENCE TO EU GOOD MANUFACTURING PRACTICE (GMP) FOR MEDICINAL PRODUCTS FOR HUMAN AND VETERINARY USE, PART 1

The present declaration is relevant to CDMO services for pharmaceutical oral dosage forms offered by

CRYSTAL FORMULATION SERVICES Co., Ltd.

PART A: Concerned Drug Products manufacturing sites

Name of medicinal products	CDMO manufacturing site	Activity performed at this site
Oral dosage forms: tablets, coated tablets, capsules	Crystal Formulation Services Co., Ltd. *Building 2, 68 Chunpu Road, Industrial Park, Suzhou, Jiangsu 215123, China*	- *Dispensing, milling, mixing, dry granulation, wet granulation, drying, compaction, coating, and packaging (blister, bottle).* - Dispensing, milling/sieving, blending, capsule filling, packaging (blister, bottle). - *Spray drying* - Warehousing of unmanufactured intermediates/FDF - *Tablets, capsules: chemical physical and microbiological testing*

PART B: Basis of QP Declaration of GMP Compliance

On-site audit of the Drug Product manufacturer.

Lead Auditor	Site audited	Date of audit
Donato Longo	Crystal Formulation Services Co., Ltd. *Building 2, 68 Chunpu Road, Industrial Park, Suzhou, Jiangsu 215123, China*	11-14 December 2023 Audit report: CR-SZ-Dec-04 01

PART C: QP declaration of GMP compliance

Manufacturing processes inspected at CDMO sites given in Part A, comply with the principles and guidelines of good manufacturing practice.

This QP declaration is not in connection with any Manufacturing / Importer Authorisation Holder(s) (MIAHs), the same has been released following the onsite GMP Audit on voluntary basis and reflects the GMP Status at the time of the audit. The QP Declaration expiry period is three years from 14th December 2023.

Signatory *Donato Longo* Date 9th February 2024

Print name Donato Longo, QP

Third-party Audit Services

SGS

September 2023

September 2024

> 30 **audits by biotech/pharma clients**

Analytical Development and QC Instruments

Agilent 1260/1290 infinity II with UV or DAD detector

Waters Acquity Premier UPLC

Thermo Fisher Vanquish Flex

Thermo Fisher Vanquish Core with CAD and UV detector

Agilent 8890 HS-GC

Waters Xevo TQ-S Micro LC-MS

Thermo Fisher iCAP RQ ICP-MS

Mettler Toledo UV-Vis Spectrophotometer

Agilent Cary 60 UV-Vis Spectrophotometer

Thermo Fisher FTIR Spectrometer Nicolet IS20

Rudolph Autopol II Polarimeter

Shimadzu TOC Analyzer

Agilent 708DS Dissolution Bath

Agilent 850-DS Dissolution Sampling Station

Ultracentrifuge Hmac Micro CS150FNX

Agilent BIO-DS Dissolution Apparatus

Sotax Xtend Online/Offline Dissolution Apparatus

Binder Stability/Light Chambers KBFP240/KMF240/KBF1020

Memmert Stability/Photostability Chamber

Pre-formulation and Formulation Instruments

XRPD
Panalytical Aeris
Research

DSC
Mettler DSC 3

TGA
TA Q500

DVS
SMS Intrinsic

PLM
Zeiss Axio Lab.A1

Contact Angle Analyzer
SINDIN SDC-200S

Flowability
Teledyne Hanson Flodex

Compaction Simulator
Medelpharm
STYL'One Evo

Single Punch Press
Natoli NP-RD10A

True Density
Micromeritics AccuPyc II
1345 Gas Pycnometer

Control Sieve Shaker
Retsch AS 200

Particle Size Analyzer
Sympatec HELOS/KR

Rheometer
Thermo Fisher HAAKE
MARS 40

Envelop Density Tester
Micromeritics
GeoPyc 1365

Formulation Development & Manufacturing Equipment

China Site

	Spray Drying	HME/WG	Dry Granulation	Tableting	Film Coating	Encapsulation	Wet Granulation/ Fluid Bed Drying	Packaging
Small Scale (Non-GMP) (≤ 5 kg)	 Buchi B290	 Leistritz ZSE 12	 Fitzerpatrick LCS Alexanderwerk WP120	 Korsch STYL'ONE Korsch XL100	 Freud Vector LDCS	 Bonapace IN-CAP XL	 CANAAN LHSM10  Glatt Midi/Mini	 Blister Packaging Jornen DPP150K-2
CTM and Commercial Scale (GMP) (0.5 – 120 kg)	 GEA PSD-1	 Leistritz ZSE 18	 Alexanderwerk WP120	 Korsch X3 Korsch XL100 Pro	 Freud Vector LDCS and Pilot	 Syntegon GKF 702 Bonapace IN-CAP XL	 Canaan LHS50/LHSM25  Glatt Multilab GPCG2	 Bottle Packaging Pharmapac PP-0601CD
Commercial Scale (GMP) (> 300kg)	 GEA PSD-3 like		 *Alexanderwerk WP200	 *Korsch XL400	 *Freund-Vector LDCS-Pro		 Leistritz ZSE 18	

*To be installed

Formulation Development & Manufacturing Equipment

Canada Site

	Spray Drying	Blender	Roller Compactor	Tableting	Film Coating	Encapsulation
Small Scale (Non-GMP) (≤ 5 kg)	 Buchi B290	 Servolift Bin	 Freund-Vector Roller Compactor  Freund-Vector High Shear Granulator	 Eliza EP-200L Rotary Tablet Press (5B+5D)	 O'Hara Labcoat M5	 Technophar S2 Capsule Band Sealer
CTM and Commercial Scale (GMP) (0.5 – 100 kg)	 BUCHI S-300	 Globe Miniblend  Freund-Vector MG5-6BC Bin	 Freund-Vector TFC220	 Korsch XL100 Pro	 O'Hara LC-M50	 Profiller 3700 Manual

Crystal Pharmatech

Crystal Pharmatech is committed to being your trusted partner and providing the highest quality deliverables through sound science and operational excellence.

Contact us at:

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609-529-4135

www.CrystalPharmatech.com

www.LinkedIn.com/Company/Crystal-Pharmatech