THE ORAL THIN FILM & TRANSDERMAL DRUG DELIVERY PARTNER EVALUATION GUIDE

A Formulation Fit and Partner-Selection Framework for Growing Pharma & Biotech Companies

Developed by ARx's formulation and program management teams.

The team behind the first FDA-approved oral thin film for systemic drug delivery.

INTRODUCTION

Most drug development programs start with a tablet or an injection, then use BCS classification, hepatic extraction ratio, and logP to optimize dosing within that format, rather than to test whether the format itself is the right one. The same physicochemical data that could answer the format question are instead used to work around the format's known limits.

That gap carries a real cost, and the two problems it produces surface on different timelines. A bioavailability problem typically shows up early, in Phase 1 pharmacokinetic data. An adherence or therapeutic-window problem tends to show up later, once a molecule reaches broader clinical use or commercial data, since neither depends on preclinical testing the way bioavailability does. Either way, the finding often doesn't reach a decision-maker until a program has already spent a full formulation cycle on a format the molecule was never suited to.

That physicochemical data determines OTF and transdermal fit just as directly as it determines tablet or injection fit. Molecular weight, logP, and required dose establish whether a compound can permeate a mucosal membrane or the stratum corneum at a therapeutically useful rate, and that threshold can be determined experimentally before the format gets locked in, not after.

Confirming fit solves the easier half of the problem. A molecule can meet every one of those thresholds and a program can still stall for months if the partner behind it cannot execute. A capabilities deck can claim purpose-built equipment and a documented track record. Neither claim is confirmed until a partner produces the underlying documentation.

By the end of this guide, you will be able to:

- Test a molecule's fit for OTF or transdermal delivery against real permeation thresholds
- Identify the manufacturing infrastructure a delivery partner needs to execute either format
- Ask the questions that separate documented capability from a capabilities-deck claim
- Score any potential partner under evaluation against the same criteria

WHO IS THIS GUIDE FOR?

Formulation scientists and business development leads evaluating a molecule's delivery format, or vetting a partner to develop and manufacture it.

That typically means one of two situations: a molecule with a bioavailability, adherence, or therapeutic-window limitation that standard oral or injectable dosing cannot solve, or an active search for a partner capable of executing OTF or transdermal delivery.

HOW SHOULD I USE THIS RESOURCE?

Use this guide to test format fit against real pharmacokinetic thresholds, then run any partner under consideration through the same set of diagnostic questions.

It provides the permeation thresholds and the partner diagnostic questions needed to determine whether a molecule fits either format, and whether a partner can execute it.

WHEN TO LOOK BEYOND STANDARD DELIVERY

Why Tablet and Injection Come First

A sponsor filing an NDA or ANDA for an oral solid follows a review pathway the FDA has run thousands of times, backed by decades of excipient compatibility data and established USP release-testing methods. An injectable follows an equally well-worn sterile fill-finish pathway. Neither format requires a review division to evaluate something it has not seen before.

Two documented cases show what that gap in precedent actually costs.

Buprenorphine reached the US market in 2002 as Subutex®, a sublingual tablet, and for eight years, the tablet's absorption profile and dissolve time were treated as the practical ceiling for a sublingual product, not because anyone had confirmed a film couldn't do better, but because nothing had forced the industry to check.

A film version didn't reach approval until 2010, driven by a different problem entirely: the tablet's shape and hardness made it easy to crush or divert for non-oral misuse. Solving that problem meant rebuilding the format from the ground up, and the resulting film dissolved in roughly half the time, with an abuse-deterrent design the tablet never had. The film didn't just fix diversion. It exposed a performance ceiling nobody had been testing, because nobody had a reason to rebuild the format until abuse potential forced the issue.

Fentanyl moved in the other direction. Approved as an intravenous anesthetic in 1968, it took until the early 1990s for a transdermal patch to reach approval. For most of those two decades, IV administration's tight control over a highly potent opioid looked like the only safe way to dose it, and continuous at-home transdermal delivery was not yet established for a compound this potent.

Once transdermal permeation science caught up, the patch replaced repeated injections with a continuous, at-home pain control option for opioid-tolerant cancer patients, using the same molecule the entire time.

In both cases, the underlying compound never changed. What changed was the industry's willingness to build a format around a real clinical constraint, diversion risk in one case, dosing convenience in the other, instead of defaulting to whatever pathway was already familiar.

Formats Already on the Formulary

Oral thin film and transdermal delivery have their own approval history, spanning addiction medicine, hormone replacement therapy, and oncology supportive care, and each approval traces back to a specific reason standard delivery couldn't do the job. The table below names that reason for each compound.

COMPOUND	FORMAT	INDICATION	WHY STANDARD DELIVERY WAS NOT ENOUGH
Buprenorphine/naloxone	Sublingual film	Opioid use disorder	Tablets could be crushed or diverted; the film's naloxone component deters injection misuse
Fentanyl	Transdermal patch	Chronic pain	Opioid-tolerant patients needed continuous analgesia without repeated injections
Estradiol	Transdermal patch	Hormone replacement therapy	Oral estrogens' hepatic first-pass metabolism raises clotting-factor synthesis and VTE risk; transdermal delivery bypasses that first pass
Granisetron	Transdermal patch	Chemo-induced nausea	Patients undergoing chemotherapy often cannot reliably keep an oral dose down

Signals a Program Has Outgrown Standard Delivery

Most programs treat the tablet or injection's known limitations as the ceiling of what a molecule can achieve, the same assumption that kept buprenorphine on a tablet for eight years. So when a signal shows up—bioavailability variability, an adherence gap, a narrow therapeutic index—the first move is almost always to solve it inside the existing format: adjust particle size, change salt form, add an excipient, tighten the dosing schedule.

Those levers are real, and they work often enough that the format itself rarely gets reconsidered. The signals below are worth checking against a different question: whether the fix belongs in the formulation, or the form:

- **Poor or unpredictable bioavailability**. A BCS Class II or IV molecule, poorly soluble, permeability-limited, or both, makes dissolution rate the bottleneck for absorption. Particle size and salt form can shift exposure between lots.
- **Adherence problems tied to pill burden or dosing frequency.** A multi-dose regimen, or one with food restrictions, can produce a weaker real-world effect than the same drug showed in a controlled clinical trial, purely from missed or mistimed doses.
- **First-pass metabolism.** A high hepatic extraction ratio compound loses a meaningful fraction of the dose to the liver before it reaches systemic circulation, forcing a higher oral starting dose and widening the window for drug interactions.
- **A narrow therapeutic index.** A small margin between an effective dose and a toxic one cannot absorb the lot-to-lot absorption variability that oral dosing produces as a matter of course.
- **Patients who cannot reliably manage standard oral dosing.** Dysphagia, cognitive or motor barriers in geriatric care, and needle aversion in pediatric populations each drive non-adherence through a different mechanism.

A molecule already showing one of these signals does not necessarily need a new chemical entity to solve it.

A 505(b)(2) filing is also a lifecycle-extension strategy, a way to protect a franchise against a patent cliff by giving physicians and patients a better version of a drug they already trust, not a new label on the same limitations.

That calculation matters as much to a business development lead evaluating a franchise's remaining exclusivity as it does to a formulation scientist evaluating whether the molecule itself can support a new format.

WHAT IS A 505(B)(2) PATHWAY?

An FDA approval pathway that lets a filing rely in part on data the agency already has for an approved product, rather than requiring a full new drug application from scratch.

It covers new dosage forms, delivery routes, dosing regimens, and formulations of an already-approved active ingredient. Full safety and effectiveness reports are still required, typically through bridging studies rather than a complete nonclinical program.

Molecular Weight, LogP, and Dose Draw the Real Line

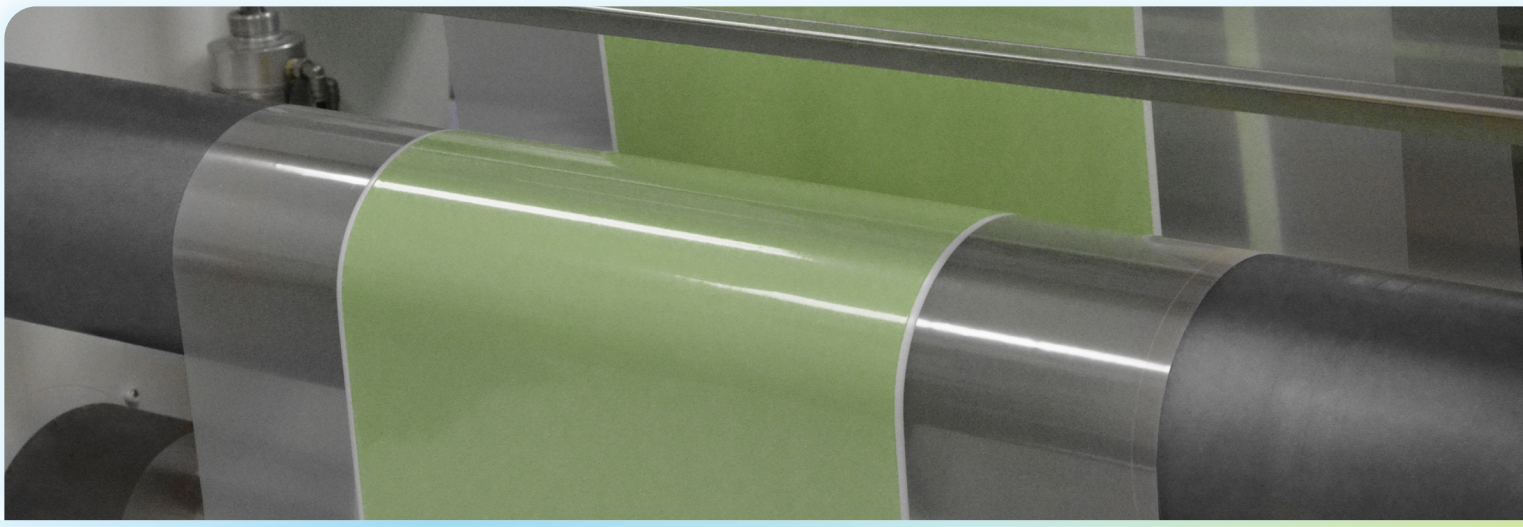
A signal to look past standard oral or injectable delivery is not proof that a molecule can be delivered in an alternative way. That proof comes down to physics, checked first against the molecule's own physicochemical characteristics, then against the required therapeutic dose.

Once a molecule clears both gates, other aspects like onset speed, duration, and whether the pharmacodynamic effect needs to be systemic or local determine which format fits the therapy.

FACTOR	OTF	TRANSDERMAL
Molecule characteristics	Bounded by drug loading capacity, taste-masking feasibility, and film-forming polymer compatibility	Requires molecular weight under roughly 500 Da and logP in the 1–3 range to passively permeate the stratum corneum
Required daily dose	A highly potent, low-dose molecule fits more easily than a high-dose one; a highly bitter high-dose API complicates the taste-masking problem	Constrained by finite patch surface area; a high-dose compound can run out of usable area before it runs out of drug
Speed of onset	Suited to rapid onset	Suited to gradual, sustained delivery
Duration of action	Suited to single-dose, short-acting needs	Suited to multi-day, continuous delivery
Systemic vs. localized effect	Reaches systemic circulation; topical oral conditions are contemplated	Patches reach systemic circulation; topical patches deliver local effect without systemic exposure

A molecule that clears molecular weight, logP, and dose thresholds has real optionality. A program can pursue a 505(b)(2) filing on an existing approved drug compound, or build a new format around a molecule that oral or injectable dosing was never going to serve well.

Either path still depends on more than the chemistry checking out. A partner has to be able to build the film or the patch to spec, at the scale a program will eventually need, under a compliance record that holds up to real scrutiny. Clearing the physicochemical bar gets a molecule in the room. It does not answer whether the partner sitting across the table can actually deliver what the molecule needs.



A FRAMEWORK FOR EVALUATING A DRUG DELIVERY PARTNER

Almost every CDMO in this space describes itself as a partner, and that description alone doesn't tell a sponsor much. What actually separates one CDMO from another shows up in specific, checkable places: the equipment running on the production floor, a compliance record that holds up under audit, and formulation science that appears in the filing itself.

Format-Specific Manufacturing Infrastructure

A molecule that clears its physicochemical thresholds still needs equipment built to the manufacturing tolerances that format actually requires: film-thickness precision for OTF, adhesive tack and peel-strength alignment for patches. General oral-solid tooling is not capable of producing oral thin film or transdermal formats; it has to be retrofitted to produce them, and that gap shows up as variability the original equipment was never designed to control.

Film production runs on precision coating equipment with real-time thickness monitoring, controlled-condition oven drying that removes solvent without degrading the API, and dedicated lines for master roll winding, slitting, and unit-dose packaging. Patch production carries its own version of the same standard: laminating equipment calibrated to adhesive tack and peel strength, and die-cutting tolerances tight enough that unit-to-unit dose does not drift across a batch.

Either way, the equipment has to have been built around the physics of that specific format, not adapted from a line designed for something else.

WHAT IS IQ/OQ/PQ?

Installation, operational, and performance qualification, the documentation trail FDA's process validation framework requires before equipment is released for production.

- IQ confirms the equipment was installed to the manufacturer's own specifications.
- OQ confirms it operates reliably within defined limits across a range of conditions, not just under ideal ones.
- PQ is the highest bar of the three, confirming the equipment performs consistently under real production conditions over time.

A partner who can produce this for the specific line running a program's format has done the work.

Regulatory and Compliance Depth

Drug cGMP compliance runs through 21 CFR Parts 210 and 211, and any delivery partner should hold current FDA registration under that framework without qualification.

Drug-device combination products add a second layer under 21 CFR 820.20, .30, .50, and .100. Practically, that means a partner should be able to show who signs off on quality decisions, how a new formulation or component gets tested before it changes, how incoming materials get qualified, and what happens when something goes wrong in production.

Controlled-substance programs add a third requirement: DEA registration under 21 CFR Part 1301, covering manufacture, storage, and distribution of Schedule II through IV compounds. Buprenorphine is Schedule III. Fentanyl is Schedule II. A partner working across a pipeline needs registration that covers the full range that pipeline might touch.

IP and Formulation Strategy

Formulation strategy starts before any bench work, with feasibility screening across solubility, permeability, and film-forming or adhesive compatibility.

In-silico modeling that predicts those outcomes computationally, before a formulation reaches the lab, cuts the wasted trial-and-error development cycles a program has to fund out of its own budget.

That same formulation work can generate IP independent of the underlying molecule's own patent position. A novel enhancer combination, a specific film architecture, or a delivery mechanism built for a hard-to-formulate API can be patentable on its own, which strengthens a lifecycle-extension filing well beyond what a simple format change alone would support.

Delivery-specific platform technology, a patented micro-deposition system built for APIs that need dosing below a standard film's lower limit, for example, is one concrete proof of that kind of formulation science. It should read as one data point in a broader capability, not the entire pitch.

Manufacturing Scale and Continuity

Real scale runs from a few thousand units for a Phase I batch through commercial orders exceeding 100 million units annually, on the same equipment, without a facility change or a process re-validation between the two scales.

Capacity reservation is a separate question from raw throughput. A partner running near full capacity for other clients can quote an impressive top-line volume and still be unable to commit to a program's actual launch date. What is contractually reserved matters more than what is available.

A recent merger or leadership turnover does not disqualify a partner on its own, but it does change who is actually accountable for a program. A partner's longevity and compliance track record in the business provide real confidence when engaging in any new program.

Access and Collaboration

A partner gives direct access to the scientists doing the formulation and analytical work. When a batch runs outside specification, that scientist can explain what happened and propose a fix in the same conversation.

A CDMO relationship that only offers a project-management layer turns that same conversation into a relay: the question goes to the project manager, who takes it to the lab, who answers back through the project manager again. Each step adds a day, sometimes more, and the delay stays invisible on a timeline until the first real problem actually surfaces.

One Team From Formulation to Launch

A partner running feasibility screening, formulation development, analytical testing, and commercial manufacturing under one roof keeps a single batch record, a single quality system, and the same regulatory documentation trail from the first feasibility study through commercial launch. Nothing has to be re-explained to a new organization partway through.

A CDMO that only covers part of that range requires handing a program to a second organization somewhere between development and commercial launch. That handoff triggers a formal technology transfer: a new site has to re-qualify the process on its own equipment, re-train its own operators, and re-establish the analytical methods the original team already validated once.

A STAT WORTH KNOWING

A 2025 industry roundtable on CDMO technology transfer found that roughly half of all tech transfers run into quality problems, most often from losing the tacit knowledge, the details never written into an SOP, that only the original formulation team actually holds.

The same roundtable flagged a related "contract-to-execution gap," the delay between signing a CDMO agreement and actually starting work, which often forces a second knowledge transfer before a program even gets moving. A single-team structure removes both failure points at once.

Partner Behavior vs. Transactional CDMO Behavior

WHAT IT REVEALS	A DRUG DELIVERY PARTNER	A TRANSACTIONAL CDMO RELATIONSHIP
Infrastructure	Equipment purpose-built for the specific format, with IQ, OQ, and PQ documentation available for the exact line running the program	General oral-solid tooling adapted to run film or patch production, with no format-specific validation history to produce
Compliance	Names the specific 21 CFR 210/211 and 820 quality-system decisions and a real inspection date history, with DEA registration matched to the exact controlled-substance schedule in the pipeline	A registration number with no CFR citation, no inspection date history, and no confirmation the DEA schedule actually matches what is in development
Formulation strategy	In-silico modeling and feasibility screening that generate independent, patentable IP, with any named platform technology positioned as one proof point among several	A single named technology or platform doing all the work of the pitch, with no formulation science behind it beyond that one name
Scale and continuity	Demonstrated batch history from a few thousand Phase I units through 100 million-plus units annually on the same line, with capacity contractually reserved and ownership stable	A theoretical top-line capacity number with no contractual reservation, or a facility that requires expansion and requalification to move from clinical to commercial volume
Access	Direct contact with the scientists running the program, so a specification deviation gets explained and resolved in one conversation	A project-management layer between the client and the lab, turning every technical question into a multi-step relay that adds days before an answer comes back
Program continuity	The same technical team carrying a program from formulation through commercial launch, with no technology transfer required	A handoff to a new site or team once development ends, the exact transition where roughly half of all tech transfers run into quality problems

QUESTIONS THAT SEPARATE REAL CAPABILITY FROM CLAIM

What Every Proposal Claims

Two CDMO proposals for the same molecule will almost always describe similar strengths: regulatory compliance, years of experience, manufacturing scale. Those assurances are rarely false. They are also rarely specific enough to separate one partner from another, since nearly every company in this category can make all three claims honestly.

The difference surfaces when you test each claim against something concrete. A compliance assurance should produce the exact regulatory framework a partner operates under and an actual inspection date history.

A claim of experience should produce a specific track record: how many 505(b)(2) or ANDA programs the team has taken through approval, and in what indications.

A claim of manufacturing scale should produce real batch data across development stages, not a single top-line number, since a partner can quote millions of units annually and still be unable to commit to a launch date, especially if that capacity is not contractually reserved.

WHAT A STANDARD PROPOSAL REVIEW MISSES

A proposal is written to answer the question a buyer is expected to ask. If the only question is batch size, the proposal answers batch size, and every generic capabilities claim sounds reassuring because nothing in the format forces a specific answer.

The real gaps behind most failed technology transfers rarely show up in that proposal: equipment validated for a different format than the one being transferred, a technical team that rotates off once the contract closes, or a quality system that can cite a CFR part number but not an actual inspection history.

They only surface when someone asks a direct question a generic proposal was never built to answer.

> What separates a real capability from a general assurance is whether a partner produces that evidence on request: validation documentation for the exact equipment running the program, the specific citation and inspection date behind a compliance claim, and the name of the team still on the program once it reaches commercial scale.

About the Manufacturing Process

What was this equipment originally validated to produce, and can you show me the IQ, OQ, and PQ documentation for the specific line that would run our formulation?

Installation, operational, and performance qualification is the documentation trail FDA's process validation framework requires before equipment is released for production. This question is designed to find out whether that documentation exists for the exact line that would run this program, not for a similar line elsewhere in the facility.

What batch sizes are realistic at each development stage, and what actually changes when we move from clinical to commercial volume?

This question is designed to surface what actually happens between a Phase I batch of a few thousand units and a commercial order in the millions: which equipment changes between stages, what requalification is required, and how long that transition realistically takes.

Where do your excipients and raw materials come from, and what happens if a single supplier goes down?

Single-source raw materials are a documented supply risk, but the FDA's public Drug Shortage Database only tracks shortages at the finished drug product level, not the excipients or raw materials behind it. That gap is exactly why this question matters: it confirms whether a qualified backup supplier exists, since the database won't surface a single point of failure at the raw-material level.

About Regulatory and Quality Systems

What is your current framework for drug-device combination product compliance, and when was your last FDA inspection?

21 CFR Parts 210 and 211 govern drug products. 21 CFR 820 governs a drug-device combination. This question is designed to produce two specific, checkable facts: the exact regulation a partner operates under and a real inspection date, both of which can be verified independently against FDA's Inspection Classification Database and Warning Letter Database.

If our program involves a controlled substance, does your DEA registration cover that specific schedule?

DEA registration under 21 CFR Part 1301 is schedule-specific. Buprenorphine is Schedule III. Fentanyl is Schedule II. This question is designed to confirm that a partner's registration matches the actual compound in development, not just to confirm that DEA registration exists in general.

About Formulation Science and IP

Walk me through your feasibility screening process for a molecule like ours. What does in-silico modeling actually predict before anything reaches the bench?

This question is designed to find out whether feasibility screening is a described process with a real example behind it, solubility, permeability, and compatibility testing that caught a specific problem before it reached the bench, or a claim resting entirely on a single named platform.

How do you generate and interpret stability data for a new film or patch formulation?

ICH Q1A(R2) sets the storage conditions, testing intervals, and data package a formulation needs to support a shelf-life claim. This question is designed to find out whether a partner accounts for how moisture, temperature, and packaging behave differently in a film or patch than in a tablet, or defaults to a generic stability protocol built for oral solids.

Does your formulation work generate IP independent of our molecule's own patent position?

An enhancer combination, a film architecture, or a delivery mechanism built for a hard-to-formulate API can be patentable on its own. This question is designed to find out whether a partner's formulation work could support its own patent filing, which matters directly for a lifecycle-extension strategy: a 505(b)(2) filing built on genuinely new formulation science holds stronger, separate IP than one that only changes the delivery format.

About Real-World Performance

For OTF programs specifically, how do you validate taste-masking?

This question is designed to confirm whether patient acceptance was tested directly, against an actual patient panel measuring flavor and mouthfeel, or assumed from dissolution data that only measures how fast the film dissolves.

How does a film's measured residence time map to actual absorption data, or how does a patch's adhesion perform outside a lab, across a full wear cycle?

A film that dissolves on schedule in a controlled setting can behave differently in a patient who talks, drinks, or swallows during the dosing interval. A patch validated under stable lab conditions can lift at the edges after a full day of sweat and movement. This question is designed to find out whether a partner has tested for that specific gap between lab and real-world performance, not just reported the lab result.

About Program Continuity and Financial Stability

Has this company changed ownership, merged, or seen leadership turnover in the past two years? Does the same technical team stay on a program from formulation through commercial launch, or hand off to a new one?

This question is designed to find out who is actually accountable for a program today, and whether that accountability survives a leadership change or a handoff between teams.

Can you provide references from current or former clients running a comparable program, and what product liability insurance do you carry?

This question is designed to produce two verifiable facts: a client reference who can speak to comparable work and a specific insurance carrier and coverage level, neither of which a proposal is likely to volunteer unprompted.

For a growing pharma or biotech team carrying a promising compound, the answers to these questions point to one real distinction. Solving the delivery problem takes real formulation science: the physicochemical fit, the permeation enhancer testing, the in-silico modeling behind a working film or patch. Executing on that solution requires real manufacturing depth: purpose-built equipment, a verifiable compliance record, and a team that stays on the program from formulation through commercial scale.

Most organizations in this space are genuinely strong in one of those two areas. Fewer are strong in both at once.

That combination, real drug delivery science paired with real CDMO manufacturing depth, sitting inside a single organization, is the actual difference. Without it, a program is not signing one partner. It is managing two vendors itself, one for the formulation science and one for the manufacturing, and absorbing the coordination risk between them.

A DRUG DELIVERY PARTNER BUILT ON MORE THAN 60 YEARS OF POLYMER AND ADHESIVE SCIENCE

ARx pioneered oral thin film for systemic drug delivery, launching the first FDA-approved OTF product in 2005. Since then, ARx has supported multiple development and manufacturing programs across both OTF and transdermal formats, including work regulated under 505(b)(2) and ANDA pathways.

This track record depends on a real combination: formulation science paired with manufacturing depth, developed under one roof rather than assembled across separate vendors. ARx's MicroDEP platform, a micro-deposition technology built for APIs that need dosing below a standard film's limits, is patent-protected through 2039, an example of independent, patentable formulation IP rather than a name doing the work of a whole pitch.

The formulation depth sits on a longer foundation. ARx's parent company, Adhesives Research, has spent more than 60 years in polymer and pressure-sensitive adhesive science, dating back to its 1961 founding by the Huber family in York, Pennsylvania. That chemistry entered medical and pharmaceutical applications in 1974 and moved into transdermal delivery in the 1990s, the technical base on which ARx's own platform was eventually built.

Today, ARx is a fourth-generation, family-owned company operating an FDA- and DEA-registered manufacturing facility in Glen Rock, Pennsylvania.

HOW ARX VERIFIES FORMULATION FIT BEFORE MANUFACTURING

Feasibility Screening

Paper-based evaluation of API solubility, permeability, stability, and film-forming compatibility before any bench work begins.

In-Silico Modeling

Proprietary computational modeling predicts solubility, permeability, and delivery feasibility specific to a molecule's physicochemical profile.

Epi-Oral Tissue Models

Characterizes mucosal absorption for OTF and buccal formats under conditions that approximate real tissue behavior.

Franz Cell Diffusion

Measures transdermal flux directly, the same permeation data behind the molecular weight and logP thresholds a formulation scientist would apply.

Cadaver Skin Studies

Provides high-fidelity permeation data for transdermal formulations ahead of clinical testing.

20+ YRS
COMMERCIAL MANUFACTURING

100M+
UNITS PRODUCED ANNUALLY

FDA & DEA
REGISTERED FACILITY

A FEASIBILITY ASSESSMENT IS THE NEXT STEP

Whether a molecule is still being tested against physicochemical thresholds or a partner shortlist is already underway, ARx's formulation and program management teams can review a program's requirements directly.

A call will cover:

- The molecule's physicochemical profile and where it stands against OTF and transdermal thresholds.
- The current partner shortlist and any infrastructure, compliance, or continuity concerns.
- The regulatory pathway under consideration, including 505(b)(2) or ANDA strategy.
- Whether a feasibility assessment makes sense as the next step.

GET A FEASIBILITY ASSESSMENT

Talk to ARx's formulation team about a molecule's physicochemical profile, timeline, and delivery requirements.

GET IN TOUCH

TECHNICAL PUBLICATIONS

Review ARx's published data on OTF and transdermal formulation, permeation testing, and commercial manufacturing.

START HERE

DRUG DELIVERY CASE STUDIES

See how ARx has taken development programs, including a buccal film technology transfer, through to FDA approval.

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