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NUMBER ONE EUROPEAN COMPANY IN BIOPHARMACEUTICAL CONTRACT MANUFACTURING 2024
BioConnection

## MERGING BIG PHARMA EXPERTISE WITH BIOTECH AGILITY

## BIOCONNECTION

Alexander Willemse,
CEO

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# Certificate

## BioConnection


*This award is in recognition of **BioConnection's** stellar reputation and trust among customers and industry peers, evident in the numerous nominations we received from our subscribers. **BioConnection** emerged as a **Number One European Company in Biopharmaceutical Contract Manufacturing 2024** after an exhaustive evaluation by an expert panel of C-level executives, industry thought leaders, and our editorial board.*

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# BIOCONNECTION

## MERGING BIG PHARMA EXPERTISE WITH BIOTECH AGILITY

**By Stacey Smith**

BioConnection is the bridge the industry needs. It blends the agility and personal touch of emerging biotech companies with the expertise of big pharma.

While larger CMOs may treat clients as just another project in a long queue, BioConnection maintains a high level of personal interaction and tailored service. Clients are never mere numbers. This personalised approach, combined with in-house expertise typically found in top-tier CMOs, sets BioConnection apart in the market.

Formed through a public-private partnership between Organon, then a part of AkzoNobel Pharma, and the Dutch government, BioConnection's roots are deeply embedded in industry innovation. From the outset, Organon's cutting-edge facilities became BioConnection's foundation, empowering emerging biotech companies to turn their ideas into market-ready products. This spirit of collaboration laid the groundwork for a strong network of trusted partners, enabling it to provide end-to-end pharmaceutical development and manufacturing services.

Today, BioConnection is known for specialising in the development, manufacturing, filling and freeze-drying of injectable biopharmaceutical products, from concept to commercialisation, with uncompromised quality and reliability.

"Think of us like a boutique hotel," says Alexander Willemse, CEO. "While we provide the same top-tier capabilities as larger CMOs, our approach is flexible. Our clients appreciate the individualised attention and agility we bring to each project without sacrificing the quality or expertise they would expect from a large-scale partner."

A critical gap it addresses in the pharmaceutical lifecycle is the transition from clinical trials to commercial manufacturing. This is often the most challenging point for biotech companies. Scaling up requires access to specialised facilities, advanced technology and a higher level of regulatory compliance, areas in which many small firms lack experience and resources. Without the right CMO, companies face costly delays and disruptions.

BioConnection solves this problem by being the single point of

contact, maintaining continuity in production. This not only ensures efficiency but reduces risk by avoiding multiple handoffs, reducing opportunities for errors, delays or miscommunications. The result is a smoother path to market.

In addition to its expertise in bridging the gap, clients can also turn to BioConnection exclusively for its commercial-scale production services. Its state-of-the-art facilities allow the company to easily handle commercial volume batches. While BioConnection successfully manages multiple commercial projects, including complex transfer processes and regulatory inspections, its focus on the small to medium-sized market benefits these clients from its superior commercial capabilities.

through its partnership with AGC Biologics, a global leader in contract development and manufacturing services. Together, they transformed what was once a complex, fragmented process into a streamlined, cohesive solution.

Historically, drug substance suppliers excelled at producing the active pharmaceutical ingredient (API), but the transition from API to a market-ready product was fraught with inefficiencies. Companies often had to manage separate contracts with multiple entities scattered across regions. This disjointed supply chain complicated management and delayed time-to-market.

In collaboration with AGC Biologics, BioConnection has eliminated these bottlenecks. From initial analytics and formulation to labelling and packing, the entire production pipeline is fully integrated under a single contract. As a result, clients now benefit from a unified process that has demonstrated its ability to manage small-scale, intricate projects as well as complex, large-scale commercial operations.

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## Always Growing with the Industry

BioConnection was among the early adopters of the virtual CMO concept, constantly adapting to the evolving needs of the pharmaceutical industry.

In 2008, the company strategically embraced this model to meet market demands more efficiently. The pivotal moment, however, came in 2016 when BioConnection transitioned from a virtual model to a fully operational entity by acquiring a manufacturing facility.

Accredited by the European Medicines Agency (EMA), the state-of-the-art facility enabled BioConnection to expand its capabilities significantly, consolidating services to meet all client needs in-house.

With the successful launch of multiple commercial products in the U.S. and consistent compliance with the Food and Drug Administration's (FDA) rigorous standards, the CMO has now earned its spot as a key player in the global market.

## Strength in Collaboration: One Contract, Complete Service

BioConnection's mission to seamlessly integrate drug substance production with drug product development reached new heights

"This collaboration reflects our technical expertise and the trust a global leader like AGC places in our capabilities," says Willemse. "Clients can rest assured that their projects are managed with utmost professionalism and industry-leading expertise."

## Your Go-to Partner for Small Indications and Orphan Drugs

When it comes to small indications and orphan drugs, BioConnection isn't just another name. It's the partner companies rely on when the stakes are high, and the path forward isn't always clear.

With extensive experience in clinical trial medications, BioConnection is the go-to choice for firms navigating the complex journey from development to market. Its expertise goes beyond the technical, ensuring that therapies—often life-saving for patients with rare conditions—are brought to life with the precision and care they deserve.

The CMO's role becomes even more crucial in the evolving field of personalised medicine. Unlike traditional medications, treatments are tailored to the needs of each individual. This means there's no room for error—every patient's treatment must be precise. The pressure is immense. Patients want to start treatment as quickly as possible. BioConnection makes that happen by working closely with customers and suppliers, coordinating every step to ensure nothing goes wrong while the clock is ticking.

The process is anything but simple. Production schedules are often locked in six to nine months ahead, yet clinical studies are unpredictable, with patient needs shifting week by week. BioConnection's team thrives in this demanding environment. Their ability to be flexible and always put the client's needs first is what sets them apart.

A perfect example is when a client needed specific changes to accommodate a small-molecule product. In just 12 weeks, BioConnection installed new equipment and reconfigured its warehouse, ensuring the needs were met.

## Scalable Fill-Finish Solutions

Starting with a small 50-litre filling line, the company has now expanded its capabilities by investing in a large-scale, 500-litre filling line. This allows BioConnection to manage the entire lifecycle of its clients' products, with the flexibility to handle both personalised medicine and larger batch productions.

This is evident in a case involving a client developing an inline system for monitoring blood gases in ICU patients. The client required a distinct reference material—vials filled with a liquid saturated with a specific amount of blood gases. This presented a novel challenge for BioConnection, requiring it to develop and implement new techniques to achieve the desired gas concentrations.

BioConnection's development team rose to the occasion by working closely with the client to understand their requirements and devise a solution. It produced the reference material concisely, enabling the client to calibrate their innovative lab-on-a-chip system.

## Extending the Shelf Life

The CMO's expertise in critical processes enhances the stability and longevity of biopharmaceutical products.

One such process is freeze-drying, crucial for preserving sensitive biopharmaceuticals like proteins prone to degradation in aqueous environments. By removing water and adding a cryoprotectant, freeze-drying can significantly extend the shelf life of protein-based drugs and other delicate formulations, sometimes from just half a year in liquid form to two to four years.

While the physical process of filling and finishing may appear straightforward, the real challenge lies in ensuring an aseptic environment where safety and quality control are paramount. In contrast to sterile processing, where products can be tested for sterility after production, aseptic processing requires precise conditions to be maintained throughout production, as sterility cannot be confirmed afterwards.

BioConnection excels in creating these critical conditions, making sure every product is handled with care to meet the highest safety and quality standards. For products that require long-term stability, the ability to freeze-dry them under aseptic conditions is vital. This not only extends the product's shelf life but ensures it remains uncontaminated and safe for patient use.

The team always determines the optimal approach for each product after collaborating closely with clients. It carefully considers formulation, stability requirements and production volumes to develop customised freeze-drying cycles that maximise product quality while minimising costs.

> **Clients can rest assured that their projects are managed with utmost professionalism and industry-leading expertise**

## Expert Support at Every Stage

At the core of BioConnection's success is its dedicated team, working behind the scenes to ensure that every phase of production is executed with exacting precision. The company's strength lies in its ability to amplify this technical mastery through its network of specialised partners. This added layer of support brings an extra focus to niche areas that demand attention, creating a seamless process that's difficult to match.

The standout strength is its comprehensive support in drafting, executing and validating the documentation required for regulatory submissions to authorities like the EMA and FDA. The company thoroughly manages every phase of the regulatory process, ascertaining all validation protocols are adhered to and that the necessary documentation is fully compliant and ready for submission. This attention to detail, paired with BioConnection's technical and logistical expertise, provides clients with a full-service approach to navigating the complexities of regulatory approval.

Connecting all these capabilities is BioConnection's promise of quality and collaboration. As a boutique CMO, a personalised and client-centric approach helps it deliver flexible solutions tailored to each product's requirements. Combining scalability with a close, collaborative relationship with clients, BioConnection becomes an indispensable partner for companies seeking to deliver life-changing treatments to patients worldwide. Ph