



# **Kingchem Laboratories**

*Contract Development and Manufacturing  
St. Francis, Wisconsin (USA)*



**cGMP Intermediates  
APIs and Excipients**

*Your way to Supply Chain Security*

# KINGCHEM LABORATORIES: ST. FRANCIS, WISCONSIN (USA)

WHAT WE ARE  
KNOWN FOR AS A CDMO

- **cGMP Services for intermediates and APIs**
- **Back-integration of RSMs with our plant in China**
- **Innovative and cost-effective applications of technology to solve manufacturing challenges**
- **Integrity:** Respect for customer IP, with **dedicated IP controls**
- **Well-established** logistical operations and systems
- **Effective EHS compliance**
- **A reliable business partner**
- **Award-winning customer service!**

## cGMP Facility for APIs, Pharmaceutical Intermediates, and Excipients

Kingchem is a diversified contract development and manufacturing organization (CDMO) with excellent process R&D, project management, QA/QC, and logistics capabilities. With each project, we set an accurate, timely schedule for our customers. Beginning with technology transfer or route selection through process R&D and scale-up – our customers enjoy our proactive responsive style of communication and collaborative work ethic. With this approach, we ensure consistent and robust production to meet your clinical and commercial needs.

### KEY FEATURES

**cGMP:** FDA registered for GMP manufacturing of pharmaceuticals (APIs, pharmaceutical intermediates, excipients)

**Experienced Staff:** Key staff with 10-35 years in GMP manufacturing from CDMO to large pharma

**Facility Footprint:** 33,000 sq. ft. (3,000 m<sup>2</sup>)

**Reactor Volume Range:** 35 L - 6,400 L

**Reactor Temperature Range:** -78°C - 160°C

**Reactor MOC:** Stainless Steel, Glass-lined, Hastelloy

**Pressure:** Up to 6 bar (90 psi)

**Dedicated Distillation Capabilities:** 20 L - 800 L, 20°C - 250°C (hot oil), <1 mmHg, up to 25 theoretical plates

**Filtration Capabilities:** Up to 2.5 m<sup>2</sup> Hastelloy/SS Nutsche Filter Dryers



*Kingchem serves global markets in the pharmaceutical industry*

# PRODUCT CATEGORIES: APIs, EXCIPIENTS, GMP INTERMEDIATES

## Production Site

### CHEMISTRY CAPABILITIES

Acid Chloride Formation  
Aminations  
Anhydrous HCl Handling  
Cycloadditions  
Cryogenic Crystallization  
Cryogenic Reactions  
Elemental Bromine Handling  
Esterification / Hydrolysis  
Fractional Distillation  
Friedel-Crafts Chemistries,  
Vinyl and Aromatic  
Grignard Chemistries  
Heterocycles  
Hydride Reductions  
Lewis Acid Catalysis  
Lithiation Chemistries  
Oxidation Chemistries  
Reformatsky Chemistries  
Solid Form Manipulation  
Steam Distillation  
Transfer Hydrogenation  
Transition Metal Catalyzed  
Coupling Reactions



### QUALITY SYSTEMS

The Kingchem Laboratories facility in St. Francis, Wisconsin is fully compliant with current Good Manufacturing Practices. The manufacturing and quality systems strictly adhere to ICH Q7 standards for Active Pharmaceutical Ingredients. ICH quality guidelines are incorporated into all aspects of our business. An effective Quality Management System led by our Quality Assurance group helps to deliver products that are consistently manufactured and controlled. KLI maintains a U.S. FDA Drug Establishment Registration and is subject to regular customer audits and routine inspections by the FDA and other regulatory bodies.

### ANALYTICAL EXPERTISE

Kingchem has a strong QC department with dedicated specialists for developing (or transferring from our customers), optimizing, and validating analytical methods. Our instrumentation list (GC, GC-MS, HPLC, HPLC-MS, IC, CAD, IR, UV/Vis, NMR, etc.) grows continuously. We employ software such as Chromeleon and Omnic 9 to insure that we meet 21 CFR Part 11 requirements for data integrity.

### RSM BACK-INTEGRATION

Kingchem can leverage our R&D in Dalian and our production site in Fuxin, China to develop and manufacture the Regulatory Starting Materials for your cGMP intermediate or API. This internal back-integration provides greater security of supply as well as cost control.

*For three decades, Kingchem has worked to develop a track record  
we call going Beyond the Chemistry.™*



# Certifications

## PRODUCTION SITE CERTIFICATIONS

- FDA Drug Establishment Registration
- State of WI, Dept. Safety and Prof. Services – Pharmaceutical Manufacture
- Food Processing Plant (Facility Identifier: 12671692120)
- FSSC 22000
- Kosher Certification (Chicago Rabbinical Council)
- Halal Facility Certification (Islamic Services of America)

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## BEYOND THE CHEMISTRY

Visit: <http://www.kingchem.com/beyond-the-chemistry/>

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### CONTACT US

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