

# Precision Particle Fabrication™

## Enabling precise control over particle structure

In pharma delivery, size matters. So, too, do the intricacies of dosage format, active ingredient compatibility, and effective delivery to patients—whatever their needs or preferences may be.

Yet standard dosage forms haven't always provided companies the options, flexibility, or performance to bring all those puzzle pieces together during therapeutic development.

So it's a relief to know that things are changing. Advances like Precision Particle Fabrication™ technology, for example, produce uniform microspheres and microcapsules with narrow size distribution and precise control over particle structure, making the platform versatile enough to accommodate a range of active ingredients and delivery formats.

We spoke with Nathan H. Dormer, PhD, Director of Drug Product Development at Adare Pharma Solutions, to learn how this new technology platform is expanding the frontiers of therapeutic delivery and improving patients' experience in the process.

**PHARMTECH:** Please tell us about Adare Pharma Solutions and your role in the organization.

**DORMER:** Adare Pharma Solutions is a contract development and manufacturing organization (CDMO) focused on providing specialized formulation solutions and manufacturing expertise to the pharmaceutical and OTC and animal health markets.

At Adare, I'm a Director of Drug Product Development, so I oversee non-GMP formulation development activities at our Kansas City location. The formulations we develop in Kansas City then go on to be tech transferred and scaled up at one of our other GMP sites, either in the United States or in Italy. Many great things are happening across all our locations, and Kansas City is where a lot of the R&D action has been taking place.

**PHARMTECH:** How does Adare solve formulation and manufacturing challenges that other CDMOs can't solve?

**DORMER:** What Adare is really proud of is our proprietary microencapsulation technologies, by which I mean that these aren't standard tableting or liquid technologies that are freely available. They're patented, and Adare retains the institutional knowledge and know-how for operating these technologies and formulating with them.



**Nathan H. Dormer, PhD**  
Director, Drug  
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For example, Adare has Microcaps<sup>®</sup>, which is a coacervation technology that can directly coat drug particles for taste masking or modified release. And the acquisition of Orbis added other proprietary technologies, like Optim<sup>®</sup> and Strat<sup>™</sup>, which are processes that create very uniform microparticulates that can be used in many different types of solid oral dosage forms.

**PHARMTECH: Could you describe Orbis's platform technologies and how those fit into Adare's portfolio?**

**DORMER:** Adare was traditionally one of the leading CDMOs in the microparticulate space, particularly in the solid oral space. The company has a handful of proprietary technologies that microencapsulate drugs and provide taste masking or modified release at a size that would be in the millimeter range down to fractions of a millimeter. When Adare acquired Orbis, what we were able to add is the ability to go even further down in particle size than before, and with greater uniformity, which translates into being able to include those particle sizes in different types of dosage forms.

For example, Orbis's technology Optim<sup>®</sup> is a melt-spray-congeal technology meant for solid oral-dosage forms that can create very uniform microspheres and microcapsules a quarter of a millimeter in size or even smaller in a single step—which was a range that no other technology could get to, and that's certainly a range that Adare is now excited to offer.

With the acquisition, Adare also added Orbis's Strat<sup>™</sup> platform, which is geared mainly toward long-lasting injectable microspheres. Prior to the acquisition, Adare wasn't active in the long-acting sterile-injectable space, but now they have that capability and the institutional knowledge behind it.

**PHARMTECH: Describe a specific case or application for each of Orbis's platform technologies.**

**DORMER:** For Optim, Orbis's solid oral platform, we've been able to do multiple applications, including taste masking, extended release, and delayed release. One of the best things that Optim can do is provide extended release in addition to taste masking.

If you look at the market, many of the extended-release pills that are available are 12-hour pills that last all day. And as an analog to that, you'd want to find dosage forms that are acceptable for little kids to take, or for people with swallowing difficulties. Traditionally, that's meant moving toward a liquid.

The problem is that long-lasting, 12-hour liquids just aren't freely available. It takes complex technology to make them, and the technologies that exist aren't able to serve every molecule.

So with the Optim platform, we've been able to take a 12-hour OTC pill and turn it into a 12-hour microparticulate suspension. That's one of the better things about Optim—it gives you that format flexibility while still maintaining performance.

For Strat, our injectable technology, one of the most impactful avenues we're exploring now has involved partnering with a women's health company to develop a long-acting contraceptive.

If you look at contraceptive options available for women today, you have the daily pill, then you have a three-month Depo-Provera injection, and then you have implants that start at three years and extend longer. There's really no option between three months and three years for patients.

So with Strat, we're working on developing a long-acting injectable contraceptive that can be used over six months or one year, which makes family planning a little bit easier for those who are looking for intermediate coverage in their contraception.

**PHARMTECH: What is your perspective on the market for drug delivery technologies and how is Adare suited to address them?**

**DORMER:** The trends we see in the industry include many pharma companies and therapeutics focused on chronic illnesses and diseases that affect a large number of patients, and then on diseases that affect a small number of patients, but in a very bad way.

What we have to remember is that when therapeutics are developed, companies focus on making sure that they have the safety and efficacy to address the problem so that patients can take them reliably while getting the outcomes they want. But sometimes a side effect of that is that these therapeutics may not taste very good or be very easy to administer, or that the regimens needed to administer the drug are less than optimal.

With Adare's proprietary technologies around taste masking and modified release, we are well positioned to address many of the solid oral-dosage form problems that are present in the industry today. With the addition of Strat, we'll now be able to provide a different play on long-acting injectables to help our pharmaceutical customers even more.