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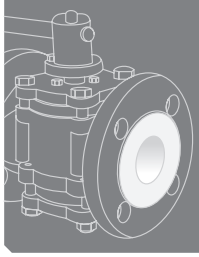

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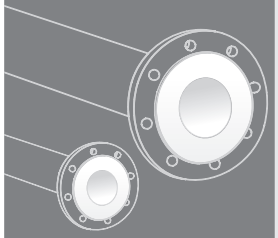

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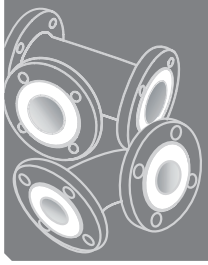

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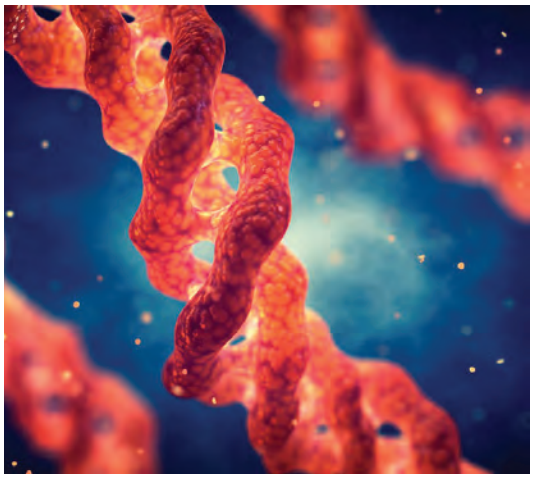

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Lincoln Pharma Reports Highest Revenue, EBIDTA, Net Profit in FY22

Mahendra Patel, MD, Lincoln Pharmaceuticals Limited

Ahmedabad, India: Lincoln Pharmaceuticals Limited has reported its Best-ever results in a financial year with highest - Revenue, EBITDA and Net Profit for the FY ended March 2022. Company has recommended a dividend of 15%, Rs. 1.50 per share on the face value of Rs. 10 per share for the FY 2021-22.

Company reported net profit of Rs. 69.36 crore for FY22 as against net profit of Rs. 62.25 crore in the corresponding period last year, growth of 11.42%. Net revenue from operations for FY22 was reported at Rs. 472.08 crore, higher by 11.63% over previous fiscal's same period revenue of Rs. 422.91 crore. Company reported EBITDA of Rs. 105.47 crore in FY22, rise of 13.67% as compared to EBITDA of Rs. 92.78 crore in FY21. EPS for FY22 was reported at Rs. 34.63 per share.

Commenting on the results and performance, Mahendra Patel, Managing Director, Lincoln Pharmaceuticals Limited, said, "We feel proud to inform all our stakeholders that the company is progressing well on its long-term growth roadmap. Company has reported excellent numbers for FY 2022 with highest Revenue, EBITDA and Net Profit reported on a yearly basis. With a robust performance, the company has recommended a dividend of Rs. 1.50 per share. Company's expansion plans for Cephalosporin products and foray in EU and Australian markets are also progressing well. Company is growing strength to strength, delivering robust operational and

financial performance maintaining healthy growth in revenue, margins and profitability. We expect the growth momentum to continue and expect to get further boost in coming years."

Biocon Biologics and Viatris Launch AbevmyR (bBevacizumab), their Third Oncology Biosimilar

Bengaluru, India: Biocon Ltd., and Viatris Inc. announced that Abevmy® (bBevacizumab) is now available in Canada. Abevmy, co-developed by Biocon Biologics and Viatris, is a biosimilar to Roche's Avastin® (Bevacizumab) and has been approved by Health Canada across four oncology indications.

Matthew Erick, Chief Commercial Officer, Advanced Markets, Biocon Biologics, said: "With the launch of Abevmy, (bBevacizumab), we are adding another world-class biosimilar to our oncology portfolio in Canada, which

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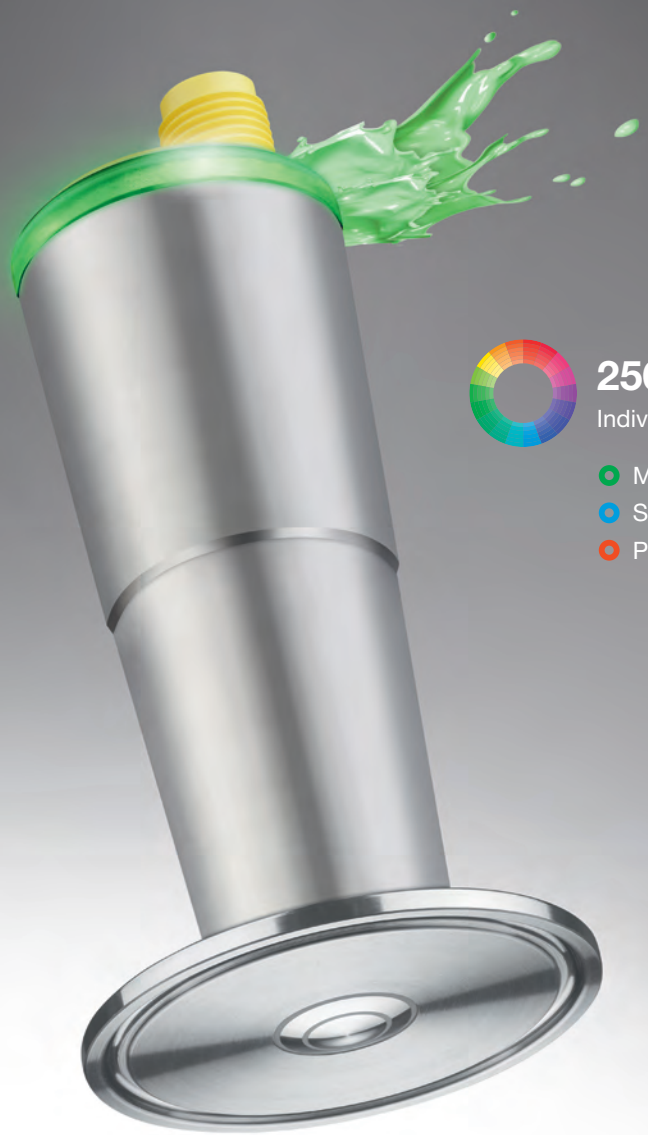

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includes Ogivri (Trastuzumab) and Fulphila (Pegfilgrastim). Abevmy will be an important addition to our existing portfolio and will enable us to expand patient access to another affordable biologic for cancer care."

Viatris Canada Country Manager David Simpson commented: "With patients at the heart of what we do, we are proud to bring Abevmy to market to provide increased access and affordability in oncology. Abevmy is the fourth biosimilar to be offered by Viatris in Canada and our third to support patients living with cancer. Our vast experience in biosimilars has resulted in a substantial oncology portfolio which expands choices for patients across the nation."

Abbott Launches HBsAg that Accelerates Early & Enhanced Detection of Hepatitis B

Dr. Jaganathan Sickan, Senior Associate Director, Medical Affairs, Core Diagnostics, Abbott

Mumbai, India: Global healthcare leader Abbott has announced the launch of the HBsAg Next Qualitative solution in India to enhance detection of the Hepatitis B virus (HBV). This assay will help improve patient outcomes while maintaining safe blood supplies. This highly sensitive chemiluminescent microparticle immunoassay (CMIA) assists in the early and enhanced detection of HBV in human serum and plasma (blood) samples and in population screening. A chemiluminescent immunoassay is a variation of the standard enzyme immunoassay, a biochemical technique used in immunology.

Early identification of HBV infections allows patients to receive the necessary care to prevent or delay progression of advanced liver diseases. Moreover, it also reduces the risk of transmission.The HBsAg Next Qualitative assay is an advanced, next generation solution to better support the earlier detection of HBV. It detects HBV surface antigen (HBsAg) in human serum and plasma. Moreover, it overcomes traditional challenges by showcasing the highest level of assay performance required to detect infection in immunocompromised groups.

Dr. Jaganathan Sickan, Senior Associate Director, Medical Affairs, Core Diagnostics at Abbott said, "In India, Hepatitis B screening is vital since it is vastly under diagnosed. With HBsAg Next qualitative assay, laboratories in India can now detect HBV earlier than ever. This will help physicians identify at risk patients sooner, which in turn leads to early treatment and care. This assay represents the next generation of HBV diagnostic performance and will enhance our comprehensive infectious disease portfolio."

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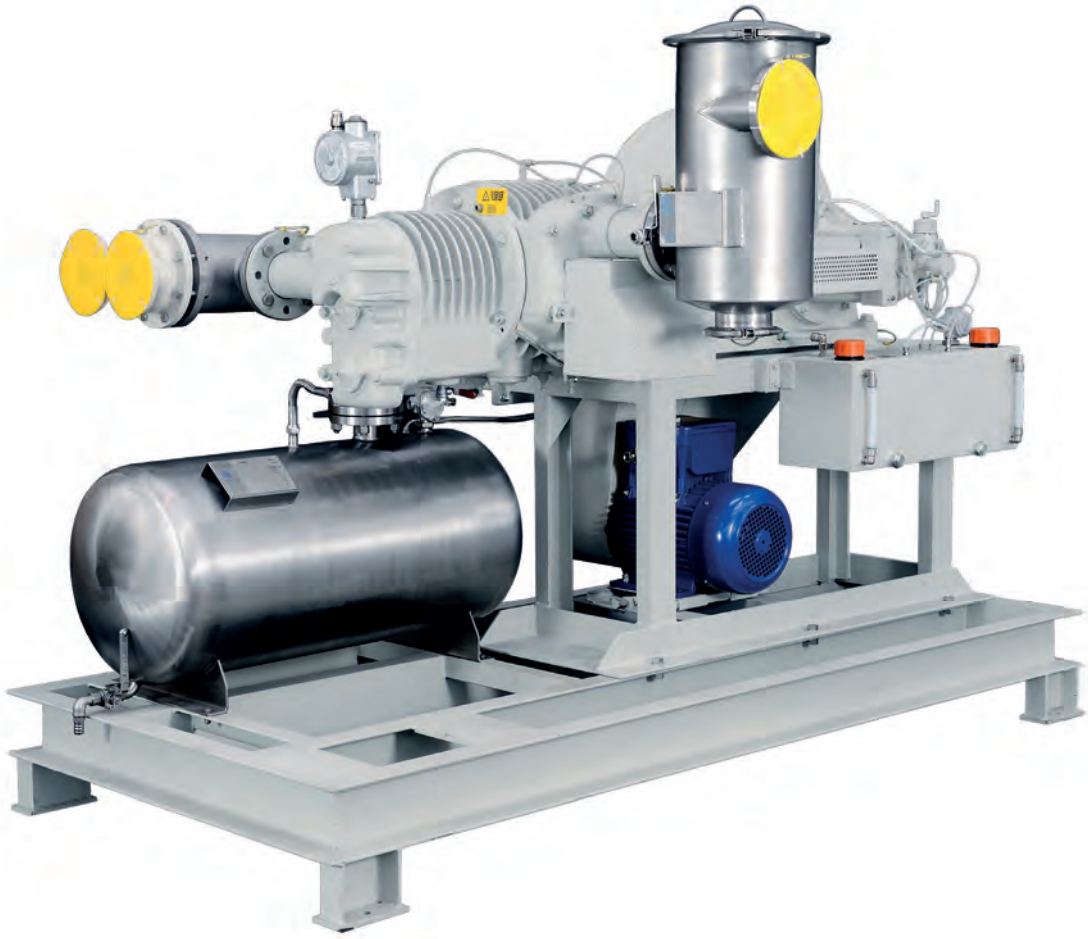

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Hepatitis B is a liver infection caused by Hepatitis B virus. It can be acute or chronic, with chronic cases potentially leading to liver failure, cirrhosis, or liver cancer. About 296 million people worldwide currently live with chronic hepatitis B, with 10 to 15% of the world's HBV carriers (40 million) found in India alone. Moreover, co-infections with HIV are also prevalent, with roughly 1 in 10 people living with HIV estimated to have Hepatitis B. However, Hepatitis B virus is often silently undiagnosed, with only 10.5% of all people estimated to be living with Hepatitis B aware of their condition.

Rajsha Pharmaceuticals raised ₹2.5 crore in Equity Funding Boosting Expansion

Ahmedabad, India: Rajsha Pharmaceuticals announced the dilution of its majority stake with an Ahmedabad-based Pharma Group. Funds received from stake dilution will accelerate the expansion of the production capacity and add to the growth capital of Rajsha Pharmaceuticals.

Founded in December 1986 by Rajendra Shah, Rajsha Pharmaceuticals is one of the fastest-growing Ahmedabad based Ayurvedic pharmaceutical companies engaged in developing, manufacturing and marketing a broad range of Ayurvedic Cream and Ointments, Churna, Syrup and Suspensions, Granules, etc for the domestic market. The company holds numerous certifications for producing quality products, including US-FDA approval for one of its products. Their products are available globally as well. The company has been witnessing exponential growth in demand for its products, needing Rajsha Pharmaceuticals to scale up its production facility, which in turn created the need for infusion of working capital. For assistance in finding the right strategic investor, they approached GetFive Corporate Advisors LLP, an Ahmedabad-based boutique Investment Banking and M&A Transaction Advisory firm.

After due diligence GetFive team advised that bringing in the investor who will provide room for production and capital for new machinery to aid the company's growth. The team approached several investors. They found the right valuation with an Ahmedabad-based Pharma Group, whom they helped close as an investor. The entire project was done on a hot-footing and turned around in 3 months.

An elated Rajendra Shah, COO, Rajsha Pharmaceuticals, said "We approached Getfive Team for bringing in the investor; their recommendation on selling the majority stake in the company to get an investor who could enable our growth quickly was invaluable. The Guidance and support from Anand Sanghvi and Shrikant Goyal during the pitching and the consequent closure helped reduce the turnaround time."

Commencement of Pharmira Co., Ltd., a Joint Venture for Contract Development and Manufacturing of Active Pharmaceutical Ingredients and Intermediates

Tokyo, Japan: Shionogi Pharma Co., Ltd. (headquartered in Settsu, Osaka; President & CEO: Ryuichi Kume; "Shionogi Pharma")

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, Chiyoda Corporation (headquartered in Yokohama, Kanagawa Pref.; President & COO: Masakazu Sakakida; "Chiyoda"), Taisei Corporation (headquartered in Shinjuku-ku, Tokyo; President & CEO: Yoshiro Aikawa; "Taisei"), Fujimoto Chemicals Co., Ltd. (headquartered in Chuo- ku, Osaka; President & CEO: Kazumasa Fujimoto; "Fujimoto Chemicals"), Takenaka Corporation (headquartered in Chuo-ku, Osaka; President: Masato Sasaki; "Takenaka"), Yokogawa Electric Corporation (headquartered in Musashino City, Tokyo; President & CEO: Hitoshi Nara; "Yokogawa Electric"), and Nagase & Co., Ltd. (headquartered in Chuo-ku, Tokyo; Representative Director and President: Kenji Asakura; "Nagase") announced that Pharmira Co., Ltd. in which the seven companies invest, has commenced development of a technology for Continuous Manufacturing (CM) of active pharmaceutical ingredients (APIs) and intermediates and a contract development and manufacturing business using CM technology.

Project outline: Aiming to transform the manufacturing technologies of APIs and intermediates, companies with specialized technologies and functions have come together to carry out contract development and manufacturing services. Following drastic changes in the environment surrounding APIs and intermediates in recent years, further acceleration of pharmaceutical development and building a stable supply network for APIs have become urgent issues, especially against the threat of infectious diseases. By introducing CM technology as an innovative new technology in response to these environmental changes, it is expected that the time required for development of manufacturing methods in the pharmaceutical development stage will be shortened. CM technology is also expected to improve the efficiency of commercial production of pharmaceutical ingredients by conserving manpower and space and to enable advanced quality assurance for high-quality pharmaceutical products.

In order to meet diverse customer needs, the joint venture will use both well-established batch manufacturing technology and innovative CM technology to provide full-range, one-stop manufacturing services of APIs and intermediates, from development of drug manufacturing methods to manufacture of APIs for clinical trials and commercial production. Upon introduction, CM will be applied mainly to the reaction and crystallization processes, which are expected to have significant benefits by switching to CM. By applying CM from the development stage, it is possible to accelerate the development of pharmaceutical products while ensuring high quality and process safety.

By contributing to greater efficiency of new drug development and a stable supply of high-quality drugs, the joint venture will strive to advance and improve the global medicine environment. ■

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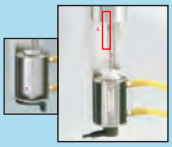
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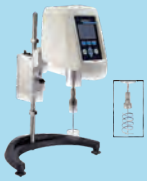
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De-bottlenecking Scale-up Challenges for Large Scale Viral Vector Manufacturing

Manish Kumar
DGM, Drug substance development,
Stelis Biopharma

Prateek Gupta, PhD
Vice President and Head, Process Development & MSAT,
Stelis Biopharma

The rush to develop an affordable and accessible COVID-19 vaccine not only accelerated research and development of therapeutic modalities like viral vector, mRNA and pDNA based vaccines but also challenged the bioprocess community to solve for unique scale-up related challenges to manufacture these important life-saving medicines. This article illustrates our current thinking and experiences on debottlenecking potential challenges to scale adenoviral vector technology at 2000 L and beyond.

Adenoviral vectors are attractive vectors for delivering genes into specific human cells, either for covid19 vaccine or other gene therapy applications1,2. These vectors can accommodate large transgenes, transduce quiescent and dividing cells, and do not integrate into the host's genome. Adenoviral vector technology using HEK293 host cells has been around for a long time and the manufacturing process (as illustrated in Figure 1) include combination of HEK293 growth and infection phases during upstream processing, followed

by series of filtration, concentration and chromatography steps during downstream processing to produce drug substance with high purity. Although, the process unit operations seem uncomplicated, manufacturing at large scale has remained a major challenge due to poor and inconsistent cell growth, low viral titers, product aggregation, inefficient separation of empty and filled viral capsids, as well as operational complexities related to handling large volume viral infection. The expected challenges during process scale-up and possible mitigation strategies have been detailed in Table 1.

Upstream Challenges & Mitigation Strategies

The entire gambit of HEK293 based viral vector serotype production in large scale bioreactors revolves around three factors: optimal HEK293 cell growth during scale-up stages, high-quality viral seed to achieve optimal Multiplicity of Infection (MOI) and optimal process parameters to maximize viral titer output during production.

Although HEK293 cells have been significantly utilized for biopharmaceutical applications, it is critical that optimal media, supplements and process parameters are selected to avoid cell clumping, lag in cell growth and drop in viability. The typical cell culture parameters like pH, temperature and dissolved oxygen levels are usually well controlled in bioreactors, however growth of HEK293 cells demonstrate higher sensitivity to dissolved CO2 levels, osmolality, media feed strategy, and metabolite levels relative to other commonly used mammalian cell types. Hence, developing control strategies to control these important parameters is highly critical to achieve consistent cell growth and product titers.

The quality of viral seed used to infect the HEK293 cells at various scale up stages during manufacturing is another important parameter, since it defines the number of viruses available to infect a single HEK293 cell during production and hence, impacts the batch output in terms of viral titer. One of the most important factors to avoid is cell clumping, which can lead to sub optimal growth and loss of infection efficiency leading to lower productivity at the end of harvest. While in some cases, addition of anticlumping agents may help in solving the clumping issues, in most cases suboptimal agitation is the root cause. Hence, agitation rates need to be optimized with well-designed strategies (P/V, KLa, Shear stress, Tip speed etc.) to avoid any mass transfer limitation and mixing limitation but at the same time maintain low shear stress. Additionally, viral titer quantitation analysis (with significantly shorter TAT) needs to be developed to reliably estimate MOI, which

is consequently used to calculate viral seed volume for infection.

Finally, the viral titer productivity at the end of harvest can be significantly impacted by parameters during the infection phase, including temperature, optimal cell cycle phase, cell density at the time of infection, infection duration as well as culture pH. These parameters need to be carefully optimized using a multivariate design of experiment approach to achieve maximum viral titer output.

Downstream Challenges & Mitigation Strategies

The major challenge in large scale downstream manufacturing is inconsistency in recovery product quality and stability at the end of purification process. Viral particles are prone to aggregation, which could be induced by pH, thermal or mechanical stress during various unit operations3. These aggregated particles bind non-specifically and strongly to the resin leading to major product loss. To minimize loss due to aggregation, the entire midstream and downstream needs to be carefully designed. Unit operations like cell lysis, endonuclease treatment and TFF need to be optimized to avoid shear stress which may also contribute to lower aggregation of viral particles. While some of the stabilizers in the buffers like Magnesium Chloride, Polysorbate 80 and Sodium Chloride can help in stabilizing the virus particles, other strategies are related to minimizing process hold times and holding process intermediates at lower temperature.

Another concern which may get exacerbated with larger scale is robust separation of unwanted empty capsids from the filled capsids (desired product) at the end of the purification process to

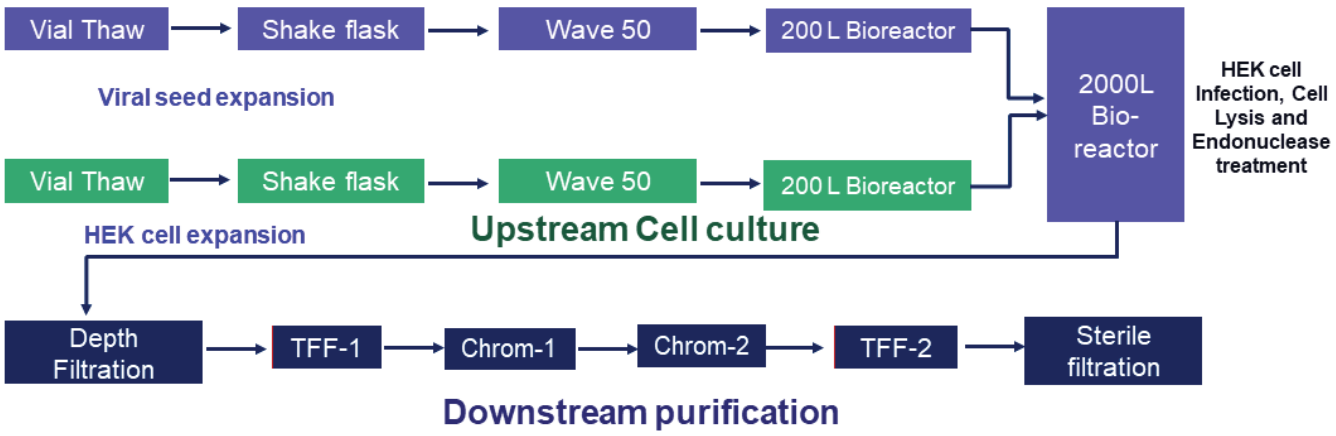

Figure 1: Manufacturing Process flow for production of Adenoviral Vector at 2000L scale

Table 1: Expected challenges during scale up of viral vector manufacturing and possible mitigation strategies

Area	Challenges	Possible Mitigation strategy
Upstream Challenges	Growth of HEK cells	Check for Premature cell infection and Optimization of cell culture parameters
	Clump Formations	Use of anticlumping agents and optimization of agitator seed
	Productivity of virus particles	Maintaining virus to cell ratio, Viral seed quality check by infectivity assays and optimization of post infection conditions
Downstream challenges	Inconsistent recoveries and quality	Check for variable input quality to downstream, Empty vs Filled particle separation optimization
	Aggregates	Minimize shear stress in TFF and other unit operation, Use of stabilizers in buffers and process intermediates
	Lower recovery	Minimize process induced aggregation, minimize process hold and define hold temperature
Facility related challenges	Premature Infection	Complete segregation of clean cell growth area, Effective cleaning procedures, Restricted man and material movement

achieve the desired ratio of empty and filled viral capsids. This inconsistency is primarily driven due to poor separation of empty and filled capsids in downstream chromatography unit operations. A thorough optimization of the anion-exchange unit operation step can help in enrichment of the filled capsid for getting better consistent ratio of these two at the final product level. specific analytical methods also need to be developed at different process intermediate stages to monitor this important product quality attribute,

Facility Design & Adequate Cleaning Controls

Careful design of facility for a viral vector product is key to achieving predictable and robust operational outcomes, because of nature of the product. One of the major challenges in adenoviral vector production is the risk of pre-mature infection of HEK293 cells, which can result in poor cell growth and early batch termination, yielding suboptimal product output. Hence, by design, different cleanrooms in the facility need to have appropriate controls in terms of

man-material movement, segregation of air handling units and other procedural controls between viral and non-viral areas. Additionally, an effective and robust cleaning, sanitization and environmental monitoring program, aided with product specific analytical assays need to be established to control and circumvent any residual risk of viral contamination.

Summary

Large-scale processes for manufacturing of important medicines like viral vector vaccine for covid-19 is essential to drive accessibility and affordability across the globe. However, specific technical and operational challenges need to be mitigated through well designed experimental approaches and empirical knowledge to ensure successful process scale-up. Stelis Biopharma was able to setup a state-of-the-art large-scale viral vector facility (with operational capacity of 10 X 2000L) to manufacture a covid19 vaccine. In a short amount of time, Stelis was also able to successfully scale-up the process at 2000L scale, through focused design of experiments and structured scale-up approaches, and consistently achieve high viral titers with uncompromising product quality, delivering close to ~5 million doses of covid-19 vaccine per 2000L batch. ■

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Drug Safety in the New Millennium for Novel Small Molecule Drugs

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The safety of a new drug is of paramount importance – even if a drug is highly efficacious but not found to be safe it will not be approved by the regulatory bodies. The safety standards that the new drugs have to meet have dramatically increased over the years. It is said that if aspirin, a decades old drug, were to be launched today, it may not have gotten approved given the range of unwanted pharmacological activities it possesses. Regulatory bodies such as USFDA and Indian DCGI place very high bar on proving the safety of a drug prior to its approval. In this short review we can examine the various types of pivotal safety studies needed for a new drug as well propose what could be done in the future.

Typical safety studies requirement currently needed is shown below

Preclinical Tox studies needed

The earliest studies that are needed are preclinical safety studies. These include both in vitro and in vivo studies. All safety studies have to be conducted under GLP compliant conditions – basically the studies are done in highly controlled and rigorous conditions with through documentation of every step.

The in vitro studies include HERG channel assays, mutagenicity and genotoxicity test for the compound. These are mandatory and a positive signal in any of these tests could be a matter of concern to the regulator.

The preclinical animal studies form the bulk of the drug safety study requirements by the regulators. These studies have to be done in at least two animal species, one usually a rodent such as mice or rat and another a higher species such as dog. In special cases depending on the expected safety liability, the regulator may ask for studies to be done in non-human primates as well. The preclinical safety and efficacy data package is submitted to the regulator in the form of an Investigational New Drug application (IND) to the regulator to get permission to initiate clinical trials.

Clinical studies

The most expensive part of drug development are the clinical trials. Clinical trials form the basis of approval of any drug. There are two aspects to clinical trials, demonstration of safety of the drug and efficacy of the drug. Phase I clinical trials are performed in healthy human volunteers and are mainly designed to explore the safety of the drug. The studies are usually done in a step wise fashion starting with single ascending dose (SAD) escalation and then multiple ascending dose (MAD) studies.

If these are successful, then the drug moves into Phase II clinical trials. This is the first time that the drug is explored in patients. Here the objectives are two-fold, to explore the safety of the drug as well as demonstrate the efficacy of the drug

at various doses chosen from Phase I studies.

The final stage of drug development are the Phase III clinical trials. This is largely an expansion of Phase II trials with the number of patients being increased as well a comparator drug is also added to the trial. The main objectives are to show the safety, efficacy and comparative activity of the drug relative to the current standard of care drug. However efficacious the drug may be if there are safety concerns then this raises a red flag and the whole drug profile is thoroughly scrutinized. Occasionally extended studies may be requested by the regulator. Successful drug development end in the submission of and New Drug Application (NDA) and its approval by the regulator.

Future of drug safety evaluations – The use of "human like" models

Despite such well organized and rigorous studies laid out by the regulators, the drug attrition rates are very high for approval of new drugs. For every single drug that enters the market, there are few hundred/ thousand preclinical compounds that do not make the cut. The biggest drop is seen when drugs transition from preclinical into clinical studies. Why is that?

One reason could be that bulk of safety and efficacy work done preclinically is done in animal models, which may or may not capture what happens in human biology. The biggest "black box" is there fore the transition from preclinical to clinical studies. Regulators globally are now thinking about newer approaches to predicting drug safety rather than solely relying on animal studies.

One approach is the use of humanized in vitro and animal models. The in vitro human like models are designed used actual healthy or patient derived human cells and are used to generate human organs or systems using organoid or the more advance 3D bioprinted tools. The idea is to capture human like biology rather than use animals which do not accurately reflect human disease.
In certain cases, the animal model themselves may not be readily available such as in the case of rare diseases or even COVID 19 when the pandemic initially struck. We designed a human vascular lung model to mimic COVID 19 damage to the lungs and searched for repurposed drugs to treat this disease. We made some startling observations using the model which later on were confirmed by others independently in clinical studies. Thus, this type of use of human like tools may well become the future of drug safety and efficacy measurements rather than just rely on animal models. The way forward will be to reduce the use of animals and create improved human like tools to better predict drug safety. Many regulators around the world are moving in this direction. ■

Pharma 4.0: Driving Digitalization in Pharmaceutical Manufacturing

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Digitalization has driven rapid transformation across many industries, but it has long eluded the pharmaceutical manufacturing sector. Compared to other industries, pharmaceutical and biotech companies have traditionally adopted emerging technologies at a slower pace due to heavy regulations, strong intellectual property constraints, and a well-known conservative culture. However, rapid business environment changes in recent times have driven many in the sector to digitalize their processes.

The Search for the Right Digital Solutions

Many pharmaceutical manufacturers are now looking to move away from traditional decision-making processes, break down organizational and data silos, and to help different functions work together — all while creating better synergies within the company. In essence, the end goal is to help manufacturers improve production flexibility and reduce operational costs and risks, which can be achieved with process analytics.

By choosing the right digital platform to integrate with existing Manufacturing Execution Systems, manufacturers can achieve paperless operations and realize quality, regulatory, operational, and data availability benefits. Such benefits include standardizing procedures, preventing human errors, reducing the need for data entry, and supporting management and manufacturing decisions through data visualizations.

Digitalizing Water Treatment Processes

One way that pharmaceutical manufacturers can effectively implement digitalization is in the area of water treatment. Given their need for a consistent flow of high-quality water, manufacturers can sometimes find water management a challenge, and tend to devote considerable resources to the development and maintenance of water treatment systems.

Compendial water and steam generation systems, as well as the associated process manufacturing controls within the system, require careful review and monitoring as seasonal fluctuations in feed water quality may impact the operation and utilization of the systems and consequently, of product quality.

With the tightening of wastewater discharge limits and the enforcement of environmental regulations in many countries across the Asia Pacific region, the treatment of wastewater (highly charged with TOC, COD, BOD, suspended matter or solvents) and removal of micropollutants before discharging the effluent has also become a key concern for the industry. Many micropollutants like Endocrine Disruptor Chemicals (EDCs) are neither biologically degradable nor absorbable, and are therefore difficult to

remove without the right technology.

Through adopting digital solutions for water management, pharmaceutical manufacturers can be better equipped to overcome daily challenges in managing their water treatment systems and meeting their compliance requirements, while improving the overall efficiency of their systems.

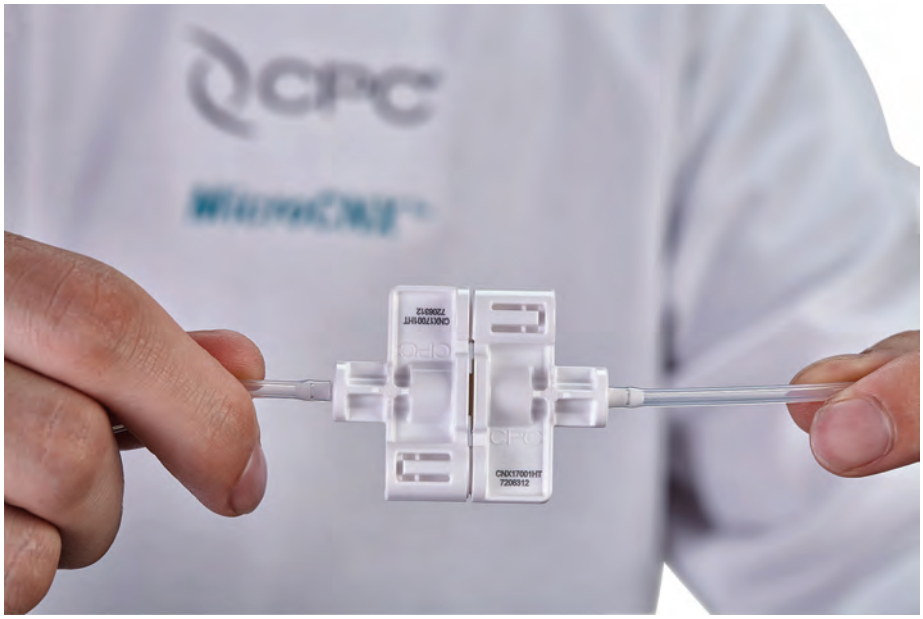
Smart Solutions for Better Optimization

Pharmaceutical companies can benefit from the latest technologies to improve production efficiency and reduce operating costs, without compromising the safety of processes or of product quality. Smart solutions like AQUAVISTA™ can help businesses who desire to integrate a digitalization module to their existing systems to optimize and manage utilities systems.

A cloud-based digital platform, AQUAVISTA™ supports global pharmaceutical manufacturers by optimizing their water and wastewater treatment processes. The platform enriches the users' aggregated data and offers a visualization of the digitalized data to support management and manufacturing decisions. For one industry-leading contract manufacturer in the United Kingdom specializing in handling volatile pharmaceuticals, the integration of the existing Business Management System to AQUAVISTA™ allowed them to achieve a cost-effective and efficient remote monitoring solution, conveniently accessible by multiple engineers on any device. Besides offering automatic color-coded alerts and alarms to enable faster responses to critical issues, the solution also facilitated data collection for predictive maintenance — further supporting the manufacturer in process optimization and improving overall efficiencies.

Through digitalization, pharmaceutical manufacturers can gain more meaningful insights on the treatment processes in their plants. As a result, these businesses achieve greater operational efficiency and quality compliance, while leveraging on existing human capital to bring about a shift towards improved process monitoring, analysis, and optimization. ■

New MicroCNX Connectors a First for Small-Volume Aseptic Processing True alternative to tube welding at small tubing sizes



A new ultra-compact sterile connector provides biopharmaceutical and cell and gene therapy manufacturers a much-needed alternative to tube welding for their small-volume closed aseptic processes. MicroCNX® Series Connectors are the newest addition to the suite of aseptic connection solutions from CPC, including AseptiQuik® Connectors. The new product is designed to provide a smaller, easier, faster and less risky method of connecting tubing for small-format assemblies.

"MicroCNX® connectors are a critically important option for a range of bioprocessing, cell therapy and gene therapy workflows," said Troy Ostreng, senior product manager for CPC's biopharmaceutical business. "We hope to present a true alternative to the cumbersome process of tube welding, ending the hassle of the weld and enable operators to make sterile closed connections more efficiently. The MicroCNX® connector represents a huge innovation for the industry, in particular for those working with very small-bore tubing."

MicroCNX® connectors are designed specifically for small-volume processes involving widely used 1/16" (1.6mm), 3/32" (2.4mm) and 1/8" (3.2mm) tubing. These include sampling, seed train expansion and early cell culture processes involving shaker flasks and rocker tables.

"The MicroCNX® series was designed to help manufacturers improve process efficiencies and reduce time and total cost in creating closed systems that deliver reliable, reproducible results," said Ostreng.

Testing indicates that making a sterile connection with the new connector is up to four times faster than an operator using a tube welder.1 Meaning, in the time required to create one weld, up to four MicroCNX® connections could be completed. Multiply those numbers over the course of a year, and the operational efficiencies are clear.

The easy, three-step process for using MicroCNX® connectors requires minimal training. Users simply "Pinch-Click-Pull": 1) pinch to remove the protective cover; 2) click together the connector halves; and, 3) pull out the protective membranes so flow can start. In comparison, tube welding involves a dozen or more steps, with operator challenges including maneuvering the tube welder into position, dealing with equipment maintenance, and requiring precise technique to create a successful weld. With MicroCNX® solutions, there is no risk of faulty welds, welder breakdowns, or production delays due to weld equipment downtime.

Use of aseptic connectors eliminates the need to purchase, calibrate, validate and maintain tube welders that can cost more than €12,700 ($15,000) each. Manufacturers often need multiple welders, which take up valuable space in a cleanroom.

"It's expensive and time consuming to validate new space," Ostreng noted. "MicroCNX® connectors can help biopharmaceutical and cell and gene therapy manufacturers make the most of their existing cleanroom space." ■

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