core Rx®

DEVELOPMENT

AT OUR CORE

[SOLID]

[LIQUID]

[SEMI-SOLID]

SPEED
QUALITY
EXPERTISE

WE PROVIDE SCIENTIFIC SOLUTIONS TO YOUR DRUG PRODUCT DEVELOPMENT CHALLENGES

CoreRx, a Contract Development & Manufacturing Organization (CDMO) with capabilities to support clinical – niche commercial manufacturing, offering state of the art facilities to support your supply chain needs. Our integrated offerings provide comprehensive services for the development, manufacturing and testing of solid, liquid and semi-solid dosage forms.

The art of drug product development is at the core of what we do. Our staff combines years of pharmaceutical development expertise to produce safe, effective, and innovative drug products, on time, and on budget. We differentiate ourselves by mixing highly experienced scientists with a wide range of technologies to deliver optimal solutions to meet our clients' needs. From simple formulations to complex, modified release dosage forms, CoreRx's solutions maximize client investments, shorten development time and reduce overall costs.

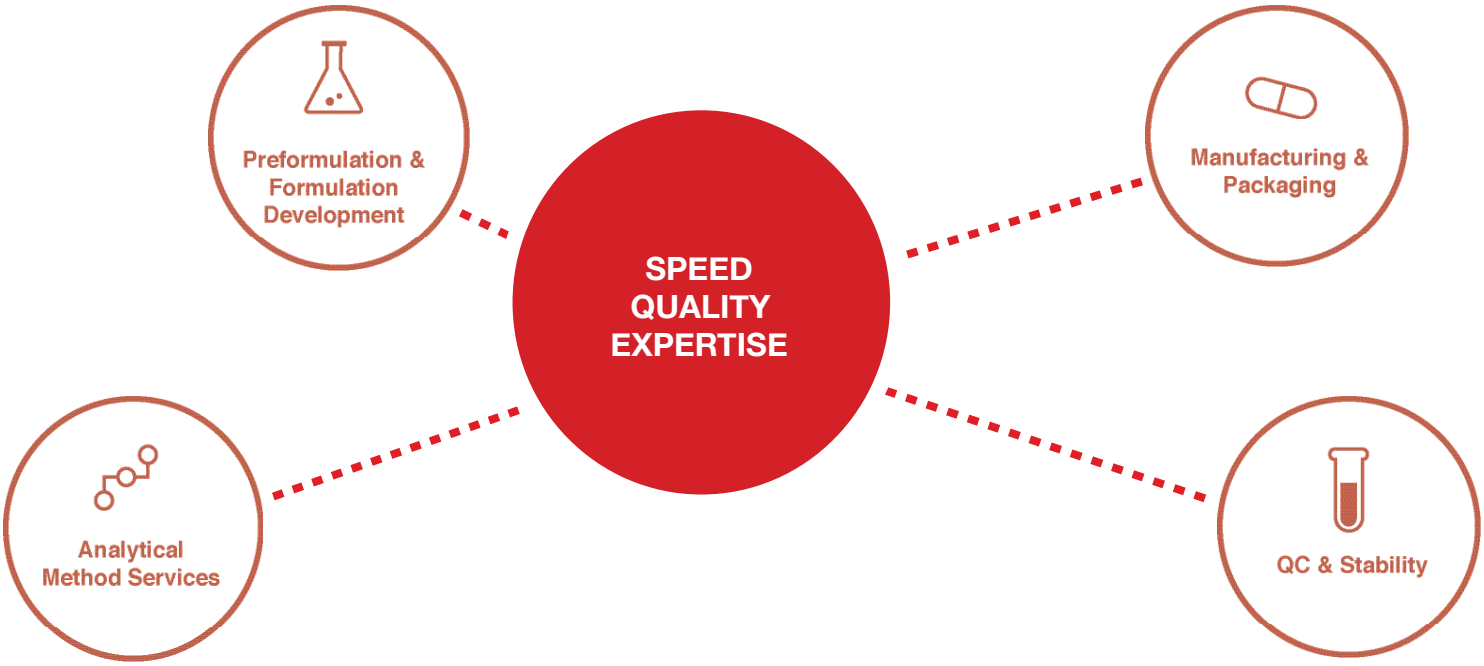
"Every formulation project starts with a strategic plan and a dedicated team."

www.corerxpharma.com

OUR SERVICES

CoreRx offers **comprehensive drug product development and manufacturing** services to the pharmaceutical and biotechnology industries. Supporting virtual, mid-size, and multinational companies, we provide novel formulation development solutions, customized manufacturing and packaging solutions, and related analytical and stability support services.

From first-in-man studies to commercial manufacturing support, CoreRx provides years of **pharmaceutical development expertise** to produce safe, effective, and innovative drug products, on time, and on budget.



PREFORMULATION SERVICES AND SUPPORT

Characterization of the Active Pharmaceutical Ingredient (API) is critical to designing a successful formulation approach. CoreRx can evaluate the characteristics of your API, control particle size, conduct small scale studies to understand key parameters around solubility and stability, and perform excipient compatibility studies to identify the right ingredients to enhance API performance across a variety of dosage forms.

Preformulation Services Include:

- API Physical & Chemical Characterization
- Particle Size Analysis
- Polymorphism Identification (XRD, DSC)
- Zeta Potential Analysis
- pH/Stability/Solubility Profiles
- Partition Coefficient
- Thermal Analysis (DSC, TGA)
- Hygroscopicity Evaluation (DVS)
- Excipient Compatibility Testing

Particle Size Control & Reduction Technologies:

Dry Process

- Jet Mill
  - Particle size range of 1 – 45 microns

Wet Process

- Microfluidization
  - Particle size reduction for low to submicron particles
- Proprietary MicroJetReactor *(MJR®)* Nanosizer
  - Extreme particle size reduction for nano-sized particles down to 100nm

FORMULATION DEVELOPMENT

Our robust experience and capabilities in formulation development covers a wide range of dosage forms and delivery technologies. Keeping goals and objectives in mind, we focus on creating formulations designed to meet our clients' needs. From early phase formulations for preclinical research through QbD evaluations, CoreRx can support your formulation needs for any phase of development.

Formulation Technologies

Solid Dosage Forms

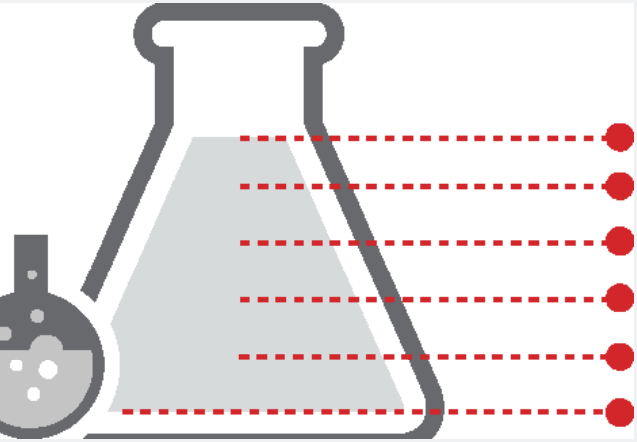
Blending
Dry Granulation
Roller Compaction
Wet Granulation
Fluid Bed Processing
Spray Drying
Extrusion/Spheronization
Encapsulation
Tableting Including
- (Micro and Multi-Layer)
Pan Coating/Drying
Milling

Liquid & Semi-Solid Dosage Forms

Mixing
Homogenization
Microfluidization
Filling
Lyophilization

Overcoming Formulation Challenges

Developing formulations is as much an art as it is a science, and it's the people that make the difference. Our formulation team consists of PhD and Master level formulators and analytical chemists that **we would stack up against any in the Industry.**



From these experts, we provide guidance and support across the following areas:

- Enhancing Bioavailability
- Solubilizing Water-Insoluble Drugs
- Creating Modified/Controlled Release Delivery of API
- Creating Fixed Dose Combination Products
- Stabilizing Unstable Molecules
- Taste Masking/Flavoring

Formulation Testing and Evaluation

- Product Potency & Uniformity Evaluation
- Chemical & Physical Stability Evaluations
- In-Vitro Release & Permeability Testing
- Photostability Studies
- Temperature Cycling & Freeze-Thaw Studies
- Material/Packaging Compatibility Testing

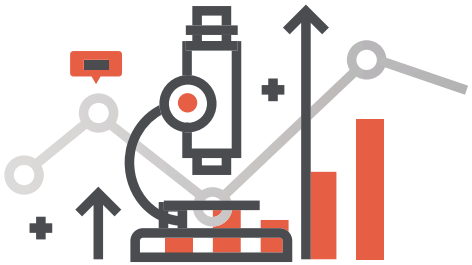
"We will supply the right ingredients to ensure your product reaches its maximum potential."

ANALYTICAL AND STABILITY

Drug product development and clinical manufacturing efforts at CoreRx are fully supported by our GMP compliant in-house analytical laboratories. Equipped with state of the art analytical instruments, CoreRx provides analytical method support, release and stability testing services for a variety of dosage forms including: oral, ophthalmic, suppository, and topical routes of delivery.

Method Development & Validation

CoreRx provides method development, optimization, transfer, and phase appropriate qualification/validation services for a variety of dosage forms.



Our Services Include:

- HPLC & UPLC Assay & Related Substance Methods
- Preliminary Impurity Characterization Using the Single Quad Mass Spec
- Single Point, Multi-Point and Two-stage Dissolution Methods
- Mass Determination for Impurities
- Franz Cell Permeability Assay Methods
- Blend and Content Uniformity Methods
- GC Assay Methods for Organic Impurities
- Cleaning Methods for Support of GMP Manufacturing

Drug Product Release & ICH Stability Services

CoreRx offers comprehensive drug product release & stability services in support of full development and manufacturing programs conducted at CoreRx.

Our QC Services Include:

- Analytical Method Qualification: Verification, Transfer, and Validation
- Release Testing & Certificate of Analysis
- Stability Protocol Generation
- Stability Storage and Testing
- Stability Summary Report Generation
- Stability Time Points and Conditions
- Ad Hoc Report Generation
- iStability LIMS for Stability Trending

GMP Stability Chambers:

Walk-In Chambers

- 5°C
- 25°C/60% RH
- 30°C/65% RH
- 40°C/75% RH

Reach-In Chambers

- Three Custom Condition Chambers
- Darwin Freeze/Thaw Chamber
- 15C Reach-in Chamber

MANUFACTURING

CoreRx offers diversified technical resources, capacity, flexibility, and experience to manufacture with strict quality compliance. Our manufacturing capabilities include a variety of dosage forms, with the scale to support phase I – niche commercial manufacturing. Our facility design, licenses, and controls allow CoreRx to provide manufacturing services for DEA schedule II - V substances as well as high potency compounds.

Tablets

- Immediate to Modified Release
- Orally Disintegrating (ODT)
- Multi-Layer Tablets
- Micro-Tablets
- Multi-API Combination Formulations

Liquid Oral Dosage Forms

- Solutions
- Suspensions
- Emulsions
- Syrups

Coating

Experience coating with:

- Functional Excipients
- Non-Functional Excipients
- Secondary APIs

Experience in coating:

- Granules, Beads
- Tablets
- Capsules: Hard Shell, Soft Gel

Capsules

- Neat API in Capsule
- Powder Blends
- Multi-Particulates (Beads & Granules)
- Immediate to Modified Release
- Tablet in Capsule
- Over-Encapsulation
- Multi-API Combination Products

Topical Dosage Forms

- Gels
- Creams
- Ointments
- Lotions

Other Dosage Forms

- Suppositories
- Powders

PACKAGING

Having packaging operations integrated with manufacturing services provides streamlined value for clients. CoreRx offers comprehensive primary and secondary packaging, labeling and distribution options linked with our manufacturing services to meet the needs of our clients.

Solids

Bottles
Blisters *(thermoform & coldform)*
Sachets

Liquids

Bottles
(commercial serialization and aggregation)
Oral Syringe Applicators
Vials

Semi-Solids

Tubes
Jars

"We support a variety of dosage forms. From phase I – niche commercial manufacturing."

FACILITY OVERVIEW

At CoreRx you will find a clean, professional environment with the latest in scientific resources that will provide the perfect setting to support your drug development efforts. Our facilities in Clearwater, Florida are FDA and Florida Department of Health registered as well as DEA approved (schedules II – V of controlled drugs).

Our analytical and manufacturing areas are fully GMP compliant and have an excellent inspection record. We welcome you to visit and tour/audit our facilities.

MYERLAKE I – 35,000 SQ. FT

- 14 cGMP Manufacturing & Packaging Suites
- 2 cGMP Analytical Labs which Support Method Validation, QC and Stability
- Qualified cGMP Stability Chambers
- cGMP Warehouse
- Office and Administrative Space

MYERLAKE II – 47,000 SQ. FT.

- Clinical Manufacturing Suites (10)
- cGMP Warehouse
- Office & Administrative Space

MYERLAKE III – 47,000 SQ. FT.

- Client Dedicated GMP Manufacturing and Analytical Testing Facility
- cGMP Warehouse
- Office and Administrative Space

MYERLAKE IV – 26,000 SQ. FT.

- Formulation Development Laboratory (9 Processing Suites)
- R&D Analytical Laboratory
- Office and Administrative Space

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WHY OUTSOURCE TO CORERX?

Whether you need specific delivery **expertise**, have outstretched your internal capacity, or are staff-limited, CoreRx consistently delivers innovative development **solutions**, on-time, and on-budget. To select the ideal development **partner**, you not only need scientific depth, but you also need a company that has the 'intangibles' that will enable them to engage well with **your team**.

- People and Expertise
- Communication
- Speed
- Quality Systems
- Flexibility

Bring us your formulation challenge!

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