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STRATEGY
There are some very innovative, cutting-edge ideas that Indian pharma leaders are adopting

INTERVIEW
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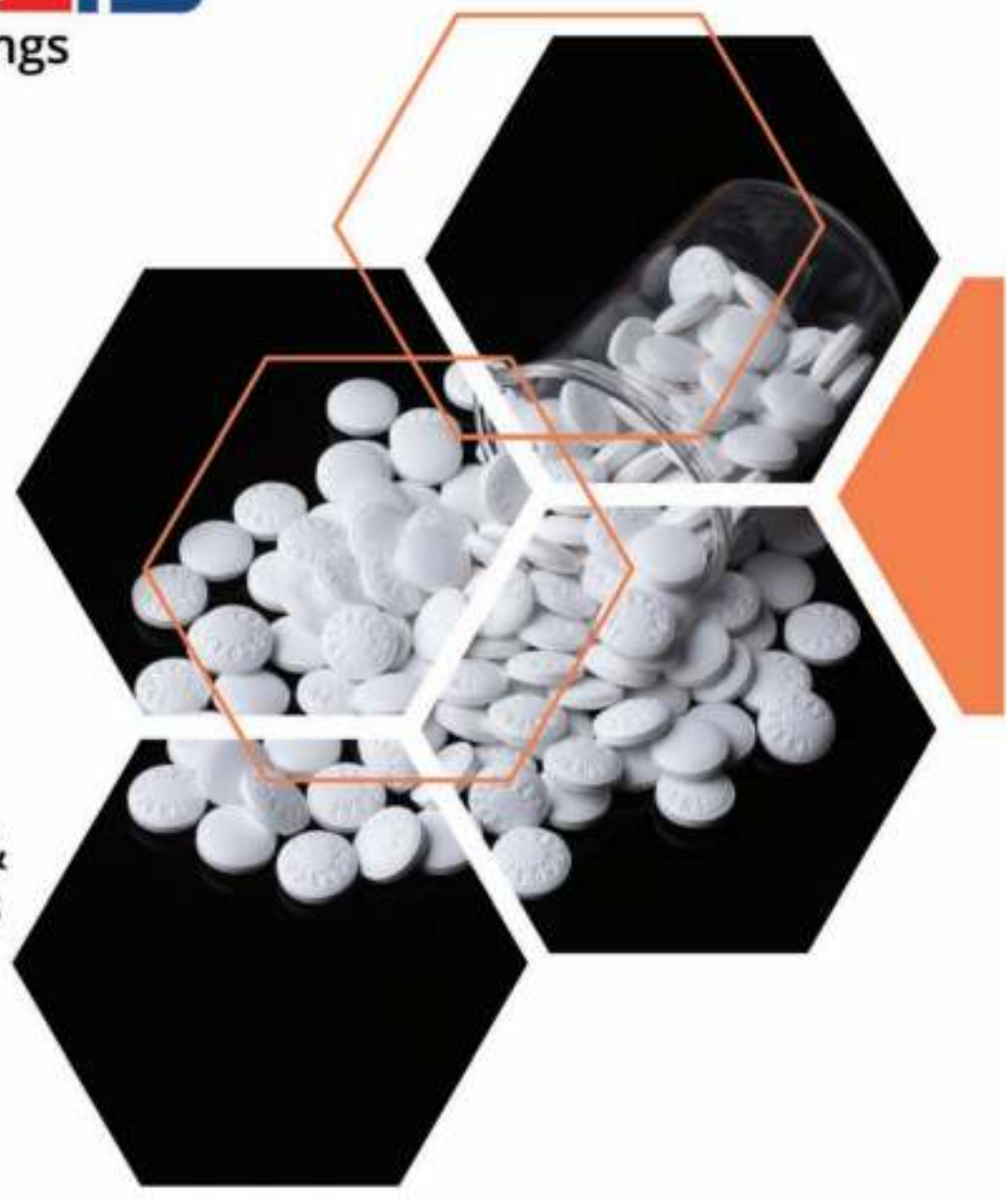

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"PERFECTing" the package selection process

Gabrielle Gehron, Scientific Support Manager, Datwyler, explains how one can successfully analyse packaging needs and navigate through the packaging selection process

With reverberations from the recent pandemic still in play, drug manufacturers continue to search for high-quality packaging products for their pharmaceuticals. Additionally, regulations are becoming increasingly strict in the name of patient safety. It is of the utmost concern to mitigate risks associated with those components which protect and package sensitive drug formulations. This collection of challenges is driving drug makers to search for ways to find the highest-quality, most compatible components as quickly as possible. Fortunately, companies can implement a simple checklist to successfully analyse their packaging needs and navigate through the packaging selection process.

"PERFECT" packaging systems

To "perfect" or more accurately speaking, improve a packaging system, it is critical to keep in mind the most important aspects of component selection:

◆ **Particles:** *The presence of foreign matter, such as fibers, on or in a component set to be used with a drug product:* Particles can include any foreign substances, such as fiber or dirt, that could enter the product by way of the packaging component. By washing and sterilising all parenteral drug components, companies can greatly reduce the possibility of particulate entering the drug. Companies such as Datwyler specialise in washing and sterilising rubber components that are then sold to companies ready for use, which decreases their customers' Total Cost of Ownership (TCO) and time spent on preparing components for filling.

Drug manufacturers will want to assess their own needs and capabilities and select compatible products. For example, a manufacturer with sterilisation capabilities may be able to purchase RfS (Ready for Sterilisation – washed, but not sterilised) products, while as a company without these capabilities may prefer RTU (Ready to Use – washed and sterilised) products.

◆ **Extractables and leachables:** *The migration of substances from a packaging component into a drug product:* These are chemicals within a packaging component that could be pulled out by the contained drug product. They also include chemicals that may be formed via reactions between the packaging and drug product. Suppliers ought to provide to their customers lists of substances that could potentially be extracted from a given product. Customers may then be able to evaluate which leachables could be problematic based on what drug is being packaged. Drug manufacturers benefit from having potential extractables information up front so they can make an informed decision on components that may react poorly with their drug product.

◆ **Regulations:** *Consideration of the regulatory environment in which a drug product will be marketed:* As different regions have different regulations, being aware of and complying with regional regulatory bodies is a prerequisite for marketing drug products. Regulations must be monitored to ensure that products align with patient safety standards. However, this must be done with respect to the region in which a drug will be marketed. For example, in China, pharma companies are still adjusting to matters concerning the Bundling Review implemented in 2016 by the China Food and Drug Administration (CFDA) (comparable to the Food and Drug Administration (FDA) system in the US). Prior to this, there was a less-strict licensing system for packaging materials in this region.

In addition to parenteral drug manufacturers maintaining alignment with regulations, suppliers must also comply with these regulations, and they can support their customers by providing parts that will be compatible with those regulations. By choosing a supplier who aligns with and prioritises core regulations, drug manufacturers can be assured their products will follow the highest standards required.

◆ **Functionality:** *Different for every type of product:* Functionality may include qualities such as break-loose and glide forces, stopper pop-up, ability to perform in certain storage conditions and more. Typically, functionality assesses a complete system of products. It refers to how a drug manufacturer's components interact with other pieces of their system. When purchasing a component for the first time, drug manufacturers must take time to test all components simultaneously to ensure a fully functioning system. Some functionality requirements for elastomer products may include:

Vial Stoppers

- Stopper twinning (preventing)
- Stopper pop-up (preventing)
- Coring and fragmentation
- Multipuncturability
- Performance at low (cryo) temperatures
- Compatibility with sterilisation processes, including, but not limited to steam sterilisation and/or gamma sterilisation

Syringe and cartridge plungers

- Break-loose forces
- Glide forces
- Orientability
- Movement during transportation
- Performance at low (cryo) temperatures
- Compatibility with sterilisation processes, including, but not limited to steam sterilisation, gamma sterilisation, and/or ethylene oxide sterilisation

◆ **Engineering capabilities:** *Similar to machinability:* This criteria analyses the compatibility between a companies' fill-finish lines and the component in question. "Engineering capabilities" (similar to manufacturability) refers to how components move on a fill/finish line. For example, a component that is under-lubricated may stick to machining lines, resulting in a cessation of fill/finish until operators can resolve the issue. However, over-lubrication can result in excess residue on lines and in the end-product, creating unnecessary particulate.

To ensure components will run successfully at a drug manufacturer's plant, newly-purchased components must go through Factory Acceptance Testing (FAT) and Site Acceptance Testing (SAT.) While FAT requires the supplier to run a product through testing at the site where a filling machine is made, SAT requires testing at the drug manufacturer's final filling site. Both tests aim to mitigate problems on the final fill line at a drug manufacturer's site and address potential issues well before that stage. Companies

who have established fill/finish lines may prefer to use components that will require only minor adjustments to their lines, when possible, across all of their projects.

◆ **Container closure integrity:** *The prevention of migration of product into or out of a system through ensuring dimensional compatibility of the components within that system:* Container Closure Integrity (CCI) is the ability for all components to fit together properly and seal fully, preventing the transfer of any substances into or out of the system. CCI can be evaluated theoretically prior to committing to a product; this is done by calculating the interference between the rubber component and its (typically glass or plastic) container, and (for vial systems) by calculating the theoretical overhang length of a seal used to cap a vial and stopper. Experimentally, many forms of testing exist to evaluate the CCI of a system, including Helium Leak and Dye Ingress. If CCI is not verified, drug products could become contaminated, adversely effecting patient outcomes and risking consumer confidence.

◆ **Total quality:** *An analysis of the quality needs of a given project, and the capabilities achieved by a given product or process:* This can encompass wash processes, sterilisation, defect limits, particulate levels, compliance testing, vision inspection systems, and more. Quality is a critical aspect of ensuring that a product meets the standards required by both regulatory bodies and internal business guidelines. Many companies have entire departments dedicated to setting and maintaining quality standards, and to ensuring that their suppliers do the same.

Potential areas to prioritise may include:

- wash process requirements
- sterilisation process requirements
- defect limits
- particulate limits
- per-batch particulate levels
- per-batch compliance testing
- per-batch dimensional testing
- vision inspection systems
- equivalency documentation

In an environment awash with complications from the COVID-19 pandemic, increasing regulations and higher-quality standards, the pharma industry must continue to serve patients and caregivers. When drug manufacturers are better able to understand and evaluate their packaging components, they gain agency and confidence in their decisions. "PERFECTing" the packaging selection process can be made easier by beginning with a dedicated checklist and partnering with reputable suppliers. By implementing these measures, pharma companies can achieve increased success and overcome whatever challenges still lie ahead.

About Datwyler

Datwyler is focusing on high-quality, system-critical elastomer components and has leading positions in attractive global markets such as healthcare, mobility, general industry and food & beverage. With its recognized core competencies and technological leadership, the company delivers added value to customers in the markets served. With more than 20 operating companies, sales in over 100 countries and more than 7,000 employees Datwyler generates annual sales of more than $1,000 million. Within the healthcare solutions business area, Datwyler develops, designs, and manufactures solutions for injectable packaging and drug delivery systems to facilitate customers to create a safer medical environment of tomorrow. Looking back onto more than 100 years of history, Datwyler is a reliable partner, now and in the future! The company has been listed on the SIX Swiss Exchange since 1986 (se-

Understanding Medium Chain Triglycerides (MCTs)

Nafeez Zaiforllah, Marketing Executive, IOI Esterchem (M) Sdn Bhd, Penang, Malaysia, explains the advantages of using Medium Chain Triglycerides (MCTs)

In the pandemic-ravaged era where every industry strives to maintain its position in the market, pharma wins at sustaining its credibility and significance. The emergence of myriad of supplements and medical remedies in all forms is deemed to be the major factor in contributing to the surge of its demands. New ingredients are introduced to aid the formulation of pharma products with enhanced and better properties. One of those is Medium Chain Triglycerides 60/40 (MCT 60/40) which IOI ECM, Malaysia, is proud having produced.

This versatile liquid comes from esterification of glycerin and mixtures of caprylic (C:8) and capric (C:10) fatty acids. Its versatility covers the applications in injection, ingestion and topical usage. One key feature of MCT making it favourable to be used is its excellent solvent characteristics. It is able to solubilise most of the oil-soluble active drug ingredients for optimum product functions. It also promotes good blending capacity where active ingredients will be evenly dispersed and distributed throughout product without disrupting the texture and sensorial properties -- being neutral, inert and stable in physical composition making it advantageous as well where MCT would not interfere products' final appearance, be it colour and odour. In the case of medical cream used for topical applications, many formulations would incorporate MCT as a carrier as it does not only solubilise, but promotes hydration and moisturisation on the skin for optimum ingredients' penetration into the skin. This is attributed by MCT's emollience property that promotes and enhances skin's natural moisture barrier. Besides that, MCT is commonly used as injection excipient to carry active ingredients via parenteral administration. It has also been used for oral ingestion where it was incorporated into popular-soft gel capsules.

One thing that is interesting about MCT is it does not only provide aid and assistance in carrying active ingredients, but also possesses health benefit that our body can reap off. It is proven through medical research that MCT has significant nutritional and functional properties that would attribute to overall body's well-being. Rapid absorption for energy usage is one of the amazing wonders purported by MCT which is endearing to athletes who are always in need for high energy for rigorous activities. Infants with malabsorption defaults would be benefitted with MCT, as well as it provides instant and substantial energy and nutrients for further growth.

MCT continues to unravel breakthrough in pharma industry as it does not only fix to a specific formulation, but it can be manipulated into many sorts of application. This level of versatility makes MCT one of the most sought-after raw material, especially in creating up-to-date formulation to satisfy the needs of consumers.