

Coldstream Laboratories, Inc.

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Vital Statistics

Year Founded: 2007

Number of Employees: 60

Key Personnel: Joseph W. Wyse, Ph.D., President & Chief Executive Officer; Eric W. Smart, Vice President Business Development & Marketing; Tom Evans, Chief Financial Officer; Tim Mitchell, Vice President Quality & Regulatory.

Who We Are

AT COLDSTREAM LABORATORIES INC., we're seasoned at turning pharmaceutical development ideas into safe, pure, and effective pharmaceutical dosage forms. We have completed more than 200 formulation development projects that led to clinical trials. This work provided us extensive clinical manufacturing experience with both commercial clients and grant-funded projects from such sources as the National Institutes of Health. We are registered with the FDA and the Commonwealth of Kentucky Board of Pharmacy for the manufacture of pharmaceutical products. Our work represents a wide range of formulations, testing, and production for a broad spectrum of clients.

Our current manufacturing capabilities include semi-solids, oral liquids, solutions, suspensions, and lyophilized powder dosage forms and parenteral products including solutions, suspensions, and lyophilized powders. Coldstream Laboratories, Inc. has a full-capabilities analytical laboratory with proven method development and validation experience. Our Formulation Development unit has experience with a wide range of drug substances and excipients. Our Quality Systems organization operates under a quality manual, a validation master plan, and standard operating procedures that comply with the FDA's cGMP regulations.

Major Markets

- Global Pharma
- Specialty Pharma
- Biotech
- Contract/Generic

Services Offered

Analytical Services:

- Analytical Method Development, Pre-Validation, and Validation
- Release Testing of Drug Product and Raw Materials
- API and Drug Product Stability
- Storage and Testing

Microbiology Services:

- Sterility Testing
- Endotoxin Testing
- Environmental Monitoring
- Microbial Limits Testing
- Methods Testing

Manufacturing:

- Process Development
- Pre-clinical to Phase III
 - Animal Safety/Toxicity studies
 - Human Clinical Products
 - Veterinary Clinical Products
- Commercial Product Manufacturing
- Pilot Scale Manufacturing

Formulation Development:

- Sterile Solutions
- Sterile Nanoparticles
- Sterile Liposomes
- Sterile Lyophilized Powders
- Emulsions
- Oral Solutions
- Oral Suspensions
- Gels and Creams
- Ointments
- Aerosols

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