Oral Dosage Forms and Tailoring Products to the Consumer

PMPS **sat down with Doug Hovey at SPI Pharma to discuss the difficulty in producing products for patients, and take a look towards the future of new drug formulation**

PMPS: **Patients with difficulty swallowing are an important area of your work. What things must be considered to ensure that oral disintegrating tablets (ODTs) can work without compromising on effectiveness?**

Doug Hovey: Patient-centric, or patient-friendly dosage forms like ODTs, are very effective products to administer to patients who may have difficulty swallowing. These types of products actually provide more dose accuracy assurance than other dosage forms, such as oral solutions and suspensions, which can also be administered to patients with swallowability challenges. The FDA released a guidance recently questioning the effectiveness, stability, and safety of oral suspensions and solutions, stating dose accuracy as one of the issues with these dosage forms. Orally dispersible dosage forms like ODTs and chewable tablets mitigate dose accuracy issues and can provide a safe and efficacious dosage form for patients who have difficulty swallowing.

What are the top three things that require innovation in the industry to accelerate its development?

As a global leader in providing products and solutions for patient-centric dosage forms, manufacturers need only to add their active pharmaceutical ingredient (API), and any ancillary ingredients if needed (i.e., flavours, sweeteners, lubricant) to these drug delivery technologies to create their final dosage form. Requirements for new innovations should be beneficial for both the manufacturers and the patients. For the manufacturer, this would include products that can help accelerate their development, as well as help with challenging formulations and active ingredients. For the patients, ease of use and consistent performance will continue to be important, but more innovation is needed to create products and technologies designed to help improve bioavailability, lessen side effects, and provide a faster onset of action.

How do you go about solving a challenging drug formulation issue?

Depending on the challenge and the critical quality attributes of the drug product, there could be several ways

to successfully develop a robust and effective product. This may include evaluating new and innovative products and solutions. Unfortunately, formulators can be hesitant to evaluate a product that is new and does not have precedence of use. As such, I would recommend evaluating a preformulated drug delivery system or enhanced excipients that consist of compendial ingredient(s). These products are designed to help with challenging formulations and have acceptability from a regulatory perspective. An example that can help resolve a formulation challenge would be enhanced mannitol grades. XL mannitol grades are engineered to produce a multifunctional, compendial mannitol with superior binding properties and rapid disintegration. The improved performance associated with XL mannitol has been successful in resolving formulation challenges as well as simplifying formulations resulting in smaller tablets or tablets containing a higher concentration of active ingredients.

Taste-masked oral dosage forms are important for drugs with APIs. What are the key considerations when developing taste-masked drugs for patients?

The patient's experience can directly affect the patient's outcome, so inhibiting the bitter taste of APIs can be critical to patient adherence. When considering the appropriate taste masking approach, the bitterness of the API and technologies available from a processing and formulation perspective are evaluated. If the API's bitterness is minor, formulating with flavours and sweeteners may be enough to provide acceptable taste masking. However, in many cases a physical barrier between the API and the patient's mouth is needed. This would require utilising an additional processing step to coat the active ingredient or the final dosage form. The coating technology utilised is often dependent on the capabilities and equipment available to a customer.

What is the importance of good organoleptics in these oral dosage forms?

Good organoleptics is a critical attribute to help ensure patient compliance. If the oral dosage form has poor mouthfeel and/or tastes bad the patient is more likely to skip a dose, or worse, stop taking the medication all together.

What difference does tailor drug delivery make to patient adherence?

In many cases, patient-centric drug products are tailored for a particular patient population to help ensure patient compliance. Specifically, paediatric dosage forms are typically formulated to be easy to administer and provide a pleasant taste and mouthfeel to the child. This may require taste masking of the API utilising a physical barrier, in addition to sweeteners and flavours. As such, a unique way to create and deliver the drug product may need to be implemented to ensure the patient is compliant.

Patient-friendly dosage forms are constantly changing and evolving, in what direction do you see the development of oral dosage forms going in the next five years?

In the next five years, I predict there will be more focus on developing patient-friendly products and technologies to provide faster disintegration and enhanced efficacy. This would include developing products to support administering drugs sublingually. Due to the abundant blood flow and high permeability in this region, drugs absorbed in this area have the potential to be more efficacious. Additionally, drugs delivered sublingually may have a rapid onset of action and avoid first-pass metabolism.

What are the growing trends you are noticing with clients approaching you for their drug delivery?

In a society that is typically 'on the go', consumers and patients are looking for products that are easy to transport and administer. As such, our clients are asking for our support in providing products and solutions to help the development of stable, robust, patient-friendly dosage forms across the pharma, over the counter, and nutritional markets. Companies are also inquiring about new and innovative taste-masking technologies.

What is next on the horizon for 2021 in pharma and what challenges do you expect to encounter?

New technologies could be used for a wide range of applications including sublingual dosage forms, a replacement for lyophilised or syrup and suspension products, or to create a novel paediatric ODT. Hopefully new platform technologies and innovative drug products in the industry will help to alleviate the technical and corporate challenges customers have, allowing them to get to market faster.

Doug Hovey is currently the Technical Development Manager in North America for **SPI Pharma**. He has been in the pharmaceutical industry for nearly 25 years with a proven track record highlighted by his direct involvement in six approved drug products. He has a diverse background with a strong knowledge in pharmaceutical sciences and understanding of the requirements needed for a successful regulatory filing and efficient manufacturing process. Doug has a broad base of experience in the areas of formulation development and technical service. He worked as a product development scientist for over 15 years before moving into a technical service and business development role within the pharmaceutical excipient industry.