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.

Advanced Capabilities

As your molecule progresses through the pipeline, it may require specialized manufacturing capabilities. Our SmartPlatform™ Portfolio is an integrated suite of technologies that enable:

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

SK pharmteco
SmartPlatform

SmartCat
Catalyst Design

SmartFlow
Continuous Processing

SmartPure
Chromatographic Solutions

SmartTest
Analytical Solutions

SmartForm
Material Science

SmartShield
High Potency Chemistry

Expanded Modalities

Innovation is embedded in our DNA. In addition to expanding our core capabilities, we are investing in new modalities such as ADC linkers & payloads 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
- Phosphoramidites & Oligonucleotides
- Peptides (LPPS & SPPS)
- Fmoc protected natural and unnatural amino acids

Your Seamless Partnership Begins Here

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 seamless partnership 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.

Highlights

Experience Meets Innovation

We leverage over 80 years of industry expertise, while offering an innovative and modern approach to drive cutting-edge solutions.

Global Presence:

Our 5 facilities across North America, Europe, and Asia, offer the flexibility and accessibility to support your projects to your geographic preference.

Scalable Production Capacity:

Our ~265,000 gallons (~1,000 m^3) of small molecule production capacity supports scalable solutions as your molecule advances from development to commercialization.

Proven Track Record:

We have extensive experience with 34 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 Steadfast 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 by 2040. Initiatives include solvent recycling evaluation program and implementation of My Green Labs.

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info@skpt.com

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

Diazomethane, Azide, Hydrazine, Ozone

Continuous Flow Processing

Fixed bed

Continuous Stirred Tank Reactor (CSTR)

Flexible modules built to purpose

Catalyst Design

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

Chromatography

Simulated Moving Bed (SMB) – from lab to commercial units (largest in North America 5 x 1,000 mm)

Batch

High Potency

Up to 4m^3 scale

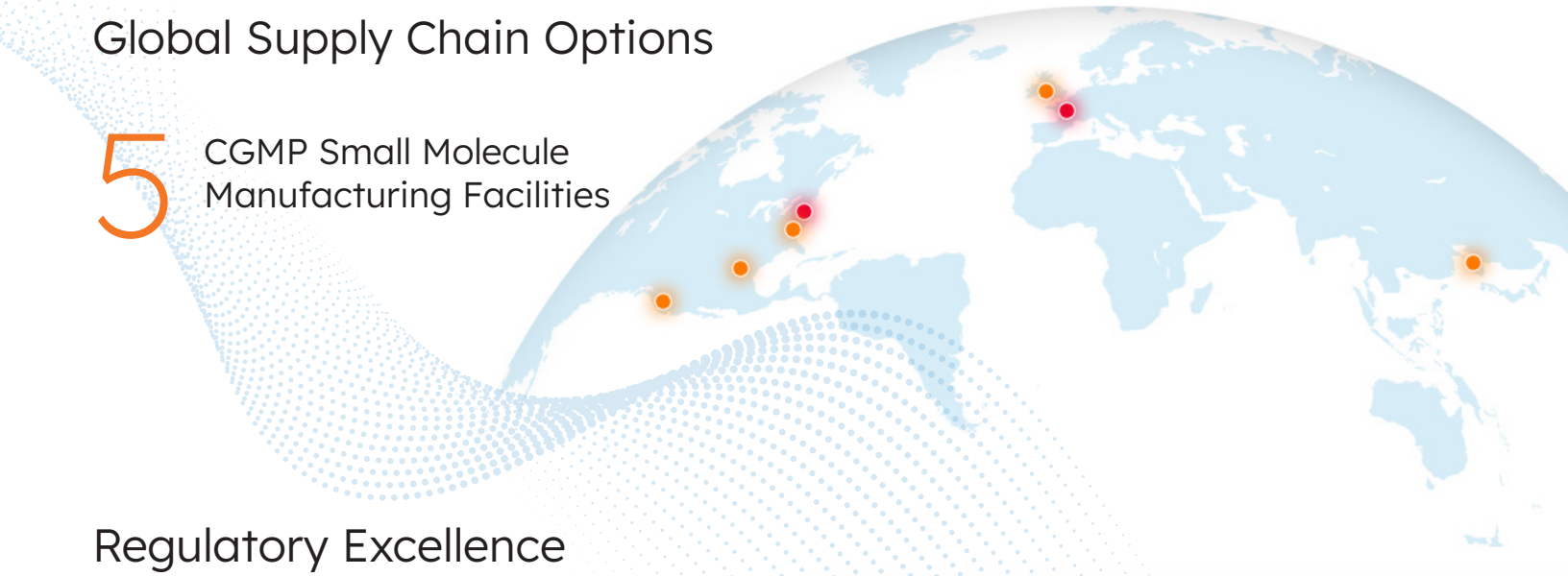
OEL down to 10 ng/m^3 containment

Particle Engineering

Crystallization, Micronization, etc

Global Supply Chain Options

5 CGMP Small Molecule Manufacturing Facilities



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

>230
FDA personnel trained on-site

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 seamlessly aligns with and 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
- Initiating “My Green Labs” program in October 2024
- Engaging employees in sustainability education programs

Comprehensive 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 comprehensive 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.
- At SK pharmteco, we have extensive experience and a dedicated sample handling facility to ensure rigorous safety and compliance.
- Capability to handle Band 5 & Band 5 SC compounds
- OEL < 0.1 µg/m³

About SK pharmteco:

At SK pharmteco our mission is to build strong relationships that create happiness for our customers through the shared goal of producing and delivering life-changing therapies that improve patient outcomes and save lives. With our network of seven global, cutting-edge, facilities our capabilities cover the entire product lifecycle, from initial development to commercial manufacturing. We work with customers in a flexible 'One Team' approach, prioritizing collaboration, transparency, and trust to make every interaction easy and seamless.

SK pharmteco offers CDMO services for small molecule APIs and cell and gene therapies as well as analytical testing services; contact our experts to learn more!

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