Chris Hwang – Scientific Advisor and ex-CTO, Transcenta

Our productivity is typically more than 10 times that of a conventional batch process.

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After 25 years at Genzyme and Sanofi, Chris Hwang joined a biotech startup in China in 2016 to develop advanced bioprocessing technologies that reduce cost of goods while maintaining reliable supply. As CTO of Transcenta, he and his team have advanced continuous bioprocessing, delivering dramatic productivity improvements over traditional batch manufacturing. In emerging markets like China, intense pricing pressure is accelerating adoption, while in more established markets like the US, strong pricing and significant investment in batch infrastructure have reduced the urgency to change. Without sufficient economic drivers, there is less appetite to move away from established batch processes. Hwang emphasizes that while this shift introduces manufacturing risks, they can be managed by avoiding over-engineering, using simpler, right-sized technologies, implementing in stages, and managing complexity to ensure reliable adoption. As Transcenta expands globally, the company is increasingly focused on technology out-licensing to extend these capabilities and improve affordability and patient access.

Could you walk us through your career journey and the path that eventually led you to join the team at Transcenta and HJB?

I am a biochemical engineer by training and earned my PhD at MIT, before spending nearly 25 years at Genzyme and Sanofi leading manufacturing process and technology development for

protein and gene therapy pipelines.

The most rewarding part of that journey was the opportunity to bring innovative therapies to patients, especially those with rare diseases. These treatments often meant the difference between life and death, or significantly improved patients' quality of life. Regardless of where I worked, the patient-centered mission was deeply ingrained. It's what drove everything we did and reminded us why our work truly matters.

I eventually joined Transcenta and HJB in September 2016 as Chief Technology Officer, with the goal of advancing how biologics are manufactured through highly intensified bioprocesses, particularly continuous bioprocessing for drug manufacturing.

Drawing on my experience in CMC and technology development and commercialization, I was brought on to build and lead this capability. HJB, a subsidiary of Transcenta, supports all CMC development and manufacturing for the pipeline, and we later expanded into a full-service CDMO for biologics.

In 2016, joining a Chinese biotech was considered a significant risk for someone with a long career in big pharma. What was the personal incentive to go against the current and move to a home-based Chinese firm at that stage of your career?

At the time, I was in my mid-fifties and very happy at Sanofi, but I had always felt a pull toward Asia. I am originally from Taiwan and wanted to give back and contribute where I could make a bigger impact. China's biotech industry was still in its early stages, and it felt like a rare opportunity to build something meaningful.

Beyond the personal draw, there was a significant technical motivation. During my time at Genzyme and Sanofi, we had developed a continuous manufacturing platform that many recognized as industry-leading and the future of biomanufacturing. I personally gave more than 30 tours for various VIPs, including a group form the FDA's Emerging Technology Team (ETT), and a presentation to the Innovation Task Force (ITF) at EMA. The feedback was very consistent, the platform was seen as a "no-brainer" and exactly what the industry needed. Yet adoption remained slow, largely due to limited economic drivers, the conservative nature of pharma, and the significant installed base of batch infrastructure.

In China, the mindset was very different, there was urgency, openness, and strong top-level support to implement new technologies. That combination of purpose, timing, and opportunity

ultimately drove my decision to join Transcenta, even though it meant building capabilities, including labs and manufacturing facilities, from scratch. It was especially gratifying to later hear that the continuous platform we developed at Genzyme and Sanofi was ultimately implemented successfully in various commercial products.

HJB began as an in-house CMC branch for Transcenta. Could you describe the specific infrastructure you established and how the pivot into the CDMO business occurred?

When we started, we knew from the very beginning that to be competitive, we couldn’t just build a cookie-cutter manufacturing platform and facility. One of the major drivers for this technology is cost reduction to address intensifying drug pricing pressure. To be competitive, we needed a new platform that could dramatically decrease the cost of goods.

When we built the facility, we used a very novel approach using G-CON prefabricated, modular cleanrooms integrated within a ballroom style layout facility, very similar to the one Just-Evotec built in Seattle years later. We worked closely with that team to build the first version of this design, which enables significantly faster facility build-out, greater operational flexibility, and reduce capital investment compared to traditional stainless-steel facilities. The concept was later expanded in facilities in Seattle and Toulouse, France. The Toulouse facility was eventually sold to Sandoz in late 2025. As a major biosimilar company, Sandoz sought that technology and continuous processing capability because it represents a significant competitive advantage in the global biosimilars market.

In terms of the processing itself, I believe continuous manufacturing has the highest potential to lower the cost of goods. At HJB, we first installed a fed-batch platform because it is a mature technology needed to support our early-stage internal programs. In parallel, we developed our continuous platform from the ground up. Once it was ready, we began using it for early-stage programs and transitioning some of our existing fed-batch processes over to it.

In terms of pivoting to CDMO business, we originally built HJB to support our own pipeline, but since we had built a very experienced team and end-to-end capabilities, moving into CDMO was a natural next step. It allowed us to maximize the value from our investment, while working on more projects helped us continuously improve and refine our capabilities.

For our readers who are not manufacturing specialists, could you explain the technical difference between traditional batch processing and your HiCB continuous platform?

Conventional manufacturing, which still represents the vast majority of products on the market, is based on batch processing. Production occurs in multiple discrete steps where you run a batch, hold the material, process the next step, and repeat, making it essentially a stop-and-go operation with built-in pauses between stages.

Our platform, which we call Highly Intensified Continuous Bioprocessing (HiCB), takes a fundamentally different approach. It uses continuous perfusion where cells are maintained at very high densities in a tightly controlled and optimized environment. Instead of starting and stopping, the process runs continuously, typically for around 30 days, without the downtime seen in batch operations. This enables a step change in productivity, often achieving 10-to-15-fold increase, compared to conventional fed-batch processes.

Perfusion itself is not new. It dates back to the early 1990s with pioneers like Genzyme where it was developed to manufacture less stable proteins. In batch processes, some products can degrade before harvest, whereas perfusion continuously feeds fresh media and removes product in real time. This shorter residence time and more favourable culture environment helps preserve product quality. We have since built on this approach to significantly increase overall productivity.

However, improving upstream alone is not enough. To truly lower cost, the entire process must work together. If downstream or even supporting operations like media and buffer prep can’t keep up, they become the bottleneck and limit plant output. At the end of the day, you’re only as efficient as your weakest step.

To address this, we partnered with MilliporeSigma in 2020 to co-develop a downstream solution that could match the high output of our continuous perfusion platform, leveraging their expertise in automation and Biocontinuum technologies. Our design philosophy is to balance innovation with practicality, using simpler, right-sized technologies, implementing in stages, and minimizing unnecessary complexity and risks. Rather than a fully end-to-end continuous system, we adopted a hybrid continuous downstream approach that captures most of the efficiency gains to ensure maximum facility output while remaining robust and easier to implement.

The result is a more efficient and flexible manufacturing model: significantly higher plant output, which can lower cost of goods and defer future facility builds, along with more agile, “just-in-time” production capacity; significantly lower upfront capital investment; and faster timelines to clinic and market.

If continuous bioprocessing offers such clear advantage, why has the adoption in the US been relatively slow? Is it purely a matter of risk, or is it the cost of changing existing infrastructure?

In my opinion, the issue is less about technical risk and more about economics. Technical risks can be managed; the key question is whether there is enough economic pressure to justify changing how we manufacture. In the US and other well-established markets, drug pricing has historically been high, so cost of goods represents a relatively small portion of the final price, and the incentive to fundamentally change manufacturing has been limited.

In the more price-sensitive markets, the situation is very different. Many established Western drugs entering China's reimbursement system see price reductions of 50 to 70 percent, and in some cases, more than 90 percent, with even more intense competition amongst domestic drugs. In this environment, cost of goods can become a much bigger portion of the drug pricing and improving manufacturing efficiency and meaningful reduction of cost of goods is no longer a "nice to have" but a necessity. In addition, any cost savings from manufacturing can be re-invested into R&D.

Of course, biopharma is inherently conservative, so risk management is critical. Any new technology we implement will incur significant risks if not managed properly. That is one major reason why we decided to not implement fully end-to-end continuous platform as the technology is less mature and more complex. Our approach is to implement continuous bioprocessing in a staged and pragmatic way, starting with continuous perfusion, which is more well understood and accepted by the industry and regulatory agencies. Then, we integrate it with continuous capture, which is a technology that has undergone significant advancement over the past five to seven years, followed by or in parallel with the rest of hybrid continuous downstream, but only after extensive testing and risk identification and mitigation. Regulatory frameworks such as ICH Q13, along with industry efforts like NIIMBL's N-mAb, are also helping to support and standardize these approaches.

The other major factor for slower adoption is the large, capital-intensive installed infrastructure for batch processing. Companies have made significant investments in existing facilities and naturally want to fully utilize those assets, which makes them more cautious about adopting fundamentally different technologies. As with single-use technologies, which took 10 to 15 years to mainstream, adoption of continuous will take time.

At HJB, we take a pragmatic approach, focusing on simplicity, comprehensive process and operational risk management, and staged implementation. To date, we have completed more than 15 highly intensified continuous perfusion at manufacturing scale with a 100 percent success rate, and our integrated hybrid continuous downstream process has been successfully implemented at commercial scale.

In a fast-moving market like China, how many other CDMOs are utilizing continuous manufacturing, and are you seeing the same trend in the US or Europe?

WuXi Biologics is certainly a major player, and many other CDMOs in China are also actively investing in continuous bioprocessing. With competition so intense, the ability to lower cost of goods has become a key differentiator, and adoption is increasing seen as essential to remain competitive.

In the US and Europe, much of the early innovation in continuous bioprocessing actually originated there, and today all major biopharma players, including those in India, are actively exploring it. You can see this in the growing number of case studies and conference presentations each year.

While implementation has been more gradual, interest is clearly strong. According to the 2025 BioPlan survey, one of the industry’s most widely referenced benchmarks, adoption is approaching one-third of facilities, with nearly 40 percent planning to evaluate continuous processing and about 50 percent of CDMOs assessing perfusion. The direction is clear, even if full implementation is still catching up. With increasing pricing pressure from policies such as the Inflation Reduction Act (IRA) and Most Favored Nation (MFN), there is also a growing focus on manufacturing efficiency and cost.

Who are your primary customers today, and how has the BIOSECURE Act impacted your ability to attract US-based clients?

In the early days, we supported both US and Chinese clients through our CDMO services. More recently, a combination of factors, including the BIOSECURE Act, broader market conditions, and tighter funding, has made it more challenging to attract new customers outside China, even though we were not specifically named. As a result, competition for domestic clients in China has intensified significantly.

In China, cost is an important consideration alongside product quality and clinical performance. While some clients still prefer established batch platforms for clinical supply, we are seeing growing interest in evaluating continuous bioprocessing against fed-batch models, particularly for its potential to reduce cost of goods and to improve stability for more sensitive proteins.

In the US, interest in perfusion is typically reserved for molecules that are less stable, such as some bispecifics, multi-specific and other complex formats that are prone to degradation/aggregation in batch processes. In these cases, perfusion offers clear advantages in product quality and consistency, making it an attractive option despite the evolving regulatory landscape.

How is Transcenta working with Eirgenix, Inc. and how does this reflect your broader strategy of technology out-licensing?

The CDMO market in China is very competitive over the past few years, so we're focusing on getting more value out of the platform we've built through technology out-licensing. It allows us to grow without significant investment in people and new manufacturing capacity and plays to our strength in developing highly productive manufacturing platforms and differentiate us from other CDMO's.

EirGenix approached us because they're projecting stronger need for solutions that can lower cost of goods for their CDMO business and, eventually, their internal pipeline.

This is a win-win partnership, we provide the technology, and partners like EirGenix bring strong execution. It allows us to scale globally, improve efficiency and affordability, and reinvest into our platform and pipeline. It's also largely insulated us from clients' concerns like BIOSECURE Act, and allows us to enable other companies globally to use our technology regardless of their location. Our deal with EirGenix is non-exclusive, so we can replicate this model worldwide. We aim to find the right partners, transfer the technology, and enable them to achieve the same efficiencies we have.

How do you see the future of the CDMO segment evolving? Will it be defined by more local manufacturing or higher technological complexity?

I believe we will see a trend toward the localization of manufacturing in China and other regions, but just as importantly, CDMOs will need to keep up with the science. Biologics are becoming more complex, moving into bispecifics, multi-specifics, ADCs, and radiopharmaceuticals. CDMOs must be

flexible enough to support these new modalities.

At the same time, the industry is moving away from the era of mega-volume blockbuster drugs toward smaller, more targeted therapies. That means success will depend less on sheer scale and more on speed, flexibility, and quality. Cost control will also remain a key focus as funding tightens and drug pricing pressure intensifies. In this environment, CDMOs that adopt more efficient technologies will have a clear advantage. For us, it’s about continuing to invest in innovation and implement the right technologies so we can lower costs while maintaining high product quality for us and for our partners.

Are there any final thoughts you would like to highlight regarding the race to stay ahead of the curve in biomanufacturing technology?

At HJB, our philosophy is not wait for a technology to be perfect before we implement it. Drug development timelines are long, so the decisions we make today need to anticipate the market several years from now where pricing pressure will likely be much higher and molecules more complex. The key is to adopt early, but in a risk-managed, staged way. Waiting until commercialization to make changes will only put you behind, and significantly increase the effort and risk associated with establishing comparability.

In many emerging markets, strong pricing pressure is accelerating adoption of new technologies. As these technologies become proven at scale, adoption in the US and Europe will follow as perceived risk decreases and as cost pressure continue to rise.

Ultimately, this is a win-win for the business, for patients, and for the environment. By improving manufacturing efficiency, we can lower costs, expand access, and improve sustainability, while staying competitive in a rapidly evolving industry. I feel fortunate to be in an environment with strong commitment to implementing these solutions, and I’m proud that our team at HJB built this from the ground up in just a few years, making a meaningful difference in improving access and affordability for patients. For me personally, that’s what makes this journey truly worthwhile, making a real difference.

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