Biopharma's Big Transformation

From digital technology to data analytics to continuous bioprocessing – the world of biopharma manufacturing is changing rapidly.

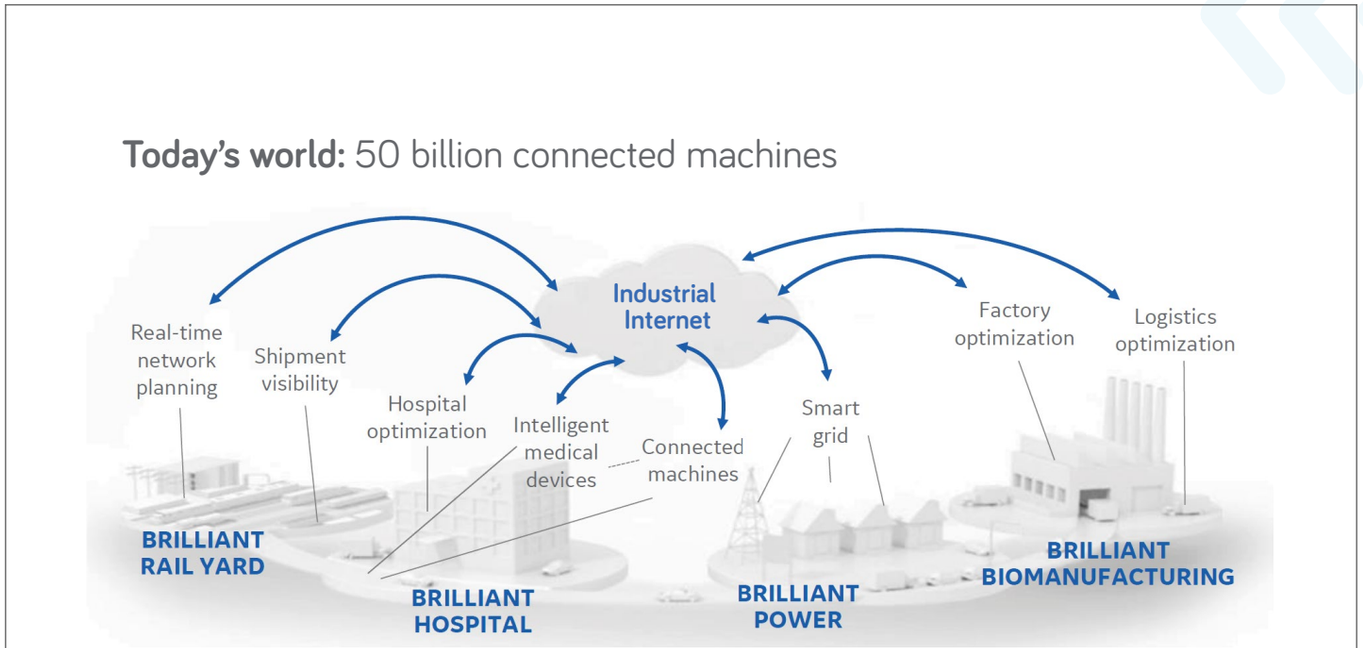
Please click the circles to navigate

- How the Industrial Internet of Things is Transforming Bioprocessing
- A Continuous Confidence Boost
- Getting Ahead of the Game in Cell and Gene Therapy
- The Future of Biopharma – Big Needs and Smart Solutions

How the Industrial Internet of Things is Transforming Bioprocessing

Digitalization means a more productive and adaptive plant through the application of analytics to leverage connectivity and data – maximizing efficiency from people, processes, equipment and core systems. How? By facilitating data driven decisions.

In May 2019, GE Healthcare brought experts together at its Uppsala, Sweden, site for Bioprocess Days: an event to discuss the future of bioprocessing. One of the key themes was the role that digital technology, analytics and data will play. This article was developed based on an interview with Jun Huang (Director/Team Leader; Process Monitoring, Automation and Control at Pfizer) who presented a case study on the "Industrial internet of things" at the event.



Digitalization means different things to different people. For me, it starts with connectivity and data. Pharmaceutical manufacturing generates a lot of data, and in many cases, operations are highly automated, but are they truly digitalized? I think many systems working in silos suggests they are not. For example, does your process control system talk to your quality system? Technologies like the industrial internet of things (IIoT) will release the data that is trapped in these silos by enabling connectivity between systems.

The idea is to combine and contextualize data from disparate sources and different core systems so that you can make it available to the people who need it; this could be an operator on the manufacturing floor, a plant supervisor or a senior manager. Your data would be unified in a central data hub and accessed by the people who need it.

This central data hub could be accessed through a persona dashboard – tailored to the needs of the individual decision-maker. For example, on the factory floor, people would be looking at operating the system in the best and most efficient way, so they might see some quite granular information. The plant manager, on the other hand, would care mainly about key performance indicators and higher-level metrics. And senior management will be keeping track of performance at the enterprise level, across various sites, enabling them to develop a long-term strategy for the entire network.

But a key question is, what exactly are these people supposed to do with all of this centralized data? Data is useless unless you can turn it into an intelligent decision. This is where analytics, AI and machine learning come in. IIoT enables connectivity, data gathering and contextualization, but you need analytics to tell you what to do with it and how to apply it to decisions regarding production.

At a process level, you can use IIoT in combination with advanced analytics in the existing process control system to improve process robustness and increase yield, ultimately enhancing productivity. In the quality and compliance department, the aim is to make sure the product is made within quality specifications. IIoT enables connectivity between quality and the production floor, allowing you to identify deviations quickly and make adjustments. Then at a higher level, realtime changes in demand could inform decisions about production.

These decisions could be made by an operator or a manager, or, in some cases, an automated process control system. Imagine developing a model that, based on data generated by the IIoT, could manipulate your process so that an economic target or quality measure is met. The model might be able to go beyond real-time monitoring and decision making by predicting deviations or failures

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before they occur, and take preventative action.

Overall, digitalization will drive unprecedented levels of visibility, productivity and quality by increasing the connectivity across systems, enabling more collaborative manufacturing and data-driven decision making.

Catalyzing a culture shift

Turning data into intelligent decisions is the goal of digitalization, but to do that, companies must create the right culture. In my view, it is the culture within a company that is the main barrier to digitalization in the pharma industry, as opposed to the technical challenges. New technologies are slowly enabling new ways of thinking and operating, but people must be receptive and mindsets must evolve with the technology.

Oftentimes, people in pharma are very busy and focused on their immediate priorities: from getting products out of the door to good safety standards – digitalization might not be top of their agenda. However, I've also seen other companies who are very progressive, innovative and proactive in adopting new technologies and who are seeing real success stories from their use. I think it's only a matter of time before digitalization becomes widespread within the pharma industry – the clear benefits will make it so. But the first step is perhaps to develop pilot studies or create user cases to demonstrate the value of digitalization to pharma businesses, before rolling out these new technologies and practices across sites. Of course, it would be remiss of me not to mention the regulatory challenges of implementing, say, an AI-based GMP solution for commercial manufacturing. Working to ensure new solutions are in line with regulatory requirements is an important challenge to overcome, but a lot of positive conversations are happening in this area.

We've only scratched the surface of what's possible with digitalization. Technology continues to evolve, and the opportunities are almost endless. New technologies such as smart and wireless sensors that will transmit into your IoT platform to remotely monitor equipment, cloud computing, 3D printing, augmented and virtual reality will all be part of the digital revolution and I can't wait to see where they lead the pharma industry.

Read more on digital transformation in biomanufacturing: bit.ly/2KVZ7bz

Building the Brilliant Factory

Jun Huang believes we're still scratching the surface of what's possible with digitalization. As Chief Digital Officer at GE Healthcare Life Sciences, Ben Newton is also optimistic about the future. He believes that digital technology could be used to build "the brilliant factory."

What developments have had the biggest impact in your field over the past five years?

I am excited by the increasing sophistication of cloud-based technologies, which allow us to compute large amounts of data in the cloud remotely. We are also seeing the emergence of technologies that extract data from patients or equipment through wearables and sensors. Then, we also now have the ability to aggregate that data in a structured way so that we can start to make predictions about disease and manufacturing methods (big data). Coupled with the digital revolution has been an increase in our knowledge of disease processes and how to use the immune system to treat cancer and this could have a real impact on how we address disease. It's a fascinating time to be involved in the industry.

What is your vision for the future of manufacturing?

We need to bring all of the pieces that we are working on together under the roof of what we might call the "brilliant factory." Right now, many in the biopharma industry are working on optimizing the cell culture and upstream process by developing smarter ways to define the right kind of process for the production of antibodies and cell therapies. We're also defining the tools to separate and purify those antibodies cost-effectively with multivariate analytics tools. And to support manufacturing, we're developing digital twins to optimize and control processes. At the moment, we're doing these things somewhat in isolation but if we can bring them together in a single manufacturing setting, where every step is optimized, and the data is aggregated and analyzed by AI, you can create a system that can learn which factors are important for optimization and that is able to self-validate to automatically improve processes. This vision of a fully automated intelligent system is what we should be aiming for.

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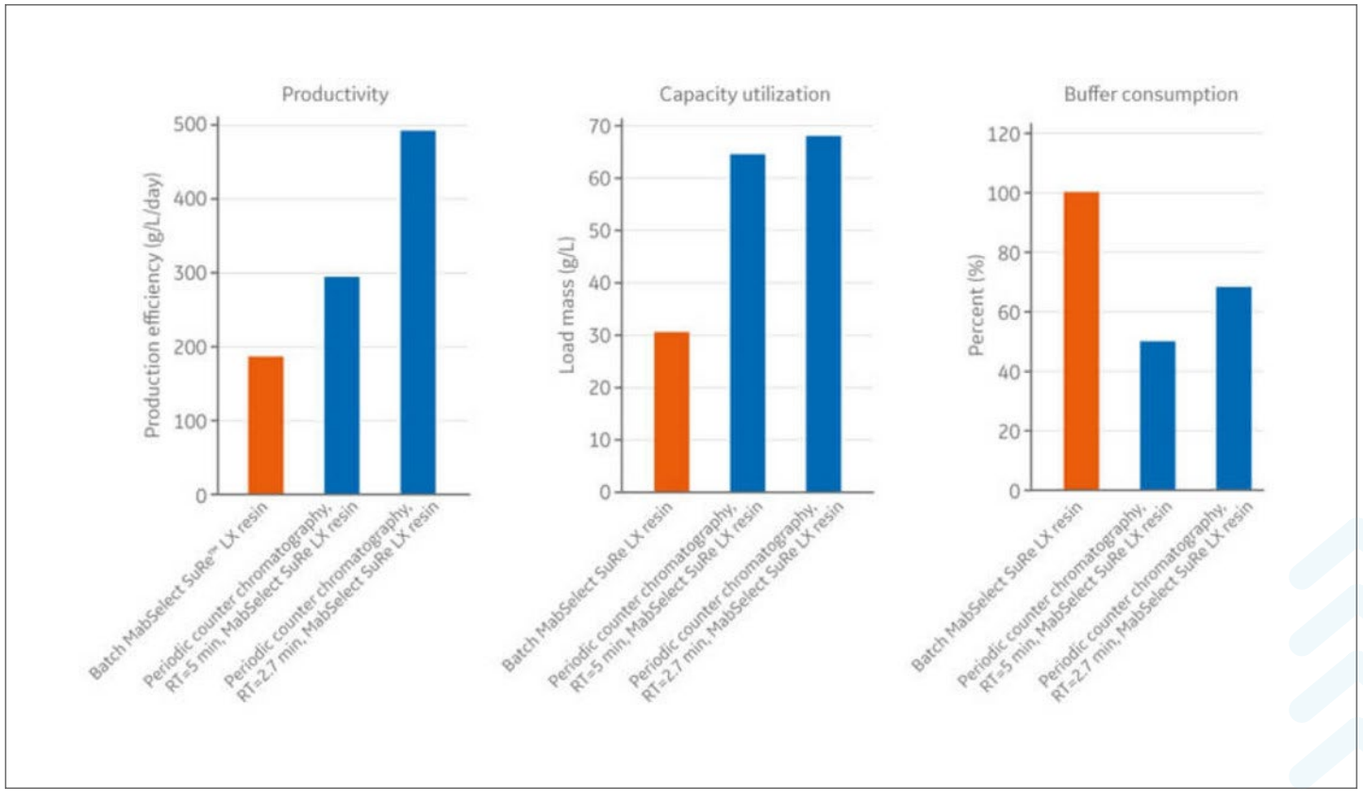
A Continuous Confidence Boost

Higher productivity, lower hold times, lower costs... Continuous processing of monoclonal antibodies could offer a number of advantages, but regulatory uncertainty and upfront investment remain sticking points. As increasing numbers of case studies emerge, the industry looks set to receive the confidence boost it needs to facilitate widespread adoption.

In May 2019, GE Healthcare brought experts together at its Uppsala site in Sweden for "Bioprocess Days." With a focus on the future of bioprocessing, one key theme of the event was continuous biomanufacturing. Here, we present an article based on an interview with Wei Gong – Director at Henlius Biotech, Shanghai – who presented a cast study at GE Healthcare's "Bioprocess Days" on "Continuous Manufacture in mAb Production."



The monoclonal antibody (mAb) field has exploded over the past few years. Case in point; 21 of the 81 mAbs approved since 1986 came in 2017 and 2018. In fact, 49 percent of all global drug sales in 2017 were for antibody drugs – a remarkable statistic. The industry appears to set to continue its upward trajectory, with one analysis projecting a compound annual growth rate of 6.3 percent to reach $131.8 billion by 2023, from $91.1 billion in 2017 (1).

As the biopharmaceutical industry matures, it has been debating which next wave of new technologies will further enhance industrialization of the sector, with the main goals being to improve manufacturing speed, flexibility, and quality, while reducing costs. To that end, several companies, including Henlius, have been evaluating connected and intensified bioprocess steps – and considering how a fully continuous process may look in the future.

Catching up with the curve

Many industries are well ahead of pharma when it comes to adopting continuous processes. In fact, the photo film industry moved from batch mode to continuous production processes in the 1890s! Petrol followed suit in the 1920-40s, and then food in the 1950-80s. For pharma industry, the progress is still ongoing – even for the small molecule sector. For mAbs and other biotherapeutics, continuous processing technologies are very much in their infancy. Noetheless many companies are beginning to see the advantages continuous manufacturing can bring – particularly when it comes to cost savings. For example, by reducing facility and equipment footprints (no hold tanks, smaller bioreactors and chromatography columns) and boosting productivity, continuous processing promises much lower capital costs over the long run. A highly automated system can reduce the amount of operator labor required, and human related errors – both of which feed back into overall cost reductions.

One of the most important advantages of continuous manufacturing is the improved resin capacity utilization with continuous chromatography systems, which leads to lower buffer volumes (and therefore manufacturing costs). We set out to discover whether this would play out in practice by comparing a protein A capture step using batch chromatography system with a periodic counter current chromatography (PCC) continuous set up.

Protein A has grown in step with the antibody market. The first time Protein A was used commercially as a capture step in the purification process was for the first therapeutic antibody, approved by the FDA in 1986 (2). But the Protein A capture step is usually

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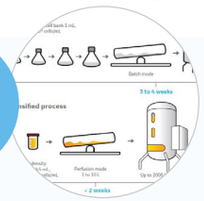

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the main cost-driver in downstream processing, with very high attrition costs. A continuous setup involves the sequential use of two columns in a chain such that, as the first column is launched, it is captured by the second one – allowing for continual loading.

With this setup, we found that continuous chromatography increased productivity by 1.5-2.5 times, resin utilization by 1.5 times, while also reducing buffer usage by 60 percent – depending on the residence time. This translates to lower resin consumption, higher productivity and reduced capital investment overall (see box, A Continuous Case Study, for a detailed breakdown).

These results were very promising, but there were a few issues that should be taken into consideration. The first is that there will always be some overload issues in a continuous mode, which may reduces the lifetime of Protein A resin. But we were surprised to find in our lifetime studies that the most important parameter wasn't the fouling of the Protein A resin, but instead the CIP conditions used. We found that the collected elution amount of mAb from each cycle during overloading of the column only decreased by around 20 percent over 200 cycle resin lifetime, which was very positive. We also looked at impurities and found that remaining host cell protein levels and protein A leakage were consistent over cycles. Overall the quality performance was similar between the continuous mode and to batch mode.

The path to adoption

Despite the strong theoretical basis for adopting a continuous approach to antibody manufacturing – backed by a growing number of case studies demonstrating the practical benefits – adoption is low. A key reason is cost; implementing new technology can be very expensive and few companies want to pay the upfront cost. Another potential barrier is the knowledge required to implement new processes; there are still many questions and a lack of experience with continuous processing as a whole. What should a continuous bioprocess look like? What are the best technologies? And although regulatory agencies have encouraged companies to adopt continuous manufacturing, there are still some details missing in their guidance.

As more companies take the plunge and as we see increasing success stories with continuous manufacturing, confidence will grow and adoption will increase. I see continuous manufacturing as a package of technologies – intimately connected with "industry 4.0" technologies. The current buzz around "digitalization" could help the adoption of continuous manufacturing across the pharma industry (3). For example, creating an effective continuous process is impossible without process analytical technology (PAT). PAT allows for instant feedback and optimization through online sensors, sampling and testing, plus real-time feedback control – it's like the eyes of a continuous process! Continuous processes will also require automatic control systems, where data is centralized, allowing communication between various machines and improving data integrity. The idea of automated "lights out" manufacturing intelligence will have to be combined with a continuous approach, without manual changeovers and monitoring. In fact, adopting digital technologies are key to successfully achieving continuous production and I see the emergence of both continuous manufacturing and digitalization driving each other forward.

Another crucial factor for the successful implementation of a continuous process is a verification strategy. Quality by Design is essential for continuous manufacturing, as are the control strategy and the viral clearance processes. The downside to a continuous process? Although the risk of a contamination event is lower because there are fewer manual interventions, if a contaminant does get in, it can quickly spread through connected systems. New purification processes will be crucial, such as continuous chromatography (as discussed earlier), single pass ultrafiltration/diafiltration (UF/DF), in-line conditioning, membrane technology and continuous clarification. And, of course, the industry will require regulatory support through additional guidance documents.

With so many companies showing interest in continuous processing, I have no doubt that we will conquer these challenges.

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2. *B Lain, "Protein A: the life of a disruptive technology", BioProcess Int., 11, 29–38 (2013).*
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A Continuous Case Study

A more detailed breakdown of Henlius's continuous chromatography case study.

- For individual columns, cycle time was reduced from 3/4 hours to 1-1.5 hours.
- Load limit increased to 60-80 g/L with continuous manufacturing, compared to 44 g/L with batch mode.
- Production efficiency increased to app. 500 g/L/day when using PCC, compared with just under 300 g/L/day when using the batch MabSelect SuRe LX.
- Capacity utilization increased from just over 30 g/L with batch to over 65 g/L with PCC.
- Buffer consumption increased from 100 percent with batch to as low as 50 percent with PCC.

Getting Ahead of the Game in Cell and Gene Therapy

Successes in the clinic have placed many cell and gene therapies on an accelerated route to market. But unless developers consider, at an early stage, how they might produce their product at scale, they may run into problems with commercial manufacturing.

Here, we present an article based on an interview with Carol Knevelman (Vice President, Head of Process R&D at Oxford Biomedica), who shared a case study at GE Healthcare's "Bioprocess Days" on large scale lentiviral vector production. Carol offers her advice for developing a futureproof commercial process.

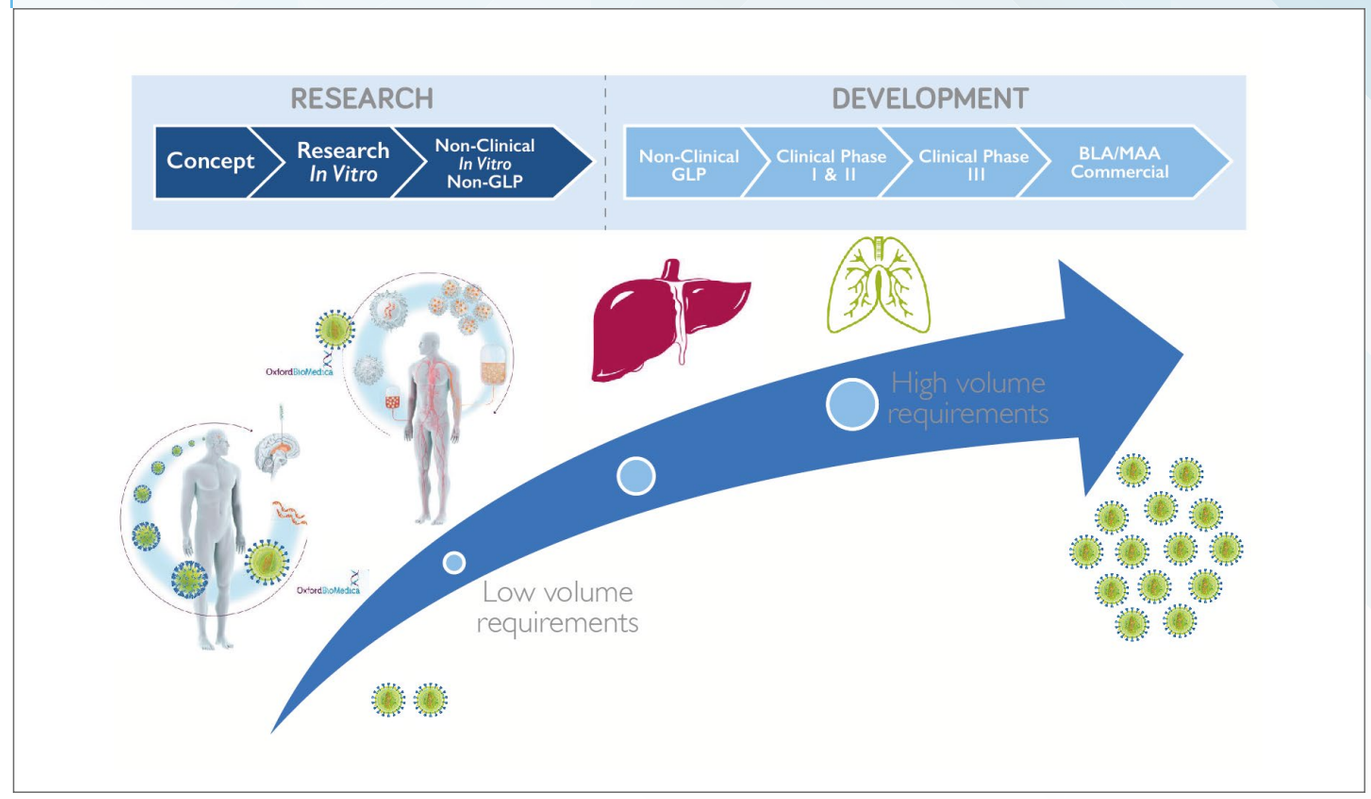

Figure 1: Typical manufacturing strategy considerations.

Many cell and gene therapies are on an accelerated route to market – sometimes skipping phase III trials entirely. With early stage development so close to commercial launch, there's little time to develop an appropriate manufacturing process for commercial supply. This can leave the commercial process looking rather different in terms of production modes and impurity profiles compared to the initial process, and this may necessitate lengthy bridging studies. Because of the fast track nature of these therapies, process knowledge can also be lacking, which can result in extended process characterization studies. All of these factors can delay time to market. Another problem is that the differences between European and American regulatory frameworks can be difficult to navigate.

In the current landscape, most of these therapies come from an academic research environment where, at the preclinical stage, many of the materials used are marked for research only, and are often undefined and uncontrolled. At the clinical stage, these materials must be replaced with GMP-grade materials where it can be difficult to find alternative suppliers or certified materials with equivalent properties. As you transition to GMP-grade materials, the risk associated with the process will decrease, but this will come with greater costs – especially with cell and gene therapies, where products can be priced at $0.5 million to $2.2 million per treatment. We found the complexity of the supply chain for our initial adherent process to be particularly challenging when moving into the clinical arena. Oxford Biomedica had 54 global suppliers for over 400 different components with this process – operating at varying temperatures. There were over 1000 line items required for each batch, which, as you can imagine, created considerable risk. This was considerably streamlined prior to process performance qualification.

Building a vector

Given the myriad challenges, how did we develop a workable manufacturing plan for a commercial process? Speaking from our experience in developing lentiviral vectors for cell and gene therapies, as well as working with companies to apply our technologies to their manufacturing processes, the first step to success involves

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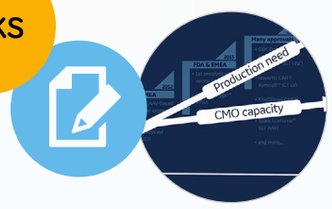

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understanding what is required for your therapy to succeed. For example, the therapeutic area will influence the amount of vector that needs to be made; programs that deliver therapies directly to the brain will have vastly lower volume requirements compared to therapies delivered to organs such as the liver or lungs.

Investing early to get ahead of future demands is also important. For our process, we invested early in suspension cell culture, which is serum and animal component free. Suspension processes can be scaled up relatively easily and can operate in fed-batch or perfusion mode to deliver productivity gains. But there were still many challenges. Vectors are incredibly fussy and sensitive to almost anything that is required for successful manufacture in suspension: pH, temperature, shear forces and so on. Removing impurities within the product stream is also difficult because of salt sensitivity, the mixture of host-cell protein and DNA, plasmid DNA, as well as empty, inactive vectors that can't transduce your target cells.

The solution was to select appropriate scaled-down models for process development. This was crucial given that development at the larger scales would be very expensive with our process! These scaled-down models allowed us to identify the optimum physio-chemical environment within our bioreactors. We were also able to identify initial critical process parameters, as well as much of the necessary engineering characterization to define the scaling criteria required to move forward. Once we had this knowledge, we were able to then identify GMP systems on the market that could satisfy our requirements – in our case, these were all single-use. The preparatory work allowed us to cut costs by minimizing the number of the scale-up evaluations that are typically needed – which is also beneficial because it can reduce overall development timelines and enable faster market access.

Future challenges

Although the majority of development work was performed in the scaled down models, there were some elements that required evaluation at larger scales. For example, in transitioning from an adherent process to a suspension process, we saw an iterative improvement in upstream titers by a factor of 10 to 20 fold, plus the three fold increase in scale. The increased titers, however, did not initially fully translate from our 5 L scale down bioreactors to our larger scale bioreactors. However, after identifying where the problems were with additional process development, we were able to achieve the same titers in our 50 L and 200 L bioreactors as in our scale down models.

This is sufficient for many of the vector quantities that are required by our partners and should see them through commercial supply for their therapies. But it's still not enough for some indications we're working with, so we will continue to innovate to ensure that we're able to deliver sufficient vector for all indications One such innovation is in an automated cell screening system we have invested in to speed up the selection of cell lines for our packaging and producer cells.

Demand for vector product will only increase throughout the industry as it matures. Indeed, there is already a shortage of vectors as current technologies struggle to keep pace with the expansion of gene therapies from ultra-rare to larger indications. I believe that the success of the industry hinges, in part, on further innovation in vector production platforms and vector purification, in particular. Vendors must continue to improve the scalability and availability of their systems. Here, much can be leveraged from the pharma industry.

I envisage the cell and gene therapy industry transitioning to more intensified processes through integrated continuous processing, automation and digitalization for data management, and single-use systems to improve speed to market. These provide opportunities for achieving cost-efficient, large-scale vector production and achieving the right quality to meet patient needs.

Enabling Technologies

With Lorenz Mayr, Chief Technology Officer, and Catarina Flyborg, General Manager for Cell & Gene Therapy, both at GE Healthcare Life Sciences

How can the gene therapy sector realize its potential?

Mayr: There is a great deal of discussion in the cell and gene therapy industry about the costs of these therapies. Pricing and reimbursement strategies are, of course, important, but developing enabling technologies to revolutionize how these therapies are produced will be vital to reducing production costs and, ultimately, prices for patients.

I believe that automation and digitalization is key to industrializing these products and unlocking the tremendous potential of the sector. Gene therapies are very specific, bespoke products, but we must find a way of effectively scaling out and making them available to a wide range of people. At GE, we believe biology and technology is converging and this is what we as a company in the biopharma space are particularly good at.

Flyborg: I agree with Lorenz, industrialization will be key. The big challenge moving forward is developing closed, automated and digitalized manufacturing platforms. But, as Carol has laid out, gene therapy developers must be thinking about these things much earlier in development – even at the preclinical stage. And when it comes to digitalization, we need solutions that both monitor and allow us to improve processes through analytics. There is also the possibility of using technology to select the right patients based on how they may respond to a given treatment.

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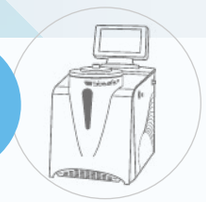

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The Future of Biopharma – Big Needs and Smart Solutions

The biopharma industry is changing but we must never forget unmet needs when developing new medicines.

We interview Günter Jagschies, Senior Director, Strategic Consumer Relations at GE Healthcare.

Why do you find the biopharma industry so inspiring?
One of my personal areas of study and research is the global healthcare situation, particularly the economics and affordability of healthcare. I am passionate about biopharma's role in bringing forward new treatments and solutions for the biggest healthcare problems. The industry has made incredible advances – and this is what motivates me day to day. We work with many different pharma companies, so are involved with a huge percentage of drugs that come to market. I always wanted to be a biochemist and I was very drawn to biopharma. I've never looked elsewhere and I've never worked for any other company either. Today, I have an ambassador role for the business. I do a lot of traveling, giving customer seminars, offering advice, speaking at conferences, and publishing articles. It's really exciting to share knowledge in this way.

What are the biggest advances to come out of the biopharma field?
When I started out in the industry, biopharma was just starting with insulin and the first proteins. For many years, there was only one insulin drug available and then slowly the others started to come through. And now there are many different options for patients! The industry has also diversified from smaller proteins made in bacteria to incredibly large, complex constructs and viruses. And the revenue coming into the industry is now huge.

Manufacturing technologies have also come a long way. There is now increasing use of single-use systems and hybrid technologies, but I think that it is the increases in the productivity of bioreactors that have had the biggest impact. In the last five years, we have gone from titers of around 5 g to 50 g per liter. Five years ago, no one would have thought such high titers would be achievable. Now, it is possible to get the amount of product required from

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one bioreactor, which opens the door to smaller facilities with a lower CapEx.

What is your vision for the future of biopharma facilities?
My vision for the future is smart and small – with increased flexibility and productivity. Digital tools will play an important role in the factory of the future, integrating all aspects of process monitoring and allowing manufacturers to make rapid decisions or corrections in real time. Biopharma facilities will also be small, working either with just one product in a large quantity or with multiple products, and most likely using connected processing.

Where do the main opportunities lie in the field?
Unmet medical needs should be the focus. There are still many diseases that have no treatments at all, so there are plenty of opportunities for companies to develop new drugs to treat the symptoms of certain diseases, or even cure the disease completely. Today, with the advent of cell and gene therapies, there are so many more options when it comes to developing treatments. We also shouldn't forget new vaccines – prevention is always better than cure!

The biggest opportunities lie in some of the most difficult areas: cancer, Alzheimer's, Parkinson's and even diabetes – which is still not fully understood. The industry should not give up on these challenging fields because there will be huge rewards for the companies that make an impact on any of these diseases.

Which challenges will require the most focus?
The greatest challenge now is the affordability of the new medicines developed. In the press and media, there are new stories every week about how expensive some of these drugs are. On one hand it may cost $1000 per year for insulin treatments, on the other hand there are therapies costing over $500,000 per patient, per year. It's obvious that few people (or governments) can afford that. We need to find a way to bring the price down. Some of this may come from new advances in manufacturing, but it may also be that the industry's business models need to change – perhaps being paid for success. And that's not easy because it goes against corporate dogma. But some companies are willing to embrace new ideas; Novartis, for example, demonstrated its openness for new payment models with Kymriah and has been exploring an outcomes-based payment model for the therapy in some countries. I don't think it is quite clear yet exactly how payment models like this will work in broader patient populations, but it's a step in the right direction. It should also be noted in this context that the pharma industry is not the only driver of healthcare costs – there are many other factors that impact the situation, such as hospital systems, insurance and general complexity in terms of how healthcare is delivered.

Ultimately, many medicines are only available to a very small percentage of the global population. We need to aspire to treat every patient in the world – and that means we need some good solutions to the affordability challenge.

Patients Need Better Biosimilars

When it comes to meeting unmet needs, biosimilars have a huge role to play, as they introduce competition to the market that can help to bring down the cost of expensive biopharmaceuticals. However, there is also an argument that biosimilars are not enough – why not update and improve on existing biologics with biobetters? Another speaker at the "Bioprocess Days" event was Soon Jae Park, CEO of Alteogen, who gave insight into the challenges of establishing a biosimilars business in South Korea.

Have you always worked with biosimilars?
After studying for my post-doc in the US, I joined LG Life Science, which was, at the time, known as LG Chemical. The company was the first in Korea dedicated to biological drugs – both new biological entities and biosimilars. I was one of the early members of the company and, during my time there, I worked on many biosimilar programs. We were one of the first biosimilar companies in the world and we obtained European approval for a human growth hormone biosimilar in 2006.

I started Alteogen in 2008 with Hye-Shin Chung – and she is our Chief Scientific Officer today. Our focus is on next-generation biobetters with improved efficacy.

What main challenges have you faced?
A few years ago, Korean biotech companies could not get enough funding because there was a perceived lack of value in the country's biotech. This also impacted us – the slow supply of funding made it very difficult to accelerate our program! Fortunately, the situation is quite different today and there is a lot more venture capital funding available for biotech – in fact, it's one of the top sectors for investment and is also attracting investment from overseas.

How can biosimilars be made better?
We focus on three areas: long-acting biobetters, proprietary antibody-drug conjugates, and antibody biosimilars with complexity. We have developed some special technologies to help us. Our NexP Fusion Technology, for example, increases the half-life of any biologic using DNA recombination and human A1AT, and means that the drug needs to be administered less frequently. We also use our NexMab ADC Technology and Hybrozyme Technology.

What do you enjoy most about the sector?
A friend of mine develops smartphones but, after six months, a smartphone is out of date. Things can change very quickly and it can be challenging to continually innovate in such a competitive landscape. Pharma and biotech have much longer timelines but it means that even if there are setbacks in the middle of the pathway, there can still be room to recover. Of course, sometimes it takes too long to develop something in the biotech world but the important part is that there is an end goal in sight. Eventually, we will arrive at that goal. And if you enjoy the journey then it's a very good sector to work in!