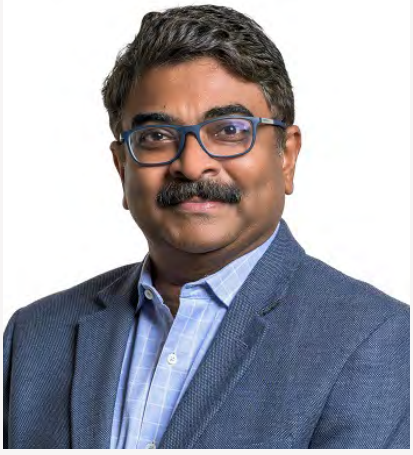
Forging Ahead in Formulation

By **Susan Haigney** | September 23, 2024

New and existing technologies, as well as a patient-centric focus, are pushing drug formulation into exciting directions.

There are a variety of factors pushing innovation in formulation of drug products forward. The desire to create new delivery methods for biologics, the need to increase patient adherence, and technologies such as artificial intelligence (AI) are some of the trends drug developers in the industry are cultivating.

According to Sibaji Biswas, executive director and chief financial officer at Syngene International, patient-centric approaches have led to formulation strategies being reshaped, especially for biologics, with compounds for low solubility and oral bioavailability in small-molecule drugs continuing to see growth. "This has increased demand for solubility and bioavailability enhancement technologies, with CDMOs [contract development and manufacturing organizations] now needing more comprehensive capabilities so they can take a 'fit-for-purpose' approach to any challenge," says Biswas. "Solid dispersion technology and other solubility enhancement methods are gaining prominence, while AI and machine learning [ML] are helping transform pharmaceutical formulation by predicting properties and behaviors."



Sibaji Biswas
ED & CFO, Syngene International

The use of ML and AI has been increasing in the bio/pharmaceutical industry. For formulation, they are being used to enhance modeling and predictive approaches, according to Shahrzad Missaghi, senior manager of Product Development, at Colorcon.

ML and AI allow for rapid innovation, according to Asma Patel, VP, Integrated Development Services, Quotient Sciences, as long as members of the industry are open to using these technologies. "From a discovery perspective, this can continue to fuel complexity in small new chemical and new molecular entities (NCEs/NMEs). Regardless of AI/ML, NCEs/NMEs continue to see an increase in average molecular weights and generation of new classes such as PROTACs [Proteolysis targeting chimeras], both creating solubility challenges for pharmaceutical formulation," says Patel.

Vincent Levet, PhD, director, Formulation Development and Production, Ardena, agrees. "[AI] is showing great potential to revolutionize formulation development, from supporting excipient selection to predicting outcomes and optimizing processes."

Additional formulation trends include delivery through lipid nanoparticles, ultra-high protein concentration formulations, continuous manufacturing, automation, and the creation of orphan drugs.

Enhancements in solid-dosage formulation

Automation has had a significant impact on the development of medicines delivered in capsule and tablet forms, according to Vinay Patil, Product Development Manager at Sharp Services. "Modern machines offer high-speed, precision filling and can handle various fill materials such as powders, granules, pellets, and even liquids," says Patil. "Even more currently, micro-dosing technology allows us to accurately dose small quantities of API, which is critical when working with potent drugs. These advancements have increased the speed and precision of drug production and expanded the range of materials that can be used." Patil also points to advances in granulation, compression, and coating that have impacted formulation.

"The introduction of high-shear granulators, fluid-bed processors, and roller compaction has enhanced the production of tablets with better mechanical properties and dissolution profiles. Coating technologies have also advanced, with enteric coatings and controlled-release formulations becoming more common," says Patil. "Recently, continuous manufacturing processes have improved tablet production efficiency, allowing for real-time monitoring and increased production speed. One very recent advancement is the use of 3D printing technology, which has allowed for the production of tablets with controlled release profiles personalized to individual patients."

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