FROM STRANDED PROGRAM TO FIRST-IN-CLASS APPROVAL

TECH TRANSFER

Buccal Film
Delivery Platform

Analgesic
API Class

NDA
Regulatory Pathway

7 Strengths
Formulations Developed

When a specialty pharma company's development partner began showing signs of financial distress mid-program, their API candidate had no clear path to clinical supply, let alone commercial scale.

ARx inherited a formulation with an unsolved suspension challenge, resolved it, and carried the program from rescue transfer to first-in-class FDA approval.

THE SITUATION

The client held proprietary IP around a buccal film delivery platform and a drug candidate targeting a specific unmet need in pain management: a rapidly absorbed opioid for patients with breakthrough and persistent cancer pain, with no adequate buccal alternative on the market.

What they lacked was a manufacturing partner capable of carrying that candidate from lab formulation to commercial scale. Their existing CRO was in financial distress and lacked commercial manufacturing capability, and the proposed product posed a formulation challenge that had not yet been resolved. API's partial water solubility, combined with the need for seven distinct product strengths, meant each blend required a different suspended drug ratio and continuous agitation throughout the entire coating process to maintain homogeneity.

Clinical milestones were fixed, and the program was already under pressure. ARx brought an established track record with this client. In a related backing film program, ARx had already demonstrated the ability to consolidate a two-step coating process into a single step, a result no competing CDMO had achieved.

That combination of demonstrated process capability and existing client relationship made ARx the clear choice for the transfer.

AT A GLANCE

Therapeutic Area
Oncology Supportive Care / Pain Management

API Challenge
Partial Water Solubility; Suspension Homogeneity Across 7 Strengths

Transfer Trigger
CRO Financial Distress; No Commercial Manufacturing Capability

Regulatory Filing
NDA, Efficacy Required; Phase 1/2/3 Clinical Supply Manufactured By ARx

First-In-Class
First FDA-Approved Buccal Film For This Indication

OPERATIONAL CHALLENGES & ARx SOLUTIONS

Three technical challenges defined this transfer, and each demanded something different from ARx that the prior CDMO couldn't deliver.

1

FORMULATION & SCALE-UP

Maintaining Suspension Homogeneity Across Seven Strength Variants

API's partial solubility in the aqueous blending solvent meant the required dosage range couldn't be achieved through surface area alone. Each of the seven strengths required a unique formulation with a varying ratio of dissolved to undissolved drug substance, and that suspended fraction had to remain uniform throughout the entire coating process. **ARx R&D developed individual order-of-addition protocols for each blend and engineered a continuous agitation system to maintain that homogeneity from start to finish.**

2

CLINICAL SUPPLY MANUFACTURING

Manufacturing Clinical Lots Under a Fixed Regulatory Clock

Clinical timelines don't flex for manufacturing delays. When particle counts from a converted cGMP space measured out of specification during Phase 1, **ARx moved its R&D scientists directly to the manufacturing floor, producing multiple clinical lots and keeping Phase 1, 2, and 3 supply on schedule for NDA submission.**

3

PROCESS INNOVATION

Outperforming the Original Manufacturer on a Commercially Active Process

The client's backing film was already in commercial production at a competing CDMO, manufactured through two separate coating and drying steps. **ARx consolidated the process into a single continuous-coating step, securing commercial manufacturing for this product and displacing the original manufacturer on process efficiency alone.**

From rescue transfer to commercial launch, ARx resolved every technical and operational obstacle standing between this program and approval.

FIRST-IN-CLASS

First FDA-approved API, opening a new delivery route for this population.

FULL NDA SUPPORT

ARx-manufactured clinical supply kept Phase 1, 2, and 3 on schedule and the regulatory timeline intact.

COMMERCIAL SCALE

ARx assumed full commercial manufacturing responsibility, validated and production-ready at scale.

ARx

FACING A COMPLEX TRANSFER OR A PROGRAM THAT NEEDS A NEW PATH FORWARD?

ARx has the formulation expertise, manufacturing flexibility, and regulatory experience to take on programs others can't.
Talk to our formulation specialists today. →