

Analytical Expertise Q&A

Putting Ingredients to the Test: How DuPont Pharma Solutions Aids Customers in Complex Product Analyses

Barbara Serr, Senior Analytical Manager for DuPont Nutrition & Biosciences, is responsible for leading in-depth product analyses for excipient customers around the world. She and her team members possess extensive knowledge of excipient testing as well as a thorough understanding of regulatory requirements and regional nuances, bolstering DuPont's efforts to bring customers' products from the R&D phase into production efficiently and without incident. Leveraging their analytical expertise, Barbara and her team continually find ways to assist customers – from helping them run difficult analyses to conducting product impurity investigations or collaborating with them to develop new testing methods.

1. What is the primary motivation behind DuPont's product analysis efforts?

We want to be a trusted partner to our customers at every step in the manufacturing process, regardless of the resources they have at their disposal. While most formulators are set up to properly develop drugs with minimal assistance, many are appreciative of and receptive to our intimate knowledge of the ingredients, which can help them achieve their goals more efficiently -- especially when it comes to excipient testing.

2. How does DuPont assist customers through product analysis?

When we make our excipients, there are usually 10 to 15 tests necessary to complete the certificate of analysis for each one. Some tests are easier than others, from checking the pH, which is a fairly simple process, to doing an assay, which can be quite complicated without assistance. When our customers buy our products, they are required to conduct their own testing due to pharmaceutical regulations. They have to do positive identification and other testing before they can incorporate

them into pharmaceutical products just to make sure no mishaps have occurred during shipping or manufacturing—it's a far more stringent process than any other chemical-related industry.

These processes are easy for DuPont since we make these products every day. But certain customers may lack the knowledge, expertise or technical infrastructure to reproduce our methods to ensure accurate identification, especially if that customer only runs two or three batches in a year. At any time, customers can call our service line and be connected with our team to get the help they need.

3. As an analytical group, what general capabilities do you offer to DuPont's customers?

We have a number of advanced analytical capabilities at our disposal to measure rheology, surface area, viscosity, analysis of texture and thermal properties, and much more. These tools enable us to assist with measurement and identification of impurities, identify degradation in products, study active pharmaceutical ingredient (API) interactions and validate

existing customer methods and applications. Since each customer has their own analytical needs, it's essential that we collaborate openly with each of them to understand how we can best assist them.

4. What does open collaboration with DuPont's customers look like?

For some customers, it means helping them develop new methods and applications from scratch. For example, if a customer mixes one of our excipients with an API and notices unknown, growing peaks during testing, we can help them develop a method to set new specifications based on small impurities.

Since many customers use our ingredients to make tablets, capsules, and coatings, they often need our help with dissolution testing. We can help perfect formulations to determine which formulations or coatings give the optimal dissolution profile for a given drug product.

And, in some cases, customers need investigations when an ingredient doesn't perform as expected. Let's say a product emits an unpleasant odor and we receive a complaint—we can investigate to detect problems with manufacturing or sample retention. Occasionally impurities can arise due to conditions during shipping, which we can troubleshoot and enforce shipping guidelines.

5. Why does DuPont invest so much time and effort into product analysis?

It may seem extreme to an outsider, but the investment we've made in our testing infrastructure gives DuPont a unique ability to solve customer issues faster than almost anyone in the industry. We've learned over the years that if you want to improve analyses and remove variability, you must account for and minimize the variability of human error.

6. Can you share an example of how your team continues to improve analyses and remove variability?

Sure, let's consider one of our most frequent troubleshooting issues. We often help customers with the assay of ETHOCEL™, our proprietary ethylcellulose resins, which are water-insoluble; and METHOCEL™, our line of water-soluble cellulose ethers that encompasses methylcellulose and hypromellose. These are two of our oldest product lines—75 and 60 years old, respectively—and both are difficult analyses to run, which is why we've spent years perfecting the process.

We built robotics systems to run these analyses for us to take out much of the variability and to ensure that each step in the process is completed each time. That's a massive benefit for our customers, who are very unlikely to have similar systems in place. We can therefore provide customers with detailed answers and recommendations about how to fix issues with either of these excipients in a short amount of time.

7. Are there other analytical resources available that customers can access right now?

Yes. While we do numerous conference calls and onsite visits with customers, there are a number of ready-made resources that customers can access. We encourage manufacturers to reach out to us with any product question or regulatory challenge at any time, and we'll provide the specific resource needed to answer their issue.

From published case studies that delve into preparation and verification of our products, instructions for proper dissolution of POLYOX™ water-soluble resins, or verification that our internal testing methods line up with USP methodology for a given product, our customers can benefit from years of documented expertise when implementing our ingredients.



Nutrition & Biosciences

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