The New Logic of Biologics

This is the first of a special three-part series presented by Patheon for BIO International.

There is a tug-of-war happening across the pharmaceuticals business, especially in the biologics sector. On one end of the rope is science, which demands tolerating countless failures before it yields a single "maybe." Pulling on the other end of the rope is business, which wants to see this discovery become a safe and effective drug. But needs proof of concept as quickly and cheaply as possible.

We don't need to tell you who wins. But it is important to realize that this tension leads to many emerging companies running up against the new logic of biologics.

Old logic dictates that small biotechs should partner with small specialized CDMOs. The assumption is that a smaller partner would be more efficient and more affordable. However, with a smaller CDMO your options are often limited, which leaves you exposed to risk.

The new logic of biologics is that the more options you have, the better your chances of finding exactly the right solution. With a larger CDMO you have more flexibility to adapt and optimize your process for whatever challenge arises.

The more capacity, expertise and technical options you have access to, the more likely your project will progress uninterrupted.

Ideally your CDMO's capabilities will cover all your needs. The more of your project you have under one roof, the more time and money you'll save by reducing the supply chain complexity. If you need everything – process development of your drug substance and development of your drug product, and manufacturing of both at clinical and commercial scales – you should start your search with CDMOs that have all those capabilities, including a comprehensive array of sterile finished dosage forms.

You should also dig into the details of what they offer. A large CDMO will have a global network of facilities, each with its own characteristics, allowing maximum flexibility. Extensive experience with upstream and downstream, perfusion, fed-batch, aseptic and analytic development technologies should be a given. Other areas of expertise should include cell line development, single-use manufacturing technologies, automated high-throughput development and lyophilization. Additionally, a large CDMO's breadth of proprietary solutions might align well with your needs. For example, Patheon offers XD® and Rhobust® technologies to increase process performance. There is also Patheon OneSource™ which combines drug substance and drug product activities into a single coordinated program that takes months off development timelines and provides a clear, accelerated path to commercial launch.

Obviously, you also want to know their quality and regulatory track records. Aside from reducing risks, just by partnering with a CDMO that has a pristine reputation for quality and Right First Time/On-Time performance can add significant value to your discovery in the investment community.

The more capacity, expertise and technical options you have access to, the more likely your project will progress uninterrupted.

There's a new logic in biologics. So don't be afraid to think big when choosing your CDMO. With a large partner on your side, you'll have access to all the expertise, resources and flexibility you need to keep your project moving forward with speed and efficiency.

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Disposable is Indispensable – More of the New Logic of Biologics

This is the second of a special three-part series presented by Patheon for BIO International.

Biopharmaceutical companies are always on the lookout for the fastest, lowest cost way to develop and market safe, effective and profitable products. Most contract development and manufacturing organizations (CDMOs) are responding with targeted upgrades. However, it is the industry's leaders that have the financial strength and depth of expertise to pull together innovative equipment and groundbreaking technologies into fully envisioned new facilities that transform how biopharmaceuticals are made with solutions not yet available anywhere else. Customers of Patheon, a top CDMO, are already reaping the benefits of disposable bioprocessing equipment, fully robotic production trains, automated optical quality testing, as well as upstream and downstream process technologies that shatter productivity benchmarks.

The 2014 winner of the ISPE Facility of the Year Award for Process Innovation is the Patheon Facility in Brisbane, Australia. Operational since 2013, this 8,000 square meter cGMP siteoffers clinical manufacturing for Phase I, II and II trials, and soon commercial manufacturing, across all major cell lines. Designed to comply with worldwide quality and regulatory standards, this remarkable facility accelerates timelines, lowers costs and increases flexibility through the novel use of custom-developed and existing equipment and process technologies.

Disposable Single-Use Equipment

Most every area of this facility, from the cell bank to the production bioreactors, utilizes disposable technologies that significantly accelerate development and production cycles by eliminating the need to develop, validate or employ time- and labor-intensive cleaning processes. This speeds up projects as well as the changeovers between projects. Another advantage is that the facility is easily configured around the needs of a project instead of the location of utilities.

The 2014 winner of the ISPE Facility of the Year Award for Process Innovation is the Patheon Facility in Brisbane, Australia.

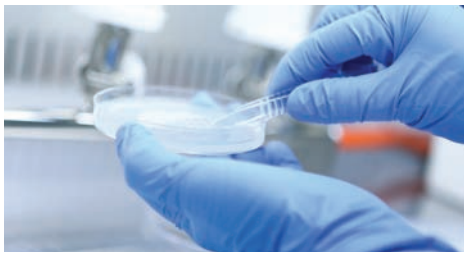
High-Yield Upstream Processes

Achieving more with less is essential to cost and time efficiency. Patheon XD® technology makes it possible to achieve outputs with a 500 L single-use system that equal the outputs of a 5000 L stainless steel bioreactor. Performance is amplified by higher cell densities and titers while retaining the product inside the bioreactor.

Direct-Capture Downstream Processes

The Brisbane facility employs a proprietary technology to achieve high yields while reducing labor costs and process times. Patheon RHOBUST® technology eliminates steps found in standard processes, along with related equipment, time, expense and exposure to risk. Centrifugation, depth-filtration and packed-bed chromatography are replaced by a single process where cells flow through an expanded bed and the product is captured directly from the culture medium.

+1 866.PATHEON • www.patheon.com • doingbusiness@patheon.com



Seamless Transitions Between Phases and Facilities

The Brisbane site is designed to work in concert its sister site in Groningen, The Netherlands, and state-of-the-art sterile fill/finish facilities in Europe and the United States. By purchasing complimentary equipment at different scales and using the same technology transfer process between sites as within a site, Patheon gives emerging biopharma companies ready access to all the resources and options of an extensive global network. They are able to take their discovery from the earliest pre-clinical stages all the way through approval and commercial manufacturing with a single dedicated partner.

The old logic of biologics was that the drug companies drove these kinds of innovations because they developed and manufactured their own discoveries at sites they built. Times have changed. Now they're asking themselves, "are we a biopharmaceuticals company or a biopharmaceuticals manufacturing company?" What they are looking for is the simplicity of a dedicated CDMO strategic partner that can deliver immediate access to all the quality, expertise and innovative options they need to develop and market safe, effective and profitable products faster and more cost effectively than if they designed, built and operated their own cutting edge facilities.

US Headquarters

Patheon
4815 Emperor Blvd, Suite 300
Durham NC 27703-8470
USA
P: +1 919 226 3200
F: +1 919 474 2269
www.patheon.com

European Headquarters

Patheon UK Ltd.
Kingfisher Drive
Covingham, Swindon
Wiltshire SN3 5BZ
UK
P: +44 1793 524411
F: +44 1793 487053
www.patheon.com

Japan Office

Patheon K.K.
7F Wakamatsu Building, 3-3-6
Nihonbashi Hon-cho, Chuo-ku,
Tokyo 103-0023
Japan
P: +81 3 6202 7666
F: +81 3 6202 7676
www.patheon.jp

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Choose the Option that Offers the Most Options – More of the New Logic of Biologics

This is the third of a special three-part series presented by Patheon for BIO International.

Speed and cost efficiency. Speed and cost efficiency. Speed and… This is the mantra of biopharmaceutical companies around the world. In the first two parts of this series we discussed how the fastest and most efficient projects are those that quickly overcome challenges. We pointed out how this has lead to a new logic in the selection of contract development and manufacturing organizations (CDMOs). The key is to choose a top CDMO partner with the breadth of capabilities, depth of expertise and wide range of options to meet as many of your needs as possible.

> The new logic of biologics states that the more of a discovery's development and commercialization you can complete with a single partner that has broad capabilities, and the more integrated those capabilities are, the more simplified your supply chain will be and the more time and money you'll ultimately save.

It's simple: The more solutions your CDMO offers, the better your chances of getting exactly the right solution, and the more flexibility you have to maintain forward momentum through any changes. Today we're going to follow that thought to its logical conclusion: An end-to-end, fully integrated, single-partner offering. One that combines drug substance and drug product development and manufacturing into a single customized solution.

The old logic of biologics warns you not to put all your eggs in one basket. It insists that a discovery's development should be dispersed among several specialized CDMOs to mitigate risks.

The new logic of biologics states that the more of a discovery's development and commercialization you can complete with a single partner that has broad capabilities, and the more integrated those capabilities are, the more simplified your supply chain will be and the more time and money you'll ultimately save.

Patheon OneSource™, the integrated offering from one of the world's top CDMOs, sets the bar high for the rest of the industry. By leveraging their global network of state-of-the-art facilities, broad expertise and unmatched track record for quality and on-time performance, they claim that it enables their customers to cut as much as 20 weeks off development timelines.

Other features of Patheon OneSource™ include:

- Parallel development of drug substance and drug product.
- Seamless supply chain from raw materials to finished dose.
- Cross-functional teams of experts to facilitate the free flow of ideas and data.
- Dedicated program managers for clear, efficient communication.
- Unmatched quality and Right First Time/On-Time Delivery.
- Non-GMP environment for accelerated development.
- Freedom from managing multiple vendors and logistics.

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Biopharmaceuticals companies that understand the new logic of biologics, are seeking to do more outsourcing, but with fewer CMDOs. They are looking to companies, like Patheon, that have decades of hands-on experience with every stage of the development cycle. They want to quickly reach their early-phase milestones with a scientifically sound product that's ready to progress directly along a well-established path through late-phase development and commercial launch. They want to work with a proven CDMO that can add value to their discovery just on the merits of reputation in the investor community. If you can achieve these goals with your project, you can be confident in your chances for success.

US Headquarters

Patheon
4815 Emperor Blvd, Suite 300
Durham NC 27703-8470
USA
P: +1 919 226 3200
F: +1 919 474 2269
www.patheon.com

European Headquarters

Patheon UK Ltd.
Kingfisher Drive
Covingham, Swindon
Wiltshire SN3 5BZ
UK
P: +44 1793 524411
F: +44 1793 487053
www.patheon.com

Japan Office

Patheon K.K.
7F Wakamatsu Building, 3-3-6
Nihonbashi Hon-cho, Chuo-ku,
Tokyo 103-0023
Japan
P: +81 3 6202 7666
F: +81 3 6202 7676
www.patheon.jp

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