ADVERTORIAL

Innovation is Key

How CDMOs Can Contribute to Pharma Supply even Better

The demand for medicines is increasing rapidly and R&D pipelines have doubled over the last decade. According to current market analyses, global spending on pharmaceuticals is expected to reach around $1,742 billion in 2025, while spending on Covid-19 vaccines and therapeutics could reach around 53 billion US dollars worldwide in the same year.

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End-to-end development services at Aenova

Two main trends can currently be identified in the pharmaceutical market: innovative drugs, which offer significant therapeutic benefits, are strongly on the rise, and the oral solid dosage form will continue to be the preferred dosage form on the global market.

Challenges in Overcoming Poor Bioavailability

On the one hand, innovative active pharmaceutical ingredients are designed to be highly specific to their biomedical targets, which enables therapeutic breakthrough and lowered side effects. On the other hand, these substances have specific challenges, especially when formulation as oral solid dosage form is targeted. Such challenges are poor solubility and oral bioavailability, as well as the highly potent nature of active ingredients (up to OEB 5).

Consequently, to meet the global demand for these drugs, contract developers and manufacturers must be able to offer their pharmaceutical customers innovative technologies to provide patients worldwide with the urgently needed medicines. This applies not only to commercial manufacturing, but already to formulation development to better meet market challenges. As a result, developers and manufacturers must use innovative technologies and offer solutions for handling highly potent active ingredients.

An example from the field of oncology can demonstrate this more clearly.

Specific Requirements for High-potent Active Pharmaceutical Ingredients

Oncology and immunomodulating therapy have become increasingly important in the past decade, as innovation in drug research allowed to develop more and more target specific substances. These active substances exhibit an improved risk-benefit profile. Consequently, high potent active pharmaceutical ingredients (HPAPIs) are on the rise and will play an important role in drug therapy in the future.

Market demand for cancer therapies in particular is growing rapidly. At the same time, the targeted patient group is becoming smaller, as are the SKUs (Stock Keeping Units) produced. However, the development and production of drugs with highly potent active pharmaceutical ingredients in the field of oncology is highly complex and often must be achieved under time pressure, as many of these new molecular entities (NMEs) are approved as "breakthrough therapy" in a fast-track process to quickly meet the high medical demand.

This makes it more important to have a competent CDMO partner who can facilitate a rapid time-to-market from development to commercial production. This includes not only innovative development know-how or experts for technical transfers, but also the right equipment for development scale-up and later high-volume production. It also requires the right concepts for handling highly potent active ingredients. These should be holistic and comprise production, processes and people as offered by Aenova at its Münster and Regensburg sites.

If development and manufacturing are then provided by the same CDMO partner, customers benefit from smooth and seamless transitions from development to production. This makes it much easier to bring new products to market quickly: in a short timeline, with low risk and cost efficiency.

Commercial manufacturing of high-potent medicines

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About Aenova Group

The Aenova Group is a leading global contract manufacturer and development service provider for the pharmaceutical and healthcare industry. As a one-stop store, Aenova develops, produces and packages all common dosage forms, product groups and active ingredient classes from pharmaceuticals to dietary supplements for human and animal health: solid, semi-solid and liquid, sterile and non-sterile, high and low dose, OEB 1 to 5 (Occupational Exposure Band). Approximately 4,000 employees at 14 sites in Europe and the U.S. contribute to the company's success. **www.aenova-group.com**

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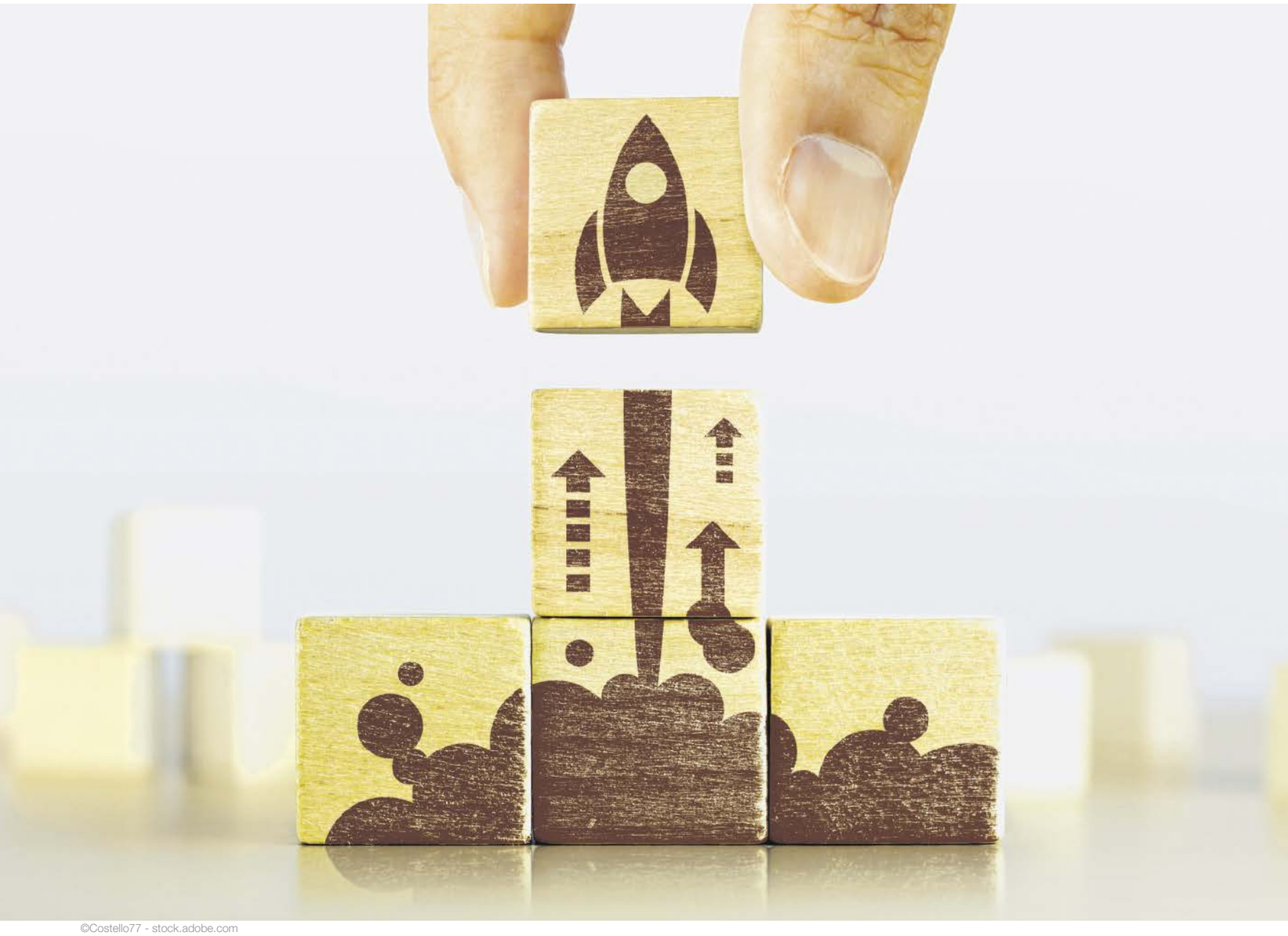

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