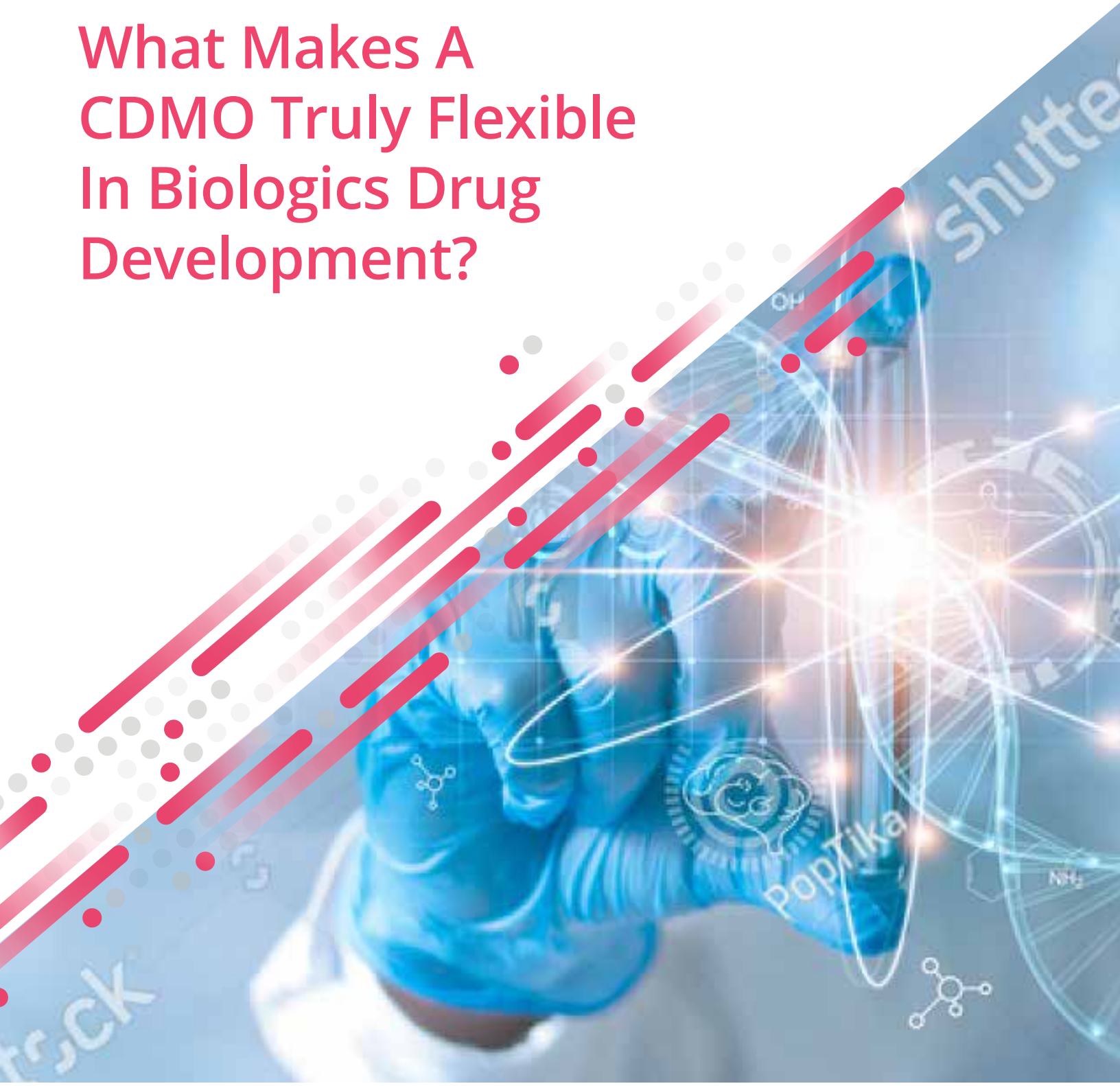
Pharma Intelligence

What Makes A CDMO Truly Flexible In Biologics Drug Development?



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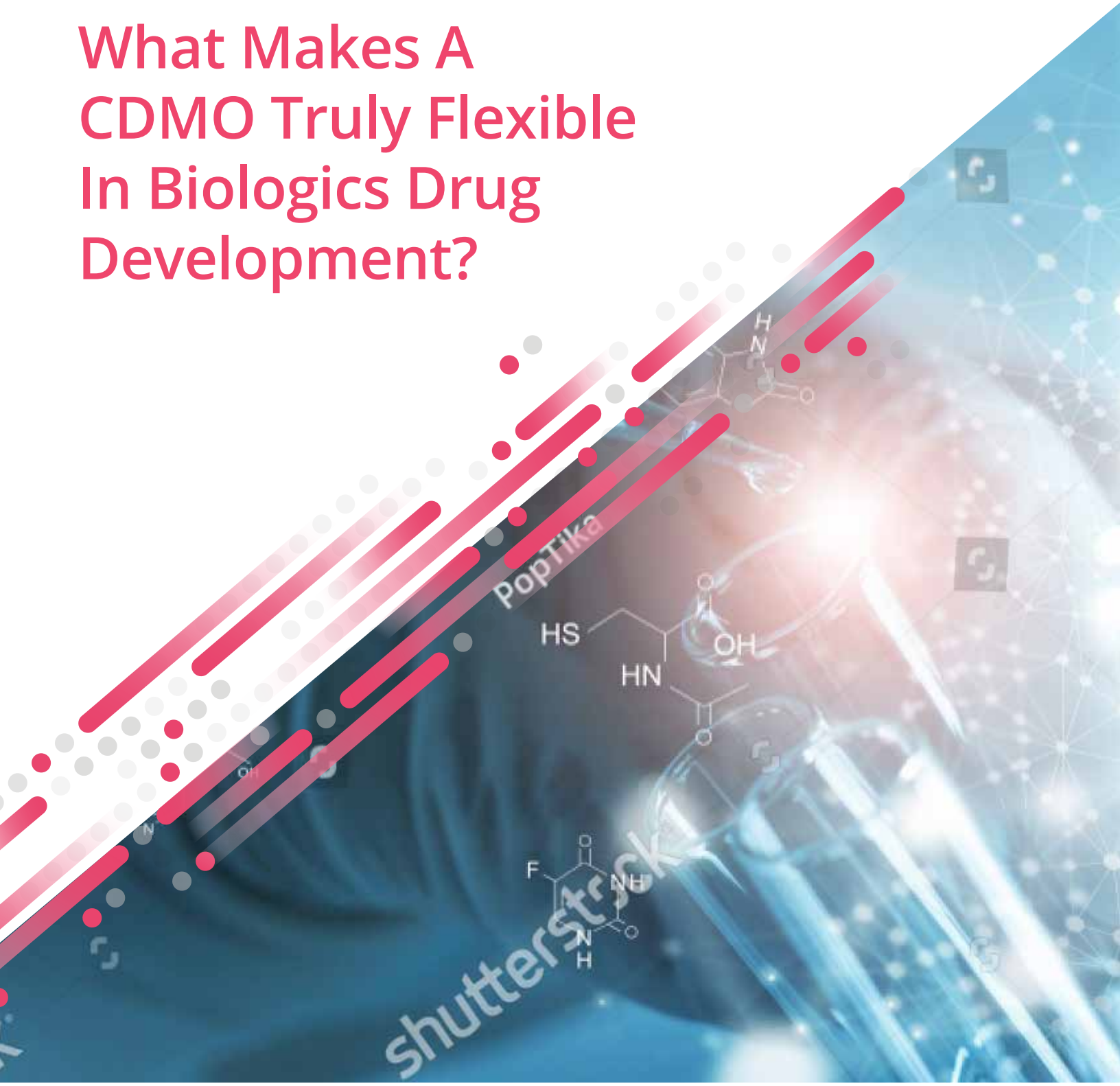

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What Makes A CDMO Truly Flexible In Biologics Drug Development?

Biologics have great potential for the treatment of many diseases, especially regarding unmet medical needs, due to their target specificity. Moreover, even for diseases where small molecule therapies already exist, there is potential for biologics to provide a more effective solution. However, developing a biologic can often be more challenging compared to their small molecule counterparts. They are more likely to become unstable, have more complex structures, and therefore require more specialized development and manufacturing processes, next to the fact that living organisms are involved in the process which leads to further volatility. It is important to work with a contract development and manufacturing organization (CDMO) that can match these requirements, accommodate challenges in a flexible way and keep the development process moving towards commercialization.

Unique Processes Call For Unique Capabilities

In biologics development there are different materials and production platforms that sponsors can work with, but most utilize mammalian cell lines or microbial expression systems. In particular, Professor Vladas Bumelis, CEO at Northway Biotech, has noticed a growth in microbial projects. “During the last five to eight years, we have definitely seen more microbial requests from our clients, including both E. coli and yeast,” he states.

Working with biologics developers results in a number of more unique requirements, such as strains needing kanamycin, being BSL2 organisms or the need for methanol usage in the process. All of these require specific facilities, equipment and knowledge from the CDMO in order to support the project. Bumelis notes their focus on becoming a biologics specialist CDMO, as not all providers have the necessary capabilities. "I find we work on projects that some other CDMOs cannot take, making us more of a niche offering to clients in need of such services," he explains.

Having this level of specialism is especially beneficial for early-phase biotech sponsors, who may not have approached manufacturing before. It enables the CDMO to support them and provide flexible options best suited to their project. There is also the need to impart knowledge of these processes to customers. Bumelis notes, "biotech companies come mainly from a scientific perspective, with a focus on the mode of action and brilliant ideas, but they often underestimate the complexity of cGMP manufacturing." In comparison to larger CDMOs with bigger teams, Northway Biotech is able to take a consultative approach to biologics partnerships and guide them through. "Our clients don´t need to be the experts in GMP manufacturing, they can focus on establishing new biological leads for medical progress, and we help them with process development and manufacturing, designing an optimal path to success", he continues.

Additionally, given the expanding field of biologics, development and manufacturing requirements are constantly evolving. It is important that sponsors partner with CDMOs that have their finger on the pulse of these changes and reflect this in their service offering. The business development team at Northway Biotech report directly into Bumelis, enabling them to communicate the needs of current and prospective customers, and thereby influencing strategy and investments.

Capacity Is Key To Reaping Flexibility Benefits

Being able to approach the drug development process in a flexible manner has real benefits for sponsors. Avoiding hurdles such as lack of access to the right equipment and technology enables accelerated timelines, which is important for hitting investor milestones. "For early-phase clients, a lot of it is about how quickly you can get them to a batch for clinic or for toxicology studies, whatever it might be. Things like high throughput systems are key to helping clients achieve this speed, without sacrificing quality," explains Bumelis.

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As well as having the advanced service offerings for these processes, it is important that CDMO partners also have capacity to ensure they can accommodate what their partners need, when they need it. Production slot availability can be a significant barrier to progression for biopharma clients and stalls their path through to commercialization if there are delays to access. Bumelis notes that Northway has recognized this and has expanded the offering at its facilities: "It's important that we increased our capacity

offering, we now offer a 5,000 liter and additional 2,000 liter bioreactor lines at our facilities."

Additionally, sponsors should consider the analytical capabilities of their CDMO partners, as they are critical to support flexible drug development. "Analytical services are really the backbone to complete manufacturing, it goes hand in hand with the development process, you're like a pilot without instruments if you don't have analytics," says Bumelis. As a result, Northway is continually improving its analytical capabilities, with newer, state-of-the-art equipment being installed at sites to ensure they are the right technical fit for their clients' projects. Since Northway is performing nearly all analytical activities in-house, this reduces the need for analytical outsourcing partners, and therefore ultimately also reduces complexity for the client.

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In light of the pandemic, the location of CDMO partners also draws more attention than it previously did. Bumelis has noticed in conversations with potential clients a reluctance to partner with providers too far from home, due to supply chain challenges encountered during COVID-19 lockdowns. With most customers being based in Europe and the US, Northway is well positioned to support them with sites in Lithuania and the biotech hub of Boston. Notably, both locations have the same technology and facilities, which also means that they can operate flexibly between the two where it proves beneficial to sponsors. "I say we are one company, two sites, which I really like because it means we are better suited to service our clients," says Bumelis.

The Importance Of A Flexible Mindset

Working with a CDMO that has a diverse service offering and facilities is critical to enabling sponsors to progress through drug development without delay, but in isolation it is not enough to embody true flexibility. The approach to partnerships and mindset of a CDMO is equally important, and they must have a vision to support clients in their projects however they can.

Bumelis directly experienced this with a returning client that needed extra flexibility in order to progress with their current project. "Our customer faced time pressure in his project and external circumstances required fast solutions and prompt attention. The relationship with them was very good and trustworthy, so we already started some additional activities for them without yet having the commercial contract in place for those tasks." While this is the exception rather than the rule, it proves a mentality of going above and beyond in the right scenario.

Regulatory support in addition to carrying out day-to-day development also provides added value to clients. Bumelis recalls one instance where Northway worked with its customer and forged an alliance with regulatory authorities on a COVID-19 project, resulting in substantial time being saved later in the development process.

Both examples are indicative of what is possible when there is intrinsic flexibility from the CDMO to provide the best service possible to their customers. This is especially important for early-phase biopharma sponsors navigating challenging development processes for the first time. Communication is key to ensuring they are reassured when undertaking projects and taking their CDMO's advice. "We are always transparent when we start a project, cooperating with the client and updating them frequently," says Bumelis.

When in-depth technical understanding, established facilities and a cooperative mindset are combined, a CDMO is in the best position to provide a flexible service to biopharma clients. Sponsors should be looking for all three when making partnership decisions, and prioritize potential for long-term project success, as opposed to just fulfilling the next step of the development process as quickly as possible. Bumelis concludes that, "a good CDMO can support in such a way that right from the beginning, the process is designed to be fast, but with an eye on the future."

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Vladas Algirdas Bumelis, Prof.

Vladas Algirdas Bumelis, Prof., is the Founder and CEO of Northway Biotech. He holds PhDs in both chemistry and biotechnology from Vilnius University and is a full member of the Lithuanian Academy of Sciences. Prof. V. Bumelis has extensive experience in the pharmaceutical and biotech industries, having previously served in senior management positions at international companies in the biopharma industry such as Teva Pharmaceuticals, Sicor Inc., Biofa, and Biotechna. His illustrious career has been recognized many times. In 2004, Prof. V.Bumelis received the Science Award of Lithuania in recognition of his achievements in the development and production of recombinant proteins, while in 2012, he was named CEO of the year in Lithuania.

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About Northway Biotech

Northway Biotech is a leading contract development and manufacturing organization (CDMO) supporting customers worldwide. Its highly experienced, professional team executes projects at any stage, from cell line construction and process development to cGMP manufacturing of biopharmaceutical products. The company's wide-ranging expertise and vertically integrated service offering translate to the ability to rapidly execute multiple projects from its state-of-the-art GMP facilities while ensuring full process and product compliance at all stages of research, development and commercial manufacturing. Northway Biotech is a privately owned company founded in 2004 and located in Vilnius, Lithuania; London, United Kingdom; and in Waltham, Mass., U.S.

Learn more at www.northwaybiotech.com