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A CEO Perspective

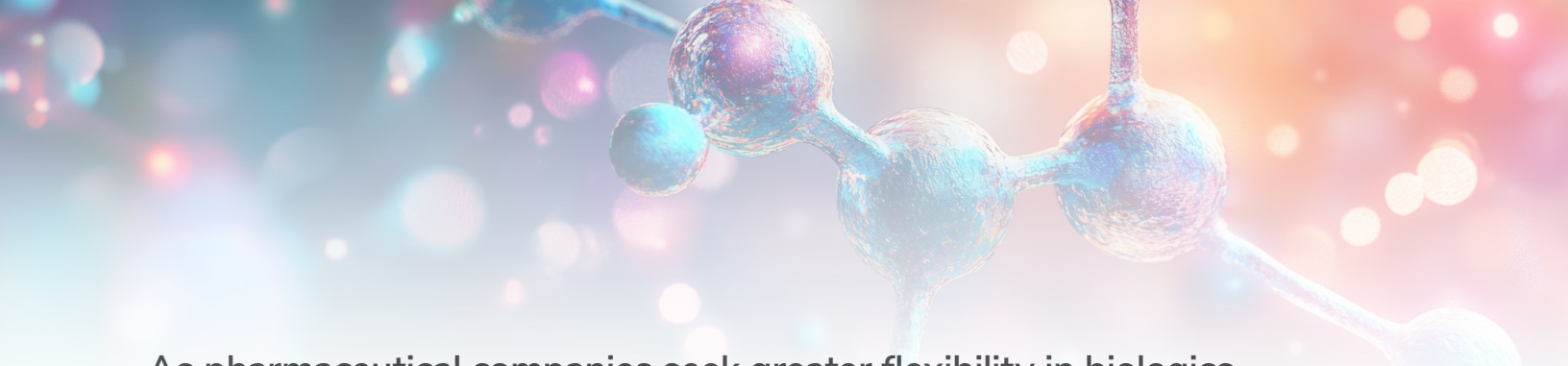
From Biosimilars to a Flexible CDMO Model: Rezon Bio's Strategy for Growth

**Dr. Adriana
Kiedzierska-Mencfeld**

CEO, Rezon Bio,
in conversation with

Unmesh Lal,
Vice President,
Frost & Sullivan





As pharmaceutical companies seek greater flexibility in biologics development and manufacturing, CDMOs are increasingly expected to provide more than technical capabilities. Cost efficiency, regulatory experience, manufacturing reliability, regional capacity, and the ability to manage development risk are becoming increasingly important when companies select a long-term partner.

For Rezon Bio CEO Dr. Adriana Kiędzierska-Mencfeld, these priorities are shaped by direct experience across the biologics value chain. Her career has included protein engineering, biosimilar development, process scale-up, Good Manufacturing Practices (GMP) manufacturing, regulatory approvals, commercialization, and the challenges of relying on external Contract Development and Manufacturing Organizations (CDMOs). Those experiences ultimately shaped Rezon Bio's strategy: combining deep technical expertise gained through the development and commercialization of biologics with a flexible CDMO model focused on reducing risk, accelerating timelines, improving cost competitiveness, and supporting customers from early development through commercial manufacturing

In this Transformational Growth Leadership discussion, [Unmesh Lal](#), Vice President, [Frost & Sullivan](#), speaks with [Dr. Adriana Kiędzierska-Mencfeld](#) about [Rezon Bio's](#) evolution, its focus on biosimilars and novel biologics, the importance of regional manufacturing, price competitiveness, technology adoption, partnerships, and the company's ambition to become a reliable CDMO partner for pharmaceutical and biotechnology companies.

“A successful CDMO is not defined by manufacturing capacity alone. It is defined by its ability to understand risk, reduce complexity, and help customers bring competitive biologics to patients.”

— Dr. Adriana Kiędzierska-Mencfeld, CEO, Rezon Bio

From Scientific Expertise to Building a Biologics Ecosystem

Unmesh Lal: *Before we get into Rezon Bio's strategy, could you tell us a little about your own journey and how your experience shaped the way you think about biologics development and manufacturing?*

Dr. Adriana Kiędzierska-Mencfeld: I am a biochemist by training, and throughout my career I have worked across every stage of the biologics value chain. My background spans protein engineering, biosimilar development, process scale-up, GMP manufacturing, regulatory approvals, commercialization, and executive leadership.

What makes this journey particularly valuable is that I have experienced biologics development from multiple perspectives: as a scientist, an operator, a developer, a manufacturer, and ultimately a business leader responsible for bringing products to market for our clients and their patients. Those experiences taught me that scientific success alone is not enough. The real challenge is translating innovation into commercially viable products that reach patients efficiently and sustainably.

Turning the Challenges of Outsourcing into a CDMO Model

Unmesh Lal: *You have experienced the development journey from the customer side as well as the manufacturing side. How did those experiences influence the creation of Rezon Bio?*

Dr. Adriana Kiędzierska-Mencfeld: Our decision to build the CDMO business came from our own experience as a biotech company. When we were a smaller company, we experienced first-hand some of the challenges of outsourcing critical development and manufacturing activities. As a smaller customer, are not always the

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highest priority, yet the quality, timelines and reliability of that work can have a significant impact on your development program. That experience led us to build those competencies internally and invest in our own development and manufacturing infrastructure.

Over time, we took our biologics programs through clinical development and into commercialization. In doing so, we built not only facilities, but also a highly experienced team and capabilities across development, manufacturing, analytics, quality and regulatory activities.

At one point, we reached a point where the capacity and capabilities we had built exceeded the needs of our own biosimilar pipeline. Biosimilar development is long and capital-intensive process, so there is a natural limit to how quickly products can utilize that infrastructure.

That created a clear strategic opportunity. By separating the businesses, the biosimilar company can remain focused on developing and commercializing its own portfolio, while our Polish sites can operate as a dedicated CDMO and make those capabilities available to external customers.

What is particularly important is that we approach CDMO partnerships with the perspective of someone who has been on the client side. We understand how important responsiveness, transparency and execution are when you are entrusting a partner with a critical part of your development program.

Building a CDMO Around Risk Sharing

Unmesh Lal: *That experience seems to have given you a different perspective on what customers actually need from a CDMO. How do you think about the role of the CDMO today?*

Dr. Adriana Kiędzierska-Mencfeld: For us, it is about understanding the risks from the beginning. We know what customers struggle with because we experienced many of those challenges ourselves. We also know how critical cost can become later in development if it is not considered early enough.

If you think about cost only at the end, it can become much more expensive, particularly when changes are required after approval. So, we focus on increasing efficiency, reducing cost, improving yield, and minimizing the time and risk associated with development.

Today, a successful CDMO must deliver much more than technical expertise. Customers expect a partner that understands development, regulatory, operational and commercial risk, and proactively helps manage those risks throughout the product lifecycle.

We often say that a CDMO should be prepared to share risk with its customers. However, before you can share risk, you first have to understand it. That understanding comes from firsthand experience of developing, scaling, manufacturing and commercializing biologics. This perspective

enables us to challenge assumptions early, identify potential bottlenecks and create solutions that improve long-term outcomes for our customers.

From Capacity to a Flexible, Customer-focused Model

Unmesh Lal: *What does that philosophy mean for the way you are positioning Rezon Bio as a CDMO?*

Dr. Adriana Kiędzierska-Mencfeld: Our first objective is to be recognized as a CDMO brand and as a reliable partner, not simply as a biosimilar developer or manufacturer.

We are building the company as a price-competitive and trusted partner, primarily for mid-sized biotechnology companies, while also supporting startups and larger pharmaceutical companies. Mid-sized biotech is our primary focus because we believe our capabilities fit their requirements particularly well, but we also have experience working with larger organizations.

We can support startups because we understand what it means to be at an early stage, but startups are not our only focus because our knowledge and experience extend well beyond early development and into late-stage development and commercialization. One of our key strengths is the ability to support customers as their products progress, from clinical to commercial manufacturing, while maintaining a strong focus on speed, scalability, and cost throughout that journey.

Why Cost Has to Be Considered from the Beginning

Unmesh Lal: *Cost competitiveness comes through strongly in your approach. How do you balance cost with quality and the regulatory requirements that come with biologics manufacturing?*

Dr. Adriana Kiędzierska-Mencfeld: Cost competitiveness has become one of the defining success factors in biologics. Scientific excellence and quality remain non-negotiable, but customers increasingly need manufacturing partners who can help them build economically sustainable products.

Our approach is not simply about lowering manufacturing costs. It is about optimizing the entire process from development through commercialization, and making the right decisions early. By improving yields, reducing complexity, and shortening timelines, we can help customers achieve a more efficient process and ultimately strengthen the competitiveness of their products in the market.

Our value proposition is therefore based on a combination of high quality, knowledge, experience, and price competitiveness. We are not trying to compete purely on the lowest possible price. We want to deliver the right balance, strong technical capabilities, high quality standards, supported by an efficient and competitive operating model.

We have two facilities with a total of four approved manufacturing lines, and we meet high-quality standards while also understanding different global regulatory and cultural requirements. We have gone through inspections from different countries, and that experience matters. You cannot learn everything from guidelines and books. You need to have the practical experience of understanding different regulatory expectations and building dossiers appropriately so that one regional requirement does not create unnecessary problems elsewhere.

Regional Manufacturing as a Strategic Advantage

Unmesh Lal: *You mentioned the importance of regional manufacturing. How do you see that shaping Rezon Bio's role for customers in Europe and beyond?*

Dr. Adriana Kiędzierska-Mencfeld: The disruptions of recent years have fundamentally changed how pharmaceutical companies think about supply chains. COVID, geopolitical tensions and increasing concerns around supply resilience have highlighted the importance of regional manufacturing capabilities.

We believe Europe needs strong and reliable biologics manufacturing capacity, particularly for companies seeking alternatives to single-source supply models. This is why dual sourcing and regional manufacturing have become important strategic themes for Rezon Bio. We see increasing demand from customers who want to strengthen supply security while maintaining competitiveness.



Scaling Through Flexibility Rather Than Overbuilding

Unmesh Lal: As you expand, how are you thinking about capacity investment and maintaining flexibility?

Dr. Adriana Kiędzierska-Mencfeld: We have the experience, capabilities, and financing to extend our capacity as demand grows. In Warsaw, we currently have two commercial lines, a third clean room ready to be equipped according to client requirements, additional space for further expansion, and another building available.

Being privately owned also gives us an important degree of flexibility. We can make investment decisions quickly when there is a clear customer or market need, which is increasingly valuable at a time when major capacity investments can take longer to implement. At the same time, we are disciplined about when and how we invest. Our priority today is to maximize utilization of our existing capacity and expand in line with customer demand. When we make the next investments, we want to take advantage of the latest proven technologies rather than invest too early in technologies that have not yet demonstrated their value at commercial scale.

Our approach is to minimize risk for the client. We are open to innovation and have the technical knowledge and experience to evaluate and test new solutions together with our clients. But when it comes to commercial manufacturing, we believe innovation needs to be balanced with robustness and reliability. We do not want our customers to take any unnecessary risks.

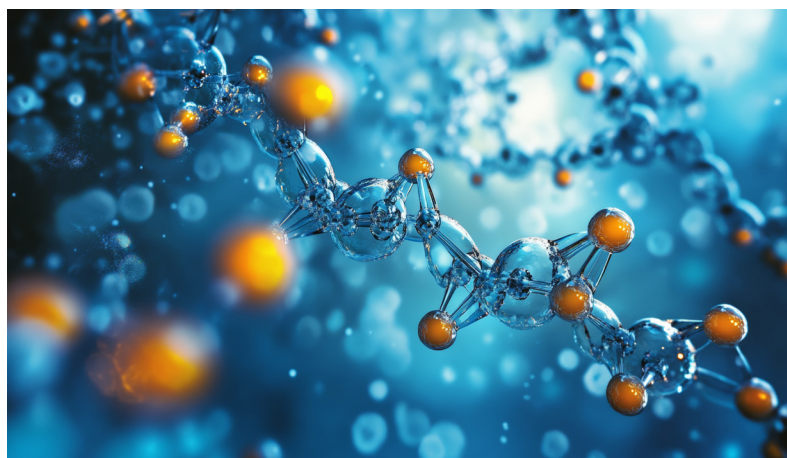
Serving Biosimilars While Building a Novel Biologics Pipeline

Unmesh Lal: Rezon Bio has experience in biosimilars, but you also mentioned novel biologics. How do those two priorities fit together?

Dr. Adriana Kiędzierska-Mencfeld: For us, biosimilars remain the primary focus in our current strategy horizon, but we are also building a pipeline of opportunities in novel biologics. Within our investor ecosystem, there are innovative biotech companies as well, so we do not want to exclude that opportunity.

Our site in northern Poland, Gdansk, has a stronger clinical and development focus and already has experience working with more complex molecules, including novel biologics and multispecific enzymes. We already have a track record in those areas.

When it comes to biosimilars, we are not going after every opportunity. We focus on specific groups where we believe we can compete on price and where our experience gives us an advantage. Many companies talk about biosimilars, but not all of them have experience taking products through commercialization. That experience is important because you need to understand not only development, but also how to deliver a commercially viable product.



Looking at the Customer's Cost, Not Just the CDMO's Cost

Unmesh Lal: *You made an interesting point about looking at the customer's economics rather than simply the CDMO's own costs. How does that influence your approach?*

Dr. Adriana Kiędzierska-Mencfeld: We look very closely at the bill of materials and the cost of the product. Not every CDMO focuses on this because some of those costs are technically covered by the customer. But we do not look only from our own perspective and consider the commercial success of a client's product.

The question for us is not only whether we can manufacture the product successfully, but whether our customer will be able to compete successfully in the market. If the cost of goods is too high and competitors enter with a more cost-efficient product, that can affect volumes, margins and ultimately the customer's ability to continue investing in the product.

Our in-house analytical capabilities are an important part of this approach. We perform around 90% of our testing internally, including techniques such as mass spectrometry and glycan analysis. This gives us additional control over timelines, quality and cost, while also allowing our development and analytical teams to work closely together.

Technology That Improves Efficiency Without Increasing Risk

Unmesh Lal: *Technology adoption is another area that stood out to us. How are you approaching AI, automation, and technology within the Rezon Bio model?*

Dr. Adriana Kiędzierska-Mencfeld: We see technology as an enabler of operational excellence rather than an objective in itself. Whether we are evaluating AI, automation,

digital tools or advanced manufacturing technologies, our primary question is always the same: can this technology improve quality, reduce timelines, lower costs or enhance the customer experience?

At Rezon Bio, we combine innovation with pragmatism. We are committed to adopting technologies that create measurable value while maintaining the reliability and regulatory compliance our customers expect.

Innovation Without Becoming a Prototype Environment

Unmesh Lal: *How do you make sure that technology adoption does not introduce additional risk for your customers?*

Dr. Adriana Kiędzierska-Mencfeld: We want to stay at the forefront of new technologies, but we are very deliberate about how and when we adopt them. We are not stepping into the prototype technologies field.

Our objective is to maximize capacity utilization at the current stage and invest when there is a clear business and customer need. When we do invest, we want to use the newest technologies, but we also want to be a reliable partner and minimize risk for our customers.

If a client wants to test something, of course we are open to it. If a customer wants to evaluate a new technology, we have the knowledge and experience to assess it, design the appropriate studies and understand its potential impact before moving further.

Building Rezon Bio's US Presence Through Partnerships

Unmesh Lal: Looking specifically at the US, what role will partnerships play in expanding Rezon Bio's commercial reach?

Dr. Adriana Kiędzierska-Mencfeld: We see ourselves as an interesting supplier for the US because we can manufacture products under FDA (Food and Drug Administration) standards while still offering a cost advantage compared with US production.

We are also open to partnerships with drug product companies in the US, and we are already in advanced discussions with potential partners. We are flexible in terms of the collaboration model because we believe the right structure should depend on the needs of the customer and the product. At this stage, we are focused on drug substance where we have strong capabilities and experience. In the future, we will continue to assess how the requirements evolve across other areas and modalities. For now, we believe the capacity available in drug product is sufficient, so rather than building everything ourselves, we would prefer to have strong and reliable partners in different locations, including the US.

Building a CDMO Around Commercial Experience

Unmesh Lal: You have emphasized commercialization several times. How does that experience translate into value for customers today?

Dr. Adriana Kiędzierska-Mencfeld: Our experience in commercialization is a very important competitive advantage. We know that getting an approval and getting a product launched are two different things.

With biosimilars, we learned how important it is to understand cost from the beginning and

how mistakes made earlier can become more expensive later. We therefore try to bring that experience into the way we work with customers.

The goal is not simply to manufacture something successfully. We look at whether the customer will be able to compete with the product, whether the economics work, and whether the infrastructure and technology are appropriate for the required volumes. That commercial understanding is something we want to continue building into our CDMO model.

The Next Phase: A Reliable Partner for Biologics

Unmesh Lal: As you look ahead, what do you want Rezon Bio to become over the next few years?

Dr. Adriana Kiędzierska-Mencfeld: Our ambition is to become one of Europe's most trusted biologics CDMOs, recognized for combining scientific expertise, commercial understanding and execution excellence.

We want customers to see Rezon Bio as a partner that understands not only how to manufacture biologics, but how to help products succeed commercially. Our goal is to build long-term relationships, support both biosimilars and innovative biologics, and become an integral part of resilient global supply chains.



What Defines Rezon Bio

Unmesh Lal: *If you had to describe Rezon Bio in a few words, what would they be and why?*

Dr. Adriana Kiędzierska-Mencfeld:
Competitive Price. CDMO delivering in full and on time.

Reliable. Price-Competitive. Commercially Minded.

Reliability is the foundation of everything we do. Customers need a partner who consistently delivers on commitments.

Price competitiveness is essential in today's biologics market, but we believe our real differentiation comes from combining that competitiveness with practical experience across the entire product lifecycle. Because we have developed, scaled, manufactured and commercialized biologics ourselves, we understand what successful products require beyond manufacturing alone.

Our goal is simple: help customers bring successful biologics to patients while reducing risk, controlling costs and ensuring supply reliability.

Closing Reflection: Building a CDMO Around Real-world Experience

Rezon Bio's approach is shaped by a practical understanding of the biologics development journey, from early-stage development and outsourcing through manufacturing, regulatory approval, and commercialization. Dr. Adriana Kiędzierska-Mencfeld's experience across these stages has informed a CDMO model focused on understanding risk early, improving efficiency, controlling costs, and supporting customers through the realities of bringing products to market.

The company's strategy combines a primary focus on selected biosimilar opportunities with a growing pipeline of novel biologics and capabilities for complex molecules. Regional manufacturing, FDA-aligned capabilities, flexible capacity, technology adoption, and partnerships are becoming important components of this model as pharmaceutical companies seek greater supply resilience and cost competitiveness.

For Rezon Bio, the ambition is straightforward: become a **reliable CDMO partner** that combines scientific and commercial experience with the flexibility to respond to customer needs. Its differentiation lies not simply in having manufacturing capacity, but in understanding the risks, costs, and decisions that determine whether a biologic ultimately reaches patients successfully.





Dr. Adriana Kiędzierska-Mencfeld | CEO, Rezon Bio

Dr. Adriana Kiędzierska-Mencfeld is the **Chief Executive Officer** of **Rezon Bio**, a science-driven, price-competitive biologics CDMO focused on the development and manufacture of biologics. A biochemist by training with a PhD in protein engineering, she has extensive experience across biologics development, process scale-up, GMP manufacturing, regulatory approvals, commercialization, and CDMO operations. Her experience spans the product lifecycle, including biosimilars and novel biologics, and has shaped Rezon Bio's focus on cost competitiveness, manufacturing flexibility, risk sharing, and reliable customer delivery.



Unmesh Lal | Vice President, Frost & Sullivan

Unmesh Lal brings over **20 years** of experience in healthcare strategy and consulting, with a focus on global life sciences and bio-pharma manufacturing. He specializes in identifying transformative technologies, innovative business models, and growth opportunities across pharmaceutical contract services. A recognized thought leader, Unmesh has authored key industry insights and presented at leading global events including J.P. Morgan, CPHI, Bio-Asia, Bioprocessing Summit, Biotech Outsourcing Strategies cmc, and others. He holds a master's degree in biomedical engineering from the University of Michigan–Ann Arbor.

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Appendix: Shaping the Next Generation of Biologics CDMO Growth

As pharmaceutical and biotechnology companies seek greater flexibility, cost efficiency, supply resilience, and specialized expertise across the biologics lifecycle, CDMOs are increasingly becoming strategic partners rather than capacity providers. The shift toward complex biologics, biosimilars, regional manufacturing, advanced modalities, and more integrated development-to-manufacturing models is creating new opportunities for differentiated CDMO providers. Frost & Sullivan provides strategic intelligence across these developments, including:

- ▶ [Growth Opportunities in Biologics Contract Development & Manufacturing Organizations, Global](#)
- ▶ [Top 10 Growth Opportunities in the European Life Sciences Industry, 2026](#)
- ▶ [Growth Opportunities in Global Pharmaceutical Industry](#)

These analyses complement the themes explored throughout this discussion, helping pharmaceutical and biotechnology leaders understand the evolving role of CDMOs, the importance of regional and resilient manufacturing, and the growth opportunities emerging across biosimilars, novel biologics, and advanced manufacturing capabilities.

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