eurofins | CDMO

Drug Product Development & Manufacturing

Eurofins CDMO Alphora is a Canadian, FDA & Health Canada approved contract drug development and manufacturing organization focused on formulation development and manufacturing services from simple to complex dosage forms. Our core strength is formulation development for smal molecule compounds, including those with challenging physicochemical properties, clinical manufacturing and creation of IP strategies.

DRUG PRODUCT CAPABILITIES

PRE-FORMULATION

- Solubility & Absorption Studies
- Salt & Polymorph Screening
- Physical Characterization
- Early liquid formulations for in-vitro & animal studies
- Compatibility Studies

FORMULATION

- Analytical Method Development & Validation
- Formulation Development
- API Bioavailability Enhancements (micronization, spray drying, lipid based formulations - SEDDS, amorphous dispersions)
- ICH/Accelarated (ASAP) Stability
- GLP Formulation Support

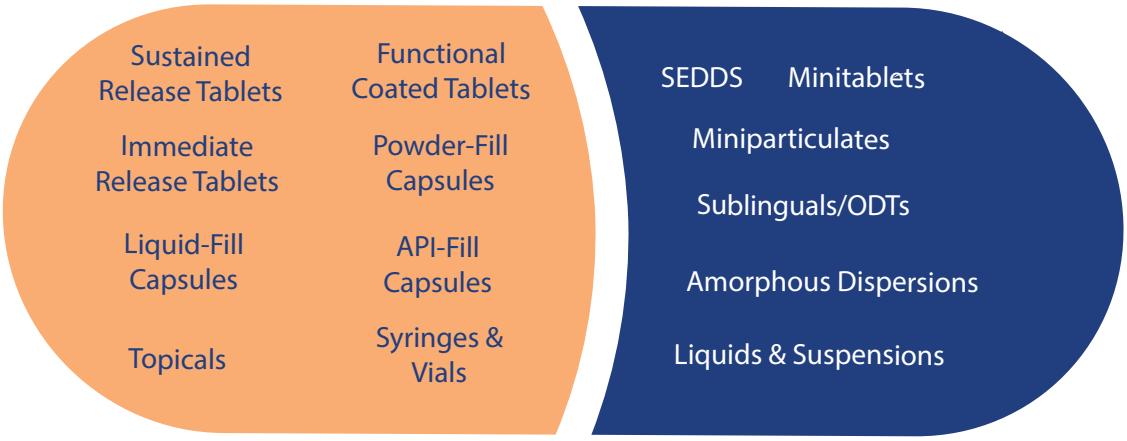
SCALE-UP & CLINICAL MANUFACTURING

- Micronization & Spray Drying
- Highly Potent APIs
- Automated Micro Dosing
- Granulation Technologies
- Encapsulation & tableting
- Clinical packaging & warehousing

QUICK-TO-CLINIC OPERATIONS

PRE-FORMULATION & FORMULATION EXPERTISE

Our Pre-Formulation & Formulation Scientists have extensive experience in the development of poorly soluble compounds, in particular material characterization, analytical chemistry and phase-appropriate strategy development for complex formulations and high containment operations.



GMP CLINICAL MANUFACTURING

Our core focus is GMP clinical drug product manufacturing. Our state-of-the-art facilities and GMP compliant systems are specifically designed for quick-to-clinic operations. We specialize in process transfer and scale-up strategies, providing a seamless transition of programs from development through to later stage manufacturing.

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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

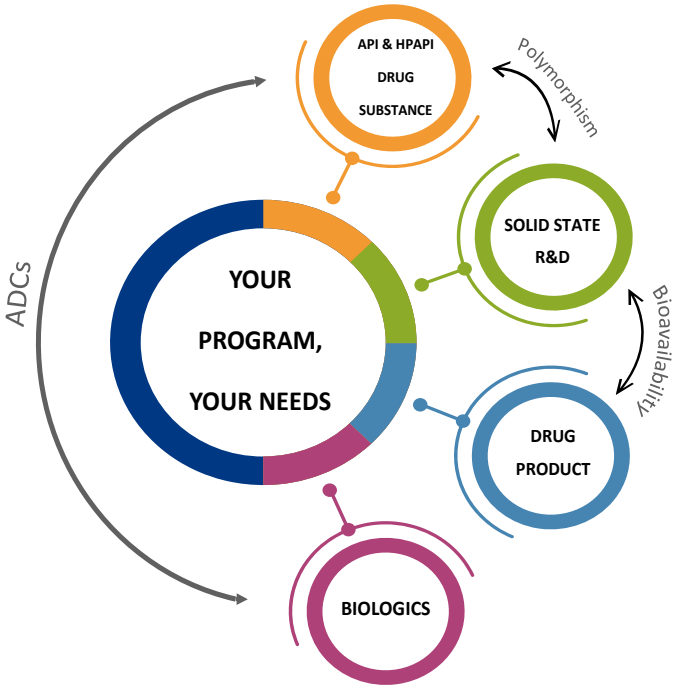
- Uncover polymorphism to reduce later stage risk and IP generation

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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