Small Molecule Drug Substance

Eurofins CDMO Alphora is a Canadian, FDA & Health Canada approved, contract development and manufacturing organization (CDMO) focused on process and analytical chemistry for non-GMP and GMP scale-up for complex, small molecule APIs, including highly potent molecules. We support IND-enabling activities through to commercialization.

API CAPABILITIES

R&D	ANALYTICAL	SOLID STATE R&D	CMC & REGULATORY
Highly Potent Expertise	Method Development	Physicochemical Characterization	CMC Content Authoring
Route Scouting & Design	Method Qualification	High Throughput Screening	Design of Experiment
Process Development	Standards Qualification	Solubility & Dissolution Screening	CMC Gap Analysis
Process Validation	Lifecycle Optimization	Polymorph Screening	Impurities Risk Assessment
Pre-Clinical Supply & Scale Up	Stability Testing	Crystallization Engineering	Nitrosamine Assessment
GMP & non-GMP Manufacturing	Lifecycle Optimization	Integrated Services or Stand-Alone	Process Validation Support

API & HPAPI SERVICES

HIGHLY POTENT

We develop, optimize and support R&D and analytical processes. Our facilities are equiped to handle high potency APIs up to Safebridge Class 4 (OEL's <30 ng/m^3), with non-GMP manufacturing in R&D up to 5 L and in our dedicated kilo lab suite up to to 100 L.

API

Our R&D facilities have development capacity from gram to kilogram quantity. Our production capacity from development to commercial for non-GMP & GMP is up to 125 kg per single batch, with scale up capacity up to 2000 L.

SCALE-UP CAPABILTIES

R&D

- Handling projects up to Safebridge Class 4
- R&D scale-up to upto 5 L

GMP KILO LAB

- 2 x GMP Kilo Labs
- 2 x 20 L, 3 x 50 L, 2 x 60 L

GMP PRODUCTION

- 4 x GMP Manufacturing Suites
- From ~25 kg single batch up to 125 kg single batch
- 2 x 200 L, 4 x 500 L, 2 x 2000 L

FDA & Health Canada Approved Facilities

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eurofins | CDMO

ACHIEVE MORE, TOGETHER

Biologics | Drug Substance & High Potency DS

- Partnership to develop ADCs under-one-roof
- Drug Substance - Linker Development
- High Potent DS - Warhead/Payload Development
- Biologics - mAbs development

Solid State R&D | Drug Substance

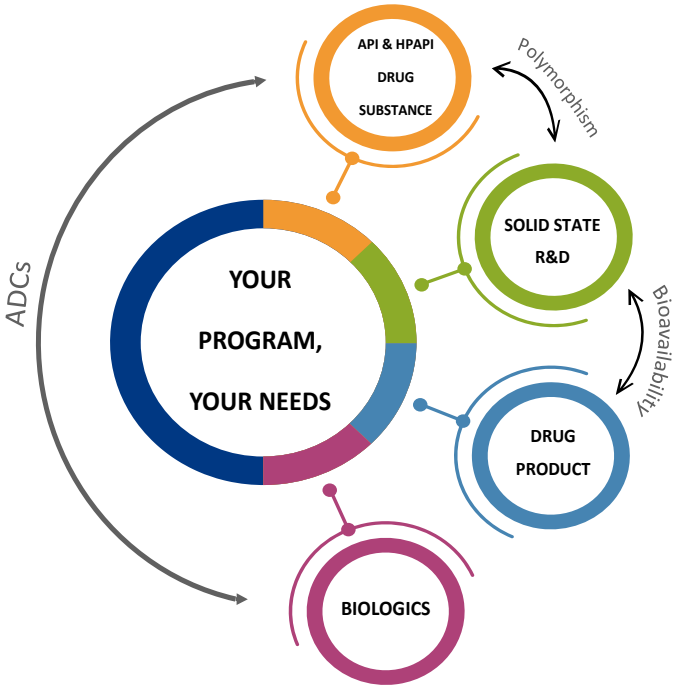
- Uncover polymorphism to reduce later stage risk and IP generation

Solid State R&D | Drug Product

- Understand solubility & candidate ranking to determine bioavailability

Drug Substance | Drug Product

- Advance small molecule drug substance programs from development to drug product formulation and solid dosage forms



20+ years of experience as a full-service CDMO

With over two decades of expertise, we deliver integrated drug development and manufacturing services, ensuring seamless pathways for your program from preclinical to commercialization.

Diverse Programs, Flexible CDMO

We are proud to serve a diverse range of clients, from early-stage startups to pharmaceutical companies, providing individualized, flexible and high-quality service to all.

Integrated, Customized Solutions Under One Roof

Currently manufacturing several API products, we combine expertise in small molecules, biologics, and ADCs with specialized services designed to de-risk and accelerate product development.

Strong Quality & Project Management Systems

Underpinned by a strong quality & project management system, our team of experts navigate complex regulatory compliance within quality frameworks with a focus on timeline, budget and communication.

Client Focus

We prioritize client satisfaction by delivering tailored solutions that meet your unique drug development needs, ensuring efficient and effective pathways to market.

FDA & Health Canada Approved

We have experience filing in 25 countries, including USA, Canada, Australia, EU, Japan, Brazil, Taiwan and more.

Advancing Drug Development, Accelerating Success

CONTACT US

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