Xcelience
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OUTSOURCING and Consulting Services

Xcelience®

Corporate Description

Xcelience is a premier provider of preformulation, formulation, and manufacturing solutions with a solid reputation for accelerating early phase development. For each project, we hand-pick a team of industry-leading experts specific to client needs. This customized approach gives Xcelience the knowledge and agility to manage even the most challenging small molecules, and to meet client objectives for speed and efficiency without compromising our outstanding quality record. We save clients time and money by offering streamlined services from preformulation and analytical services through formulation, manufacturing, packaging, storage, and distribution—all under a single project manager.

Xcelience Advantage

Partnering with a specialized team of experts from Xcelience can reduce product risk and accelerate development timelines. Since 1997, Xcelience has earned a reputation for reliably expediting drug development and reducing compound risk. Armed with the latest technology, our scientists excel in overcoming challenging physical and chemical properties to improve solubility and compound bioavailability. Recent improvements include:

- A three-phase facility expansion to increase capacity and speed for formulation development, analytical, GMP manufacturing, and packaging.
- Extensive clinical trial supplies manufacturing capabilities to increase overall capacity, improve production times and expand existing capabilities for production, coating, and encapsulation.
- A new, fully-automated packaging line for primary bottling of tablets and capsules to increase the speed of batch packaging, shorten timelines and to package larger batches.
- Global access to four Xcelodose precision power micro-dosing systems, allowing clients to fill very small amounts of powder into capsules and speeding time to first-in-human studies.
- Liquid in capsule services to improve aqueous solubility and increase compound bioavailability.
- Small-scale batch production for companies with limited API.
- Comparator product blinding.

Services and Capabilities

Preformulation

- Salt screen
- Polymorph screen
- Drug substance characterization
- Excipient compatibility
- Accelerated stability

Analytical

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

Formulation

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

Manufacturing

Clinical supplies manufacturing:

- Tablets and capsules
- API into capsule
- Liquid in capsule
- Semi-solids
- Non-sterile liquid

Stability

- ICH conditions
- Protocol design
- Report generation
- Sample analysis
- Secure storage area

Clinical Supplies

- Primary and secondary packaging
- Label development
- Global distribution
- Inventory Management
- Procurement IVRS/IWRS
- Storage
- Returns, Retains and Destruction
- Clinical Supplies Project Management

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