

Making Complex Science Dependable

Small molecule development and manufacturing solutions to support your program at every phase, every scale.

CDMO SERVICES

Process Development • GMP Manufacturing
Analytical Testing • Regulatory Support

Advancing Small Molecule Manufacturing at Scale with SK pharmteco

As a global CDMO, SK pharmteco understands the complexities of small molecule development and manufacturing—from accelerating timelines and scaling complex chemistries to navigating evolving regulatory requirements. Our experienced teams help advance molecules from early development through commercialization with the technical expertise, manufacturing capabilities, and regulatory experience needed at every stage.

Across our global facilities, we provide custom development and manufacturing of small molecule APIs, advanced intermediates, and regulatory starting materials (RSMs), with scalable capabilities from grams to multi-ton production. Our focus on scientific rigor, reliable execution, and manufacturing flexibility helps clients address complex technical challenges and confidently advance their programs.

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



Energetic Chemistry



High Potency



Particle Engineering



Continuous Flow



Chromatography



Catalyst Design



Biocatalysis



Analytical Testing



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 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 m³ / ~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 current commercial products, 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.

Expanded Modalities

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

Peptides (LPPS, SPPS, Hybrid approaches)

Integrated Supply of Protected Amino Acids

ADC Payloads & Linkers

Our Small Molecule Services



Custom Development

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



Custom Manufacturing

- Clinical
- Commercial



Regulatory Support

- IND, NDA (CMC section)
- DMF

Specialized Capabilities



Energetic Chemistry

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



High Potency

- Up to 4 m³ scale
- OEL down to 10 ng/m³ containment
- Facilities designed to support ADC payload manufacturing



Particle Engineering

- Crystallization, Milling, Micronization, Spray Drying, and Characterization



Continuous Flow

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



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 other modalities



Catalyst Design

Custom catalysts for continuous flow and advanced processes including:

- Hydrogenation
- Oxidation
- Coupling Reactions
- De-protection
- Others



Biocatalysis

- Over 6,000 enzymes for diverse transformations (KREDs, IREDs, transaminases, EREDs, esterases, and more)
- Access to enzyme bioengineering and optimization



Analytical Testing

- In-house testing for streamlined operations for both drug substance & drug product

Global Supply Chain Options

Our sites across North America, Europe, and Asia deliver flexible solutions to help mitigate geopolitical risk, optimize costs, and strengthen supply resilience.



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), HPRA (Ireland), Health Canada, PMDA (Japan), MFDS (Korea), and ANVISA (Brazil).

47

Successful regulatory inspections since 2020

14

PAI approvals over the past 5 years

39

Current commercial products across all sites

260+

U.S. FDA personnel trained at our sites

100%

Inspections passed at all SK pharmteco facilities



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:

- Greenhouse gas emissions reduction targets officially validated by the Science Based Targets initiative (SBTi)
- Targeting net zero carbon emissions by 2040
- Utilizing solvent recovery strategies to achieve ~99% waste reduction
- Sourcing ~50% of our electricity from renewable sources
- Achieved 4 “My Green Lab” certifications
- Engaging employees in “No Harm” safety and sustainability education programs
- Sustainability performance reporting through Secaro and CDP

Powerful In-House Analytical Testing Services

Whether you require analytical services through our manufacturing partnership, or independent contract analytical services, our GMP 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 down to 10 ng/m³
- 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) with production sites, research & development facilities, and analytical laboratories across the U.S., Europe, and South Korea. The company's core capabilities center on small molecules, peptides, and viral vectors, providing the specialized expertise needed to bring complex therapies to market. Through these pillars, SK pharmteco supports biopharmaceutical partners of all sizes with comprehensive development and manufacturing solutions worldwide. SK pharmteco is a subsidiary of SK Inc. (KRX: 034730) (SK), the strategic investment company for SK Group, South Korea's second-largest conglomerate.

