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PRODUCT DEVELOPMENT: ENGINEERED AT EVERY STAGE, FROM DISCOVERY TO DELIVERY



At ARx, we turn breakthrough drug formulations into robust, scalable, and regulatory-ready manufacturing processes. With over 60 years of polymer and coating expertise, our engineering team optimizes every phase of product and process development—bridging discovery to delivery with precision and speed.

BUILT FOR SCALE. BACKED BY SCIENCE.

ARx's proprietary in-silico and experimental pre-formulation model enables our partners to evaluate formulation feasibility and identify optimal enhancer packages earlier—reducing development costs, accelerating timelines, and minimizing risk. This strategic approach helps reveal novel IP opportunities and ensures the strongest possible formulation path forward.

OUR STREAMLINED PRE-FORMULATION WORKFLOW

- **Proprietary Solvent & Enhancer Screening**

We start by testing your API with a proprietary list of solvents and enhancers, built from decades of success in transdermal and transmucosal delivery.

- **In-Silico Modeling**

Data from initial tests is entered into our modeling system to simulate enhancer-polymer interactions and narrow down the best combinations for lab testing.

- **Experimental Verification**

Shortlisted enhancers are re-verified for solubility and compatibility before advancing to full permeation testing.

- **In-Vitro Permeation Studies**

Up to 8 enhancer systems are evaluated using diffusion cell assays to measure flux, absorption potential, and delivery feasibility. These studies guide key formulation decisions, including dosage strength and delivery format.

- **Decision & Final IP Strategy**

Together, we review feasibility data and select the most promising formulation path in consideration of your targeted strengths and delivery pharmacokinetics.



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ADDITIONAL ARX PROCESS DEVELOPMENT SERVICES INCLUDE:

Feasibility & Design:

- API/excipient compatibility evaluation
- Proprietary in-silico + experimental screening
- Solubility verification & initial permeation testing

Pilot Production & Scale-Up:

- Formulation optimization based on target QTPP, formulation design, target flux, PK, & dosage route
- Bench-to-clinical to commercial-scale translation
- Mixing, coating, and packaging process registration

Validation & Transfer:

- Full QbD implementation
- Equipment qualification (IQ/OQ/PQ)
- Tech transfer support and regulatory documentation


Ongoing Optimization:

- Root cause analysis & deviation response
- Continuous improvement systems
- APR Authorship and Continuous Process Verification



LOOKING TO INTEGRATE YOUR API INTO A NEXT-GEN DELIVERY SYSTEM?

Partner with ARx to transform your therapeutic concepts into scalable, regulatory-compliant products.

 **Phone:** +1(717) 235-7979
Toll-Free: +1(800) 445-6240

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REALIZE YOUR PRODUCT'S POTENTIAL, FASTER

ARx doesn't just scale your formulation. We build smarter, more resilient processes designed for quick decision making and success in commercial manufacturing environments.

From predictive modeling and QbD standards to regulatory-ready validation, our approach helps reduce development time, increase yield reliability, and accelerate your path to market, with product integrity and compliance ingrained at every step.

60+

Years of film, adhesive,
and coating science
manufacturing

300x

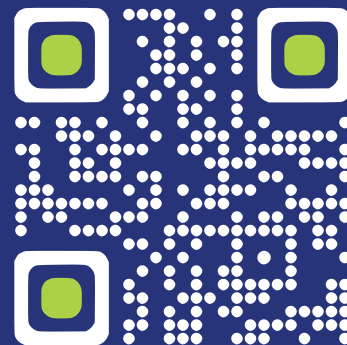
Development-to-
commercial scale
capabilities

100M+

Drug delivery units
manufactured annually
in cGMP facilities

9

Positive FDA inspections
and 3+ "No Observation"
DEA inspections



For More Information, Please Visit:
arxpharma.com