SK pharmteco

Small Molecule CDMO Services

Process Development | CGMP Manufacturing
Analytical Testing | Regulatory Support

www.skpharmteco.com

Solve Complex Small Molecule Challenges with SK pharmteco

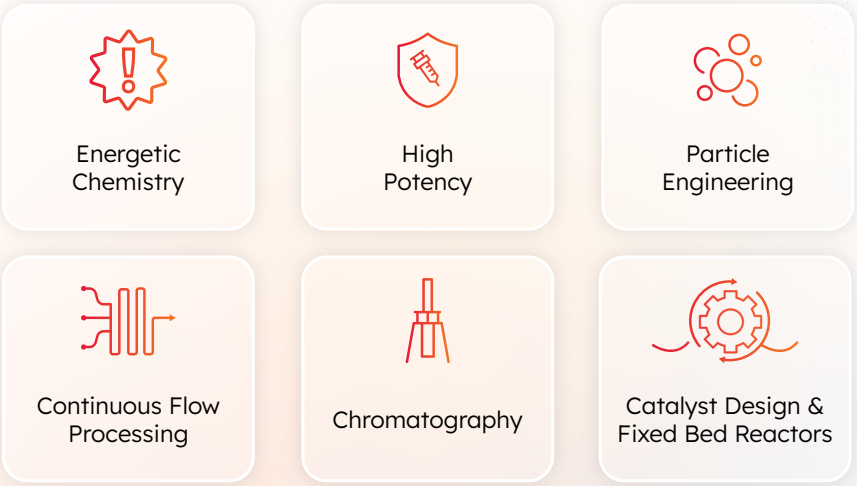
As a global CDMO, we recognize the complexities you encounter in drug manufacturing – whether it's expediting timelines, scaling-up complex chemistries, or navigating regulatory requirements. To accelerate your molecule from concept to commercialization, it's essential to partner with a trusted CDMO. With SK pharmteco, you'll gain a dedicated partner committed to delivering excellence at every stage of your drug development journey.

Our global facilities and expert teams deliver high-quality, reliable solutions tailored to your objectives. We specialize in the custom development and manufacture of small molecule APIs, Intermediates, and RSMs, with scalable solutions from kilograms to multi-tons.

Small Molecule Specialties

As your molecule progresses through the pipeline, it may require specialized manufacturing capabilities. Our technologies enable:

- Fewer steps
- Faster turnaround times
- Higher purity
- Reduced costs
- Enhanced sustainability



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Advancing your science with the purpose it was built for

Built on decades of experience, our teams understand the intricacies of drug development and manufacturing. We are committed to making your journey easier by offering flexible and custom solutions.

Experience a strong collaboration with simplified contracts, prompt communication, and a dedicated program manager to keep you informed throughout your project. We strive to be the easiest CDMO to work with and are committed to your success.

Experience Meets Innovation

We leverage over decades of industry expertise, while offering an innovative and modern approach to drive cutting-edge solutions.

Made Where You Are

Our 4 facilities across North America, Europe, and Asia, offer the flexibility and accessibility to support your projects to your geographic preference.

Scalable Production Capacity

Our ~915 m^3 / ~241,717 US Gallons of small molecule production capacity supports scalable solutions as your molecule advances from development to commercialization.

Proven Track Record

We have extensive experience with 39 approved products currently in production, serving as a reliable CDMO partner to drive your success.

Commitment to Safety

With our stellar safety record, you can trust that your project will be managed with the highest safety standards.

Regulatory Excellence

Our 100% adherence to global regulatory agencies offers you confidence in our compliance and quality standards to accelerate your path to the market.

Our Devotion to Environmental Stewardship

We are dedicated to sustainability through the adherence to the 12 Principles of Green Chemistry and broader sustainability goals in alignment with our Net Zero Carbon Target by 2040. Initiatives include solvent recycling evaluation program and implementation of “My Green Labs.”

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Expanded Modalities

Innovation is embedded in our DNA. In addition to expanding our core capabilities, we are investing in new modalities such as ADC payloads & linkers and peptides. These strategic investments ensure we have the capacity and capability to support your needs in a rapidly growing market.

Small molecule APIs, intermediates, RSMs

ADC payloads & linkers

Peptides

Fmoc protected natural and unnatural amino acids

Our Small Molecules Services

Custom Development

- Process Development
- Process Safety
- Analytical Development
- Technology Transfer

Custom Manufacturing

- Clinical
- Commercial

Regulatory Support

- IND, NDA (CMC section), PAIs
- DMF

Specialized Capabilities

Energetic Chemistry

Reductions, Oxidation, Azide/ Diazo, Chlorination, and Others

Continuous Flow Processing

- Continuous Fixed Bed Catalytic Reactions
- Tubular Reactions
- Continuous Stirred Tank Reactor (CSTR)
- Plug Flow, Loop Reactors, SMB, Membrane/TFF, and Tricklebed Reactors

High Potency

- Up to 4 m^3 scale
- OEL down to 10 ng/m^3 containment
- Facilities designed to support ADCs payloads manufacturing

Chromatography

- Batch low/High Pressure, Small (mg) to Large scale (MT)
- Simulated Moving Bed (SMB) – from lab to commercial units (largest in North America 5 x 1,000 mm)
- Complex separations for ADCs, Peptides, and Oligonucleotides

Particle Engineering

Crystallization, Milling, Micronization, Spray Drying, and Characterization

Catalyst Design & Fixed Bed Reactors

Customized catalyst development for optimized performance in continuous flow or batch processes

Global Supply Chain Options

4 CGMP Small Molecule Manufacturing Facilities

A wide array of analytical testing methods are available to support your CDMO program across all sites and provide contract analytical testing services.

Regulatory Excellence

Safety and quality are critical to the success of your program. Our proven track record of regulatory compliance guarantees that your product is manufactured with the highest quality standards in mind to mitigate risks and ensure a seamless path to market.

Our facilities are successfully audited by global regulatory agencies, including the FDA (U.S.), EMA (Europe), Health Canada, PMDA (Japan), MFDS (Korea), ANVISA (Brazil), and TGA (Australia).

100%
inspections passed at all facilities

9
recent PAIs waived

31
PAIs approved over the past decade

37
Successful regulatory inspections since 2020

Our Commitment to Environmental Stewardship

We recognize that our clients have their own sustainability objectives to achieve. We are committed to reducing our environmental impact and serving as a green supplier that supports your sustainability ambitions.

Our key initiatives include:

- Targeting net zero carbon emissions by 2040
- Utilizing solvent recovery strategies to achieve ~99% waste reduction
- Sourcing ~50% of our electricity from renewable sources
- Ongoing “My Green Labs” program
- Engaging employees in sustainability education programs

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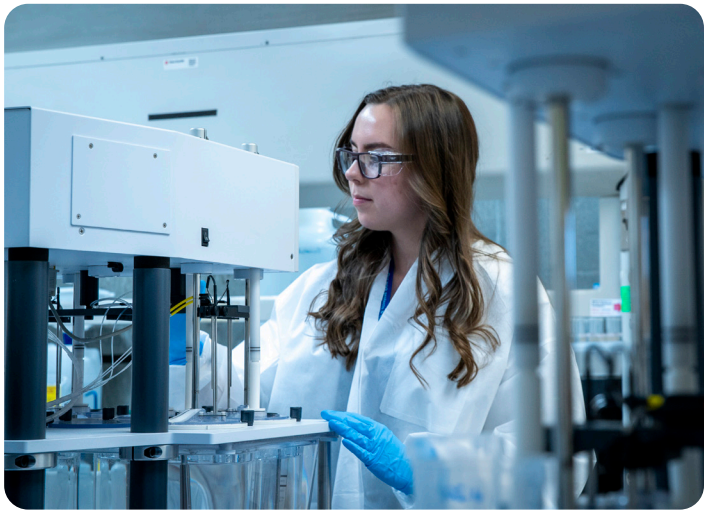
Powerful In-House Analytical Testing Services

Whether you require analytical services through our manufacturing partnership, or independent contract analytical services, our CGMP laboratories deliver accurate, reliable, and timely solutions.

We offer robust analytical testing services for both drug substances and drug product formulations.



OUR CAPABILITIES

- Analytical Development
- Nitrosamines & Genotoxic Impurities
- Extractables & Leachables
- Stability Studies & Storage
- Release Testing
- Raw Material & Excipients Testing
- Material Science & Characterization
- Reference Standard Management
- Elemental Impurities
- Residual Solvents

SPECIALIZED CAPABILITIES

- High potency and cytotoxic compounds require specialized expertise for safe and secure handling.
- Capability to handle OEL 10 ng/m^3
- At SK pharmteco, we have extensive experience and a dedicated sample handling facility to ensure rigorous safety and compliance.

About SK pharmteco:

SK pharmteco is a global contract development and manufacturing organization (CDMO) serving the pharmaceutical and biopharmaceutical industries. With CGMP manufacturing sites, research and development facilities, and analytical laboratories across the United States, Europe, and South Korea, the company provides integrated services spanning Active Pharmaceutical Ingredients (APIs), advanced intermediates, registered starting materials, viral vectors for gene therapy, and analytical capabilities in support of client programs. SK pharmteco partners with companies of all sizes to enable the development and delivery of transformative therapies worldwide. The company is a subsidiary of SK Inc. (KRX: 034730), the strategic investment arm of SK Group, South Korea's second-largest conglomerate.

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