DEVICETALKS TUESDAYS

No Sugar-Coating: How to Optimize and Scale Your Coating Solution

WHITE PAPER

APTYX™ Making it happen

Overview

Over the past 20 years, coatings for medical devices and drug products have evolved from a value-added option to a must-have feature. With the bar for device performance continually rising and material requirements frequently changing, coatings that respond to and evolve with these requirements can provide many benefits, including increased wear, reduced surface friction, improved barrier to moisture, or a novel method of drug delivery.

To make the most of those opportunities, medical device and pharmaceutical companies need to familiarize themselves with the key considerations, challenges, and use cases for selecting and implementing coating solutions.

Aptyx's 20 years of experience and expertise in a range of coating types and applications, as demonstrated by its more than 500 completed projects involving coating and automation solutions, enable Aptyx to provide unique insights that foster such learning.

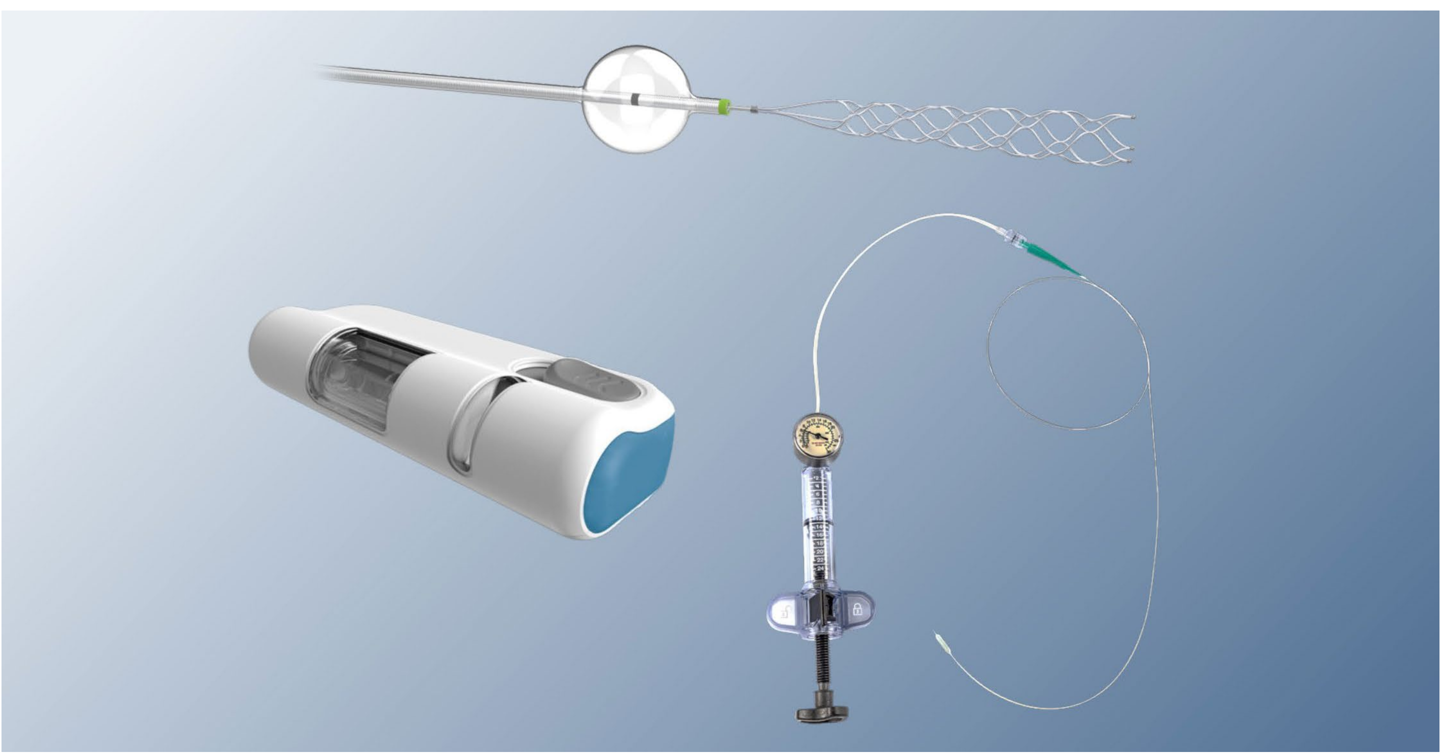
Key Takeaways

Selecting the right coating material is key for enhancing a product's surface and performance characteristics.

Common coating types in the med tech and pharma industries include lubricious/hydrophilic, silicone, wear-resistant/extended use, antimicrobial, drug-eluting, anticoagulant, and UV inhibitor materials.

Typical use cases for each of these coating types and materials are:

- **Lubricious/hydrophilic:** catheters, cannulas, guidewires, needles
- **Silicone:** injection-molded products, instruments, components such as syringe or infusion pump needles
- **Wear-resistant/extended use:** surgical and exam gloves, scopes, sheath covers, ingestible balloons
- **Antimicrobial:** catheters, sutures, gloves
- **Drug-eluting:** stents, sutures, intrauterine devices
- **Anticoagulant:** heart assist devices
- **UV inhibitor:** glass and molded polymers subject to UV radiation such as glass vaccine vials



While not a coating supplier itself, Aptyx collaborates with companies that often seek its expertise once they have chosen an off-the-shelf coating type or have developed a custom coating. In some cases, further customization may be required or an alternative coating, and the team's experience with an extensive range of both custom and commercially available coatings enables guidance in meeting the desired performance requirements. Similarly, companies may first try a material with additives to achieve their objectives, but ultimately find that they need a coating to meet the desired performance requirements.

"When an application is brought to us and the customer does not have a specific coating defined, we look at the attributes they're looking to achieve and suggest a coating that might be suitable for reaching those goals. Then we offer to apply that coating [in a test environment] and evaluate its pros and cons, based on the process, cost, and product features the company is looking to achieve."

—Jeff Charlton, Aptyx

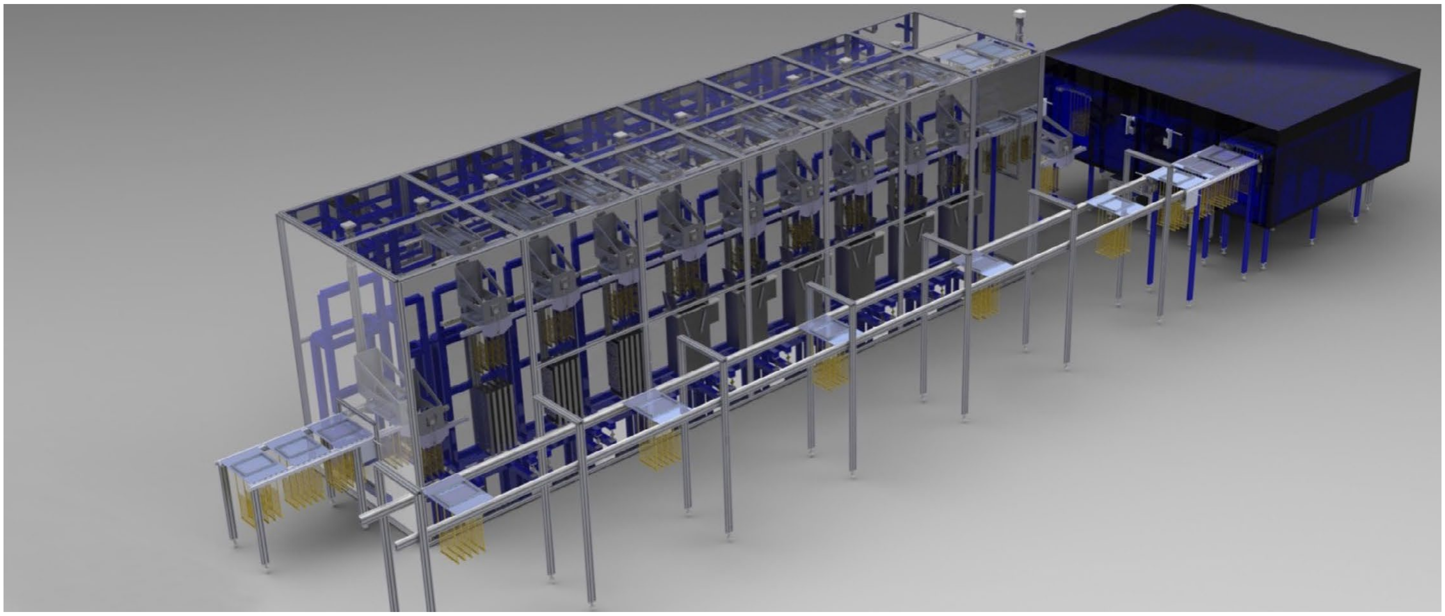
"You can't always depend on a pre-compounded plastic or rubber material, as they typically require actuation, allowing the lubrication to bloom to the surface. For this reason, we may use topical silicone coatings for projects such as a prefilled syringe, an auto injector, or an infusion needle," Mr. Allenbrand said.

In addition to customization, companies come to Aptyx for help with choosing a coating type when they do not have a specific coating in mind.

Selecting the right coating application method and equipment type are critical for optimizing product performance.

Coating solutions can be applied via two main methods, dipping or spraying, with the dipping method being more complex and thus the focus of Aptyx's expertise.

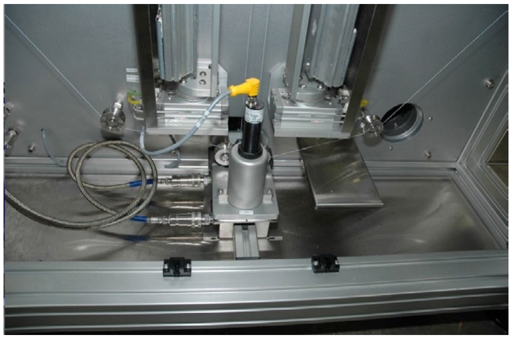
Applying dip coating requires the use of one of two specific equipment types: continuous motion systems or robotic batch systems.



Continuous motion

Continuous motion equipment applies coating by drawing the product through stations at continuous speed, with no pauses in between. It is suitable for process parameters that are well-defined, such as the precise timing for each step being performed; therefore, it lends itself to a mature process.

This equipment type is ideal for delivering coating to a single product type made of woven materials, such as sutures, that can be presented in a reel and introduced into the machine in a continuous manner and at continuous velocity.

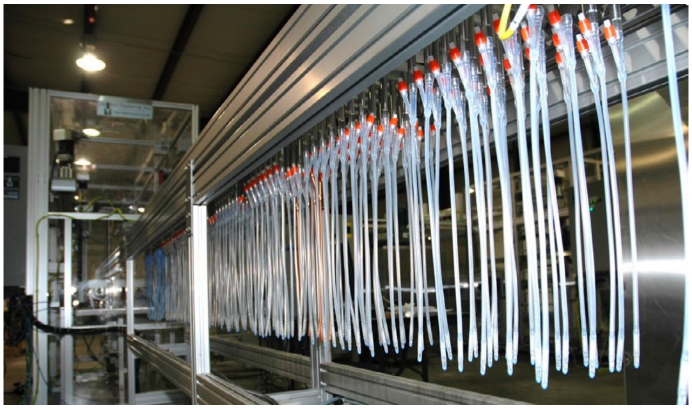


Robotic batch

Robotic batch equipment applies coating to products or components that require one or more layers of coating and adjacent processes (e.g., cleaning cycle, base coat, top coat, UV or thermal drying), performed at different stations. Most process steps are automated, except for the loading and unloading of the stations, which are done separately by a robot or manually.

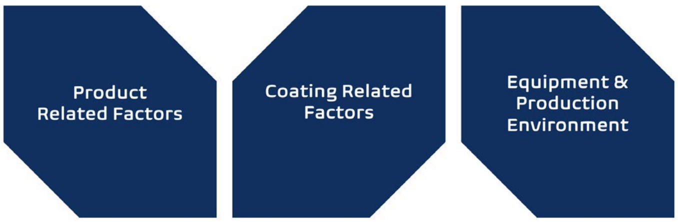
“The batch method allows the product to walk through the various stations until it is completed and exits to the unload queue or until an operator or some type of automation takes it onto the next step within the process, or to packaging, or to transfer to the final facility,” Mr. Charlton explained.

Products that are typically coated using robotic batch equipment include products such as catheters, guidewires, balloons, needles, tubing, and drug delivery components.



Evaluating process requirements upfront is key to success for scalability.

When seeking a coating solution for their product, in addition to selecting an optimal coating and equipment type, companies must also consider factors that are critical for achieving scalability. For that, they need to evaluate process requirements upfront, with an emphasis on three key factors:



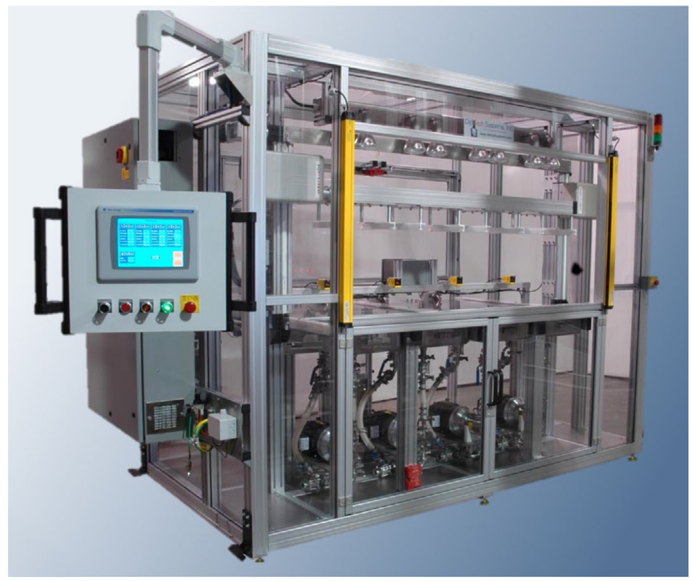
- **Product-related factors:** Considerations include product rigidity (which influences the choice of coating equipment) and product geometry/areas to be coated (which influences the level of control or finesse required during the coating process).

  "The area to be coated is important from the standpoint of minimizing the volume of the coating solution, which is often key to success of the project because in some cases the coatings are very expensive or have a short shelf life," Mr. Charlton explained.

- **Coating-related factors:** Considerations include the solvent used and how it binds to substrate, the shelf life of the coating solution, process monitoring controls (e.g., mixing, temperature, humidity), level control, drying process (UV or thermal), and scalability (performance in large-scale production vs lab or small-batch environment).

  "We're looking at the properties of the coating material dynamically as well with regards to production. Many coatings require monitoring and adjustment, and integrating this ability into the coating automation is often the key to success.," Mr. Charlton said, explaining how Aptyx supports clients at this stage of their search for an optimal coating solution.

- **Equipment**- and production environment-related factors: Considerations include equipment and process controls (e.g., equipment process timing—entry and exit speeds, controls of process chemistry, process monitoring for historical trending and data collection) and production factors (e.g., internal vs outsourced production, alignment with other processes).



Referring to these process factors and considerations, Mr. Charlton said, "That's the level of detail we look into with customers in order to adjust their expectations about what's realistic from a production viewpoint. Giving them that information allows them to understand what's the true cost of applying a particular coating to their component and the feasibility of moving forward and maybe automating the process at a future point."

> "Early conversation sometimes can be a litmus test for whether or not a project is viable based on client expectations."
>
> —Jeff Charlton, Aptyx

Conclusion

When med tech and pharma companies arrive at the decision point of selecting a coating solution for their product, choosing the right coating is only the first step in a complex process. To successfully implement the chosen coating on time, on budget, and within the capacity of their production facilities, they can benefit from collaborating with an external partner such as Aptyx. Doing so can help define with expert precision the best coating option for their product and their broader objectives early in the process, match that process with desired automation and scalability, and build a solid business case.

White Paper Contributors

Jeff Charlton

General Manager, Coating and Automation Solutions, Aptyx

Jeff has more than 35 years of experience with custom automated equipment for the medical device and pharmaceutical industries and has designed automation methods for applying a wide range of coatings. In 2004, he founded DipTech Systems, which specializes in polymer dip molding and dip coatings. DipTech was acquired by Molded Devices Inc. in 2018 and recently became Aptyx. The group has completed more than 500 projects in 20 years, including more than 40 major automation projects with high-volume production systems. He has a bachelor's degree in mechanical engineering from the University of Akron.

Beth Harrison Meyer

Global VP of Marketing, Aptyx

Beth brings more than 25 years of strategic marketing leadership in diverse environments ranging from the Fortune 50 to startups. She is known for building brands and launching disruptive products and programs. Before joining Aptyx earlier this year, she led marketing at Viant. She has also held marketing positions at Integer; Duracell Powermat; HoMedics; Anchor Hocking, a Newell-Rubbermaid company; and Bacardi. Beth has a bachelor's degree in Spanish from Tulane University and an MBA from the University of California, Berkeley.

Tobe Allenbrand

Global VP of Operations, Aptyx

Tobe has 30 years of experience in manufacturing sales and operations, with 15 years specializing in medical device contract manufacturing including tool building, packaging, automation, part decoration, and assembly. He joined Molded Devices Inc. (now Aptyx) in 2014 as Director of Business Development and has also served as Vice President of Sales and Marketing. Prior to that, he was West Coast Sales Manager at Flambeau Inc., specializing in injection molding and blow molding of thermoplastics.