

Xcelience

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OUTSOURCING and Consulting Services



Xcelience

Xcelience is a premier provider of formulation development and manufacturing solutions with a solid reputation for accelerating early development activities to speed potential drugs to clinical trials. We have one focus: the success of your project. Our experienced staff and unique corporate structure result in project teams that maximize speed and flexibility. We are more than just a service. We are formulation development and manufacturing made easy – at last.

Xcelience provides formulation development, preformulation and analytical services, and clinical supplies manufacturing, packaging and labeling solutions for companies focused on early phase small molecule development.



Xcelience Advantage:

- global access to four Xcelodose® precision powder micro-dosing systems, which enable clients to fill very small amounts of powder to capsule speeding time to first-in-human studies
- expanded formulation development capabilities and commitment to help clients build towards improved manufacturing outcomes in a manner consistent with the FDA's Quality by Design initiative
- liquid in capsule services for overcoming the challenge of poor aqueous solubility and improve compound bioavailability
- small scale batch production for companies facing the challenge of limited API
- comparator product blinding

Major Products / Services

- API Characterization
- Salt screens
- Polymorph screens
- Drug substance characterization
- Excipient compatibility
- Accelerated stability
- Chiral stability

Analytical Services

- Method development
- Qualification and validation
- Raw material testing
- Stability sample analysis
- Dissolution testing
- Residual solvent analysis
- Chiral determination
- Cleaning evaluations
- Technical packages for drug substance



Formulation Development

- Solids (tablets, gelatin or HPMC capsules, sustained release and coatings)
- Semi-solids (ointments, creams and gels)
- Dispersed systems (emulsions, suspensions)
- Liquids (orals, ophthalmics, parenterals)

GMP Manufacturing

- API or powder in bottle
- Powder-into-capsule
- Tablets and capsules
- Liquid in capsule
- Semi-solids
- Non-sterile liquid

In addition, we provide reference product blinding, packaging and labeling services, and offer expertise in the creation of matching placebo formulation, creation and qualification of blinded reference product, process qualification, process definition optimization, and technology transfer.

Stability Program Management

- ICH conditions
- Protocol design
- Report generation
- Sample analysis
- Secure storage area
- SLIM, laboratory information management system, meets FDA standards for 21CFR11 compliance

Facilities

Xcelience operates out of a cGMP compliant, DEA licensed facility located in Tampa Bay, Florida, one of the most desirable cities in the world.



CORPORATE CAPABILITIES