Technology Demonstration & Feasibility

The Focus and Expertise to Perfect Formulation and Development

The quality J-Star provides and the more than 150 years of cumulative experience of our team – most with a background in "Leading Pharmaceutical Brands" – gives us the ability to deploy innovative solutions at a cadence unrivaled in the CRO sector.

At J-Star, our in-house expertise uses spray drying technology beyond its traditional use to generate not only amorphous material unlike other CRO's, but to generate nanoparticles, coated particles, inhalable particles and more. Unlike big CDMOs, we have the focus and skill to perfect the formulation and development processes through novel approaches that involve extensive measurement of the material properties of the drug substances themselves. This makes API even more rugged and reliable than the original requirements.

Our advanced and synchronized capability to orchestrate API properties on a "boutique" basis gives us many competitive advantages, including the ability to supply data rich submissions for eventual FDA approval.

Enabling Technologies to Improve Powder Flowability

- Co-Precipitation Technology (CPT)
- Adsorption
- Moisture Activated Dry Granulation (MADG)
- Dry/Wet Granulation
- Hot Melt Extrusion (HME)
- Spray Drying (SD)
- Dry Particle Coating

Enabling Technologies to Improve Solubility and/or Dissolution

- Amorphous by Spray Drying (SD)
- Amorphous by Precipitation
- Amorphous by Adsorption
- Nano-Particles
- Co-Processing
- Hot Melt Extrusion
- Other Solubilization Techniques (LBDDS, SEDDS, etc.)

Continuous Process Evaluation

- Powder Characterization
- Unit Operation Testing
- Equipment Modeling
- Process Train Modeling
- Implementation Strategy
- Regulatory Strategy

Enabling Technology Equipment

- GEA MOBILE MINOR® Spray Dryer
- Thermo Scientific™ Pharma 11 Twin-screw Extruder
- Mini/Midi Glatt Fluid Bed System
- Resodyn Bench Top Mixing System, Pharma RAM II
- Sturtevant Jet Mill SDM2
- Natoli NP-RD30 Tablet Press
- Co-Processing Chamber

Connect With Us

Visit jstar-research.com
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J-STAR RESEARCH, Inc.

Partnering with the Pharmaceutical Industry to Make New Therapies Possible

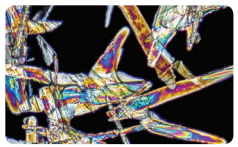
The Industry Leader in Small Molecule Process, Research Crystallization and Drug Product R&D

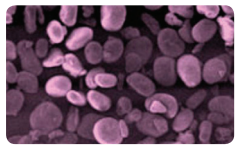
Bridging the Drug Substance and Drug Product Interface

Our mission at J-STAR Research is to help pharmaceutical small molecule R&D programs succeed in all phases of development.

With the ability to develop both Drug Substance (DS) and Drug product (DP) under the same umbrella, our team enjoys a synergism absent in most CROs. The ability to bridge the DS/DP interface is a major competitive advantage, and we are able to shorten development timeline and to improve ruggedness of the DP process.

Our technology platforms provide but are not limited to optimized API powder properties and improved aqueous dissolution as needed. We can effectively address issues affecting formulation early in Phase 1. This fundamental material knowledge forms the basis of our Quality by Design approach to improving Phase 2, Phase 3, and commercial processes.





API Crystal → Drug Product Intermediate (DPI) → Drug Product

We enable drug products to reach target product profile by optimizing desirable DPI properties such as:

- Improved powder flowability
- Optimum shape and size
- High bulk density
- Enhanced solubility and dissolution
- Improved bioavailability

PHASE 1

Clinical Supply

Our expertise encompasses early drug product development including the preformulation studies and formulation, and process development of novel dosage forms. We strive to make rapid deliverable drug product supplies in support of preclinical to Phase I clinical studies

Preformulation Study Service

Characterize physical and chemical properties of a drug molecule alone or combined with excipients at early stage of drug product development to ensure formulation and process development can be carried out to a safe, effective, and manufacturable dosage form.

Pre-Clinical and Clinical Supply Service

The pre-clinical study comes before clinical trials and tests a new chemical entity (NCE) in animals to study drug safety and potential administration route, etc. The aim is to determine the safe dose for first-in–human and assess a product's safety profile.

PHASE 2 & 3

Drug Product Development and Troubleshooting

Scale from Small-Batch Lab to Multi-Kilo GMP

Once Phase 1 is complete, we develop late-phase formulations in our R&D lab, but what if you need to quickly scale to GMP manufacturing?

At J-STAR Research, we have the ability to quickly pass your formulation to our parent company (Porton) for large-scale, multi-kilo GMP. If you prefer stay local, we also have many national partners with robust commercial capacity whom collaborate with on a regular basis.

Regulatory Support Services

J-Star Research experienced specialists can compile high-quality drug product development report for CMC section in support of regulatory flings (IND, NDA, and/or ANDA); and can provide documents in the desired format to facilitate any response to CMC questions raised for the global regulatory applications.

Formulation Development

Across every phase we are guided by formulation decisions based on fundamental material properties, supported by appropriate use of Quality Target Profile

Product Development Approaches