Scientifically Adept - Platform

Particle Sciences positions itself as a bioavailability tool for most drug forms

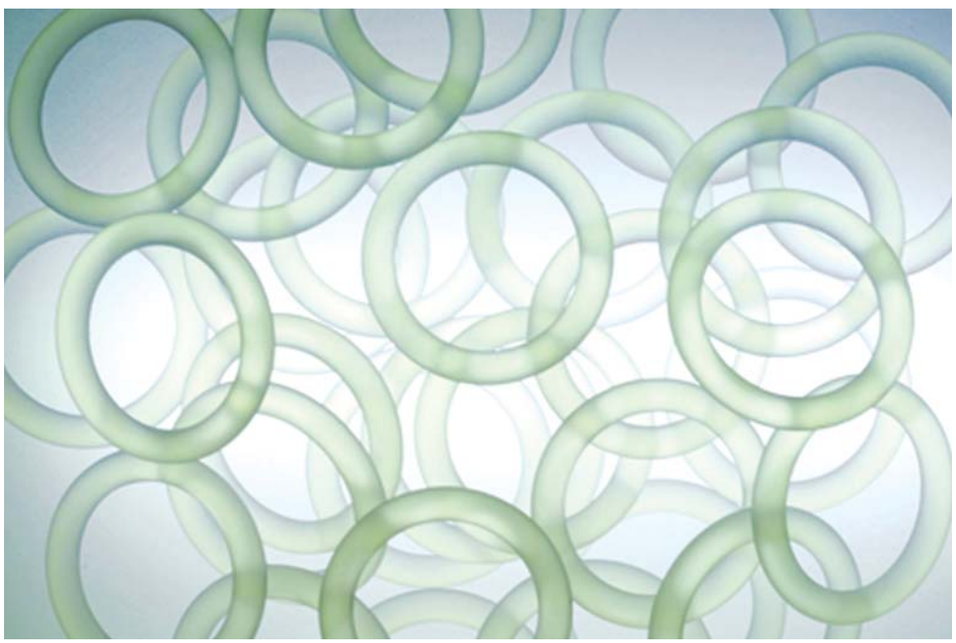
By Mike Auerbach, Editor-in-Chief

In 1966, American psychologist Abraham Maslow published his book *The Psychology of Science.* It is from this book that we learn about the phrase he coined, commonly referred to as Maslow's Hammer; "I suppose it is tempting, if the only tool you have is a hammer, to treat everything as if it were a nail." Over time, it has been paraphrased to: "if all you have is a hammer, everything looks like a nail" and has come to mean that if you are overly familiar with only one type of instrument or process, you tend to believe that is the answer to every problem.

In the business of pharmaceutical contract manufacturing and services, many companies approach every problem as a nail and endeavor to put their hammer to work; whether it's a certain well-defined skill set, a specific inventory of equipment or instruments, or a proprietary technology, they are going to bend your problem to fit their solution.

Particle Sciences, a drug development services company located in Bethlehem, Pennsylvania, has based its business model on being platform/technology agnostic. Bring them your drug development, formulation or dosage form problem and they will apply the right set of tools and technology to advance your project.

Particle Sciences is working to position itself as a leader in the CDMO formulation sector.



BACKGROUND

Particle Sciences traces its roots back to 1991 and a company call Sunsmart. Sunsmart was supplying zinc oxide to sun screen manufacturers as a nanoparticle.

According to Mark Mitchnick, M.D., the company's Chief Executive Officer, who has been with the company since the beginning, the company essentially started out a supplier of raw materials. The business grew and in 1999 the assets of that business were sold to BASF.

Mitchnick continues, "In 2004 we determined there was a need for a pharmaceutical CDMO that specializes in formulation. Formulation was a skill set we had acquired with the previous company and we still had the staff on hand."

In 2004 the company was renamed Particle Sciences and was refocused as a formulation-driven CDMO.

"At that time," says Mitchnick, "we had only four people, really just a nascent company. Fast-forward today and we have more than 60 people working in a 40,000-square-foot facility."

BIOAVAILABILITY SPECIALISTS

One of the most critical decisions a pharmaceutical company makes when developing a new product is the dosage form.

Mitchnick explains, "If you need to solubilize a drug you need to do it whether it's going to be a solid oral dosage product or if it's going to be administered IV. Historically however, formulation groups have defined themselves around specific dosage forms, but that's a kind of legacy distinction that makes no sense in today's day and age. We can do most dosage forms here – because what we really focus on is bioavailability enhancement, the underlying theme to all drug delivery. Whether it's solid dosage or parenteral.

"We have projects in here including topical creams, simple solid oral dosage, front of the eye, intra-thecal, back of the eye, subcutaneous implants, etc. – we are unique and part of a small club of companies that have these capabilities. Technologies employed in these drug products range from polymeric devices to nanoparticles. To further distinguish ourselves, we have made the investments needed to support highly potent compounds and aseptic production"

Particle Sciences is particularly adept at helping companies with New Chemical Entities (NCE) determine what dosage form makes the best sense for their particular product, and helping groups tackle complex 505(b)2's and ANDA's.

Mitchnick explains how the industry is changing in regard to dosage form. "What has happened over the last 5 to 10 years is that dosage form has become an early-stage consideration. It

Agnostic

used to be that a medicinal chemist would craft their molecule and they likely do a salt and/or polymorph screen to see what they could do to enhance the utility of that molecule. Now they know that dosage form can provide true performance differences and that, for instance, a nanoparticle or a solid dispersion has the same potential impact as a polymorph. The more clever companies are looking at dosage forms earlier and earlier to make sure their molecules make it out of pre-clinical. We have a whole set of NCEs in here."

Beyond the pre-clinical stage, Particle Sciences also helps a lot of companies in Phase I and Phase II trials that are running into CMC issues, as they need to look at a product reformulation to advance their drug.

Mitchnick also mentions another change that the industry in general, and Particle Sciences in particular, is seeing: the subject of 505(b)2's.

"We are doing a lot of work on 505(b)2's that are new formulations, but the toxicology risk is already largely taken out - so it's all about dosage form. Even though they are early stage programs they are in the clinic 6 – 12 months after they start."

Right now the company has the capability to manufacture Phase I and Phase II products for clinical trials, and they have already started the build-out for Phase III and commercial manufacturing.

"We have a lot of knowhow and technology here that is not available at other CDMOs," says Mitchnick. "So our clients have asked us to be their commercial manufacturer. As soon as they are approved, we will be ready for them."

For Phase I and Phase II products, Particle Sciences employs a flexible arrangement in their manufacturing suites. Of course once the product moves to Phase III and then commercial manufacturing, processes and equipment get "locked down" and are essentially inflexible.

CLIENT EXPECTATIONS

With the downsizing of the industry and the concurrent growth of pharmaceutical service suppliers, there has been a ramping up of expectations from companies looking to contract out some, or all, of their product development and manufacturing needs. Particle Sciences has seen a definite increase in the number of clients with year over year sales growing over 30 percent from 2013 to 2014. Further trend-confirming evidence is the increasing stream of client cGMP audits Particle Sciences is experiencing.

"How much of that is an industry trend or that we are just busy is impossible for me to say," says Mitchnick. "My sense is that clients audit more often, and it has to do with what they want from us. We are more than just a "set of hands' for the client. We are their development arm.

"They rely on us, not only to execute on their plan, but also to originate and actively participate. They want us to collaboratively address their problem, and to have a solution. We have, on average, more than one client audit per month and sometimes we will have up to four a month."

Offering multiple solution options has enabled Particle Sciences to set itself apart from other CDMOs.

A DIFFERENT APPROACH

Particle Sciences has become a successful drug development service provider by differentiating itself from other companies in both the technologies and approaches they use.

Mitchnick explains, "Our approach differs because we are not a platform company – we don't have a hammer and everything has to be a nail. We have very methodically assembled a team and an array of technology solutions to address recurring drug delivery problems. Our portfolio continues to grow through both in-house innovation and in-licensing."

Particle Sciences currently has four in-licensed technologies. "Everything we have in-house we do ourselves," he says. "We don't take in a project and then hire someone else to do it."

What sets Particle Sciences apart from other service providers is that when a client shows up with a problem, they don't have a predetermined solution.

"We listen to their problem. We listen to their goals," says Mitchnick. "We have a process. It pivots around an understanding of the client's goals, both technical and business, as the two are not really separable. We delve fairly deeply into what they need as far as IP. Sometimes this involves using their IP, ours or using public domain IP – it's a project by project decision."

He continues, "What also sets us apart is the expertise to have that discussion and the appropriate tool set – which we are pretty agnostic about. Our driver is to find the solution to the problem, not to use a particular tool that we already have. And that's unique – there are not that many CDMOs that can do that and no others with our particular mix."

Mitchnick explains that when Particle Sciences was formed they had a choice to focus on a single proprietary

technology and leverage that or come up with different business model, which is exactly what they chose to do.

"We don't want to be a specialty pharma company, not that that's not a highly profitable business, but it's not what we are built for," says Mitchnick. "Our strategy is to broaden our platforms and dive deeper as a solution focused CDMO - not a technology looking for an application. With this as our driver, we become a value-added partner to our pharma clients and a true resource. "

MAKING CLIENTS HAPPY

Particle Sciences' development staff are divided into a few divisions: Formulation, Analytic/Characterization, Quality, Production and Project Management. Most projects that come to Particle Sciences naturally originate in the formulation division, but benefit from the resources of all groups.

Mitchnick provides more details as to how client's needs are handled. "When a client shows up they are assigned a project manager. They are also assigned a formulation lead and an analytic lead. In most cases formulation drives the project. These three people stay with the project for its entire life. These project leads can call in additional resources as needed. We could have five analytic people working on a project – but are all working under that one analytical leader. And within our groups, the senior people are designated as project leads – the others will eventually also be able to be project leads."

A LOOK TOWARDS THE FUTURE

As mentioned, Particle Sciences is expanding their services to include Phase III and commercial manufacturing at their present location in Bethlehem, Pennsylvania. Mitchnick offers more details, "In terms of the business, we are going to dive deeper into what we do. This means becoming a Phase III and commercial producer of non-commodity products. We are going to do things around technologies for which there are not good CMOs out there yet. There is both good opportunities and significant competitive barriers."

He continues, "It's more about the interface of specific technologies and dosage forms for which there aren't good CMOs. We see opportunities in areas around complex formulations where there are, at most, only a handful of companies operating. These products could in fact be very large volume – though often they are not. We are not necessarily aiming for the largest market segment just, from our perspective, the most attractive." ■