

DRUG DELIVERY *Executive*



PharmaForm[™] LLC
Excellence & Innovation in the Pharmaceutical Sciences

PHARMAFORM, LLC: DRUG DELIVERY & PRODUCT DEVELOPMENT EXPERTISE

PharmaForm, LLC is a pharmaceutical contract service organization with a national and international reputation for delivering novel and innovative solutions to challenging problems in pharmaceutical product development, manufacturing, and analytical services. In addition, the Austin, Texas-based company offers private-label and contract packaging, blending, and filling services. PharmaForm has worked with client groups varying from emerging virtual companies to the largest pharmaceutical companies in the world. Its products are made under the supervision of the highest quality systems in abidance with FDA regulations, taking great pride in its ability to provide exceptional service to each customer group by listening to and responding to the individualized needs of the client. Drug Delivery Technology recently interviewed Michael Crowley, PhD, Vice President, Business Development of PharmaForm, to learn more about his perspectives on providing services to the pharmaceutical and biotechnology industries.

Q: Can you provide a brief overview of PharmaForm's services and technologies for our readers?

A: As a pharmaceutical contract service provider, PharmaForm offers a wide range of formulation, product and process development, GMP manufacturing, analytical testing, and patent litigation support services. We have helped clients develop products meeting important clinical challenges using oral, nasal, pulmonary, dermal, mucosal, and vaginal delivery. Beyond formulation, we offer our clients GMP manufacturing and analytical services throughout the development process from the preclinical to commercial stages.

Many clients have come to us for patent litigation support. The services we provide in this area include case evaluation, analytical characterization, critical data review and

interpretation, as well as trial preparation. When it comes to trial support, we provide assistance through expert deposition and testimony. Our scientific team is recognized as drug delivery experts, and we have successfully assisted our clients in defending several pharmaceutical products.

Q: What are PharmaForm's core areas of expertise?

A: PharmaForm is renowned for its expertise in Hot-Melt Extrusion. Our scientists have published about 45 peer-reviewed publications on this topic and have developed significant intellectual property. We have R&D and GMP hot-melt extrusion equipment that supports product and process development as well as small commercial-scale manufacturing. We have expertise in developing low-dose, high-potency



**Michael Crowley,
PhD**
Vice President, Business
Development
PharmaForm

"We are finding more and more that client companies are looking for external resources to help them find a better solution, faster. It often isn't just a question of sourcing additional expertise, it is also a question of getting more hands to move the project to the next milestone more quickly."

DRUG DELIVERY *Executive*

oral dosage forms. PharmaForm has developed tablet formulations with doses ranging from 500 micrograms to as low as 50 nanograms that meet USP content uniformity requirements. Our facility and GMP suites were designed to work with potent and scheduled compounds, including many SafeBridge class III compounds. We are DEA registered and licensed, with the necessary infrastructure to support handling and inventorying of scheduled products.

In the area of formulation, our scientific team has core expertise and experience in improving the solubility of poorly soluble compounds. Our clients have been very pleased with formulation enhancements that have led to significant improvements in clinical bioavailability. We have considerable experience with bioadhesive systems and the targeting of drug delivery along the GI tract. One client recently received marketing approval for its drug product in a pulsatile-release system developed at PharmaForm.

In most of our client's formulation development projects, we have generated new intellectual property for them that provides additional layers of protection and exclusivity. Our team members have been invited to chair and speak at national and international conferences and symposia in the areas of formulation development and hot-melt extrusion. Many of our

clients come to us through word-of-mouth referrals, management personnel who have moved to another company, or companies directed to us by venture capital investors who saw what we were able to do for another of their portfolio companies.

Q: What is your unique approach to solving product development challenges?

A: Our approach to solving product development challenges is to begin with the basic research needed to understand the source of the challenge or problem, whether it be a solubility study, excipient compatibility study, or forced degradation studies. We integrate our drug delivery technology team with formulation development, analytical, materials, and manufacturing groups to communicate across the departments and work closely with our clients. Two, three, or more heads are always better than one.

We also assess the potential of novel delivery systems and evolving technologies to address client-specific needs. For example, we have developed pulsatile drug delivery systems, sustained-release liquid filled capsules, and products for delivery to the buccal mucosa and vaginal cavity in response to particular client needs. We are one

of the few service providers with expertise in both nasal and pulmonary delivery. Our team and facility can provide clinical supplies for prototyping and proof-of-principle trials through commercial scale.

Q: How do you maintain robust quality systems for your customers?

A: Our Quality Assurance team stays on top of all quality systems and is involved in all aspects of drug product development, analytical testing, clinical trial manufacturing, and commercial manufacturing. Our state-of-the-art facility is approximately 50,000 square feet and registered with the US FDA and DEA. The FDA inspection was part of a pre-approval inspection that was successfully concluded without a 483. We have had about 100 client and consultant quality audits. Because we are DEA registered and licensed, we are regularly audited by the DEA as well. All employees are trained for compliance with GMP.

The facility is temperature controlled and continuously monitored. Our manufacturing personnel are highly trained and operate in multipurpose suites designed to support preparation of pharmaceutical dosage forms for clinical and commercial products. The production areas are continuously blanketed with single

DRUG DELIVERY *Executive*

pass, HEPA-filtered air. The production area has been designed to facilitate the simultaneous execution of multiple operations to expedite the manufacturing processes.

Q: How do you manage projects with your clients?

A: All of our projects have an assigned lead project coordinator who schedules regular teleconferences and meetings throughout the project. PharmaForm maintains an open-phone-line-approach to project management. Clients may contact any PharmaForm team member at any time. We provide meeting minutes and update reports as needed throughout the program. Programs are also actively managed using Microsoft Project. Gantt charts are routinely updated and provided to the client during the project.

Q: What proprietary technologies does PharmaForm offer?

A: Through our parent company, Akela Pharma, we have access to drug delivery platforms for pulmonary administration, transmucosal delivery, and oral sustained release. We have a proprietary multi-dose dry-powder inhaler, named Taifun™. The device combines integrated and patented

deaggregation and humidity control systems that provide for highly efficient and reproducible powder flow. The patented LURUX® wet suspension technique ensures excellent powder homogeneity and dose-to-dose content uniformity. The mechanical robustness and flexibility of Taifun, its functional strength, and adaptability, coupled with a low manufacturing cost, position it as a very attractive dry powder inhalation platform. Salbutamol Taifun™, the first Taifun product, has been approved in 10 European countries.

Our oral sustained-release technology suite, PADT™, was developed to deter the abuse of scheduled products, including narcotics and stimulants, and prevent alcohol-induced dose dumping with any oral pharmaceutical product. Drug abusers typically prefer opioid and stimulant formulations that provide rapid absorption of the drug in order to obtain a desired euphoric effect. Abusers can bypass the sustained-release features of current products by crushing and mixing them with alcoholic drinks or by crushing and snorting or dissolving and injecting the drug. Our PADT systems provide a solution to this problem by virtue of a dosage form that is very difficult to crush or chew. Our PADT systems also prevent alcohol-induced dose dumping and alcohol extraction by maintaining sustained-release characteristics in 40% alcohol, comparable to the release in water or normal dissolution media, for more

than 3 hours.

PharmaFilm™, our transmucosal delivery system, is a patented, bioadhesive, thin film for delivery to the buccal mucosa and gingival, rectal, vaginal, and dermal surfaces. Current prototypes have demonstrated in vitro release times ranging from 5 minutes up to 24 hours and in vivo release times from 15 minutes to 20 hours, depending on the half-life of the active therapeutic agent. The film can be produced in single or multiple layers and is suitable for combination therapies.

Q: What are you seeing in terms of the use of outside resources?

A: We are finding more and more that client companies are looking for external resources to help them find a better solution, faster. It often isn't just a question of sourcing additional expertise, it is also a question of getting more hands to move the project to the next milestone more quickly. By providing our clients with proposals that outline the project costs and timelines, they are better able to budget their resources and manage internal expectations. We expect to see a continuing movement to outsourcing critical path activities to experienced companies like PharmaForm as well as technical challenges for which there are limited internal resources. ♦