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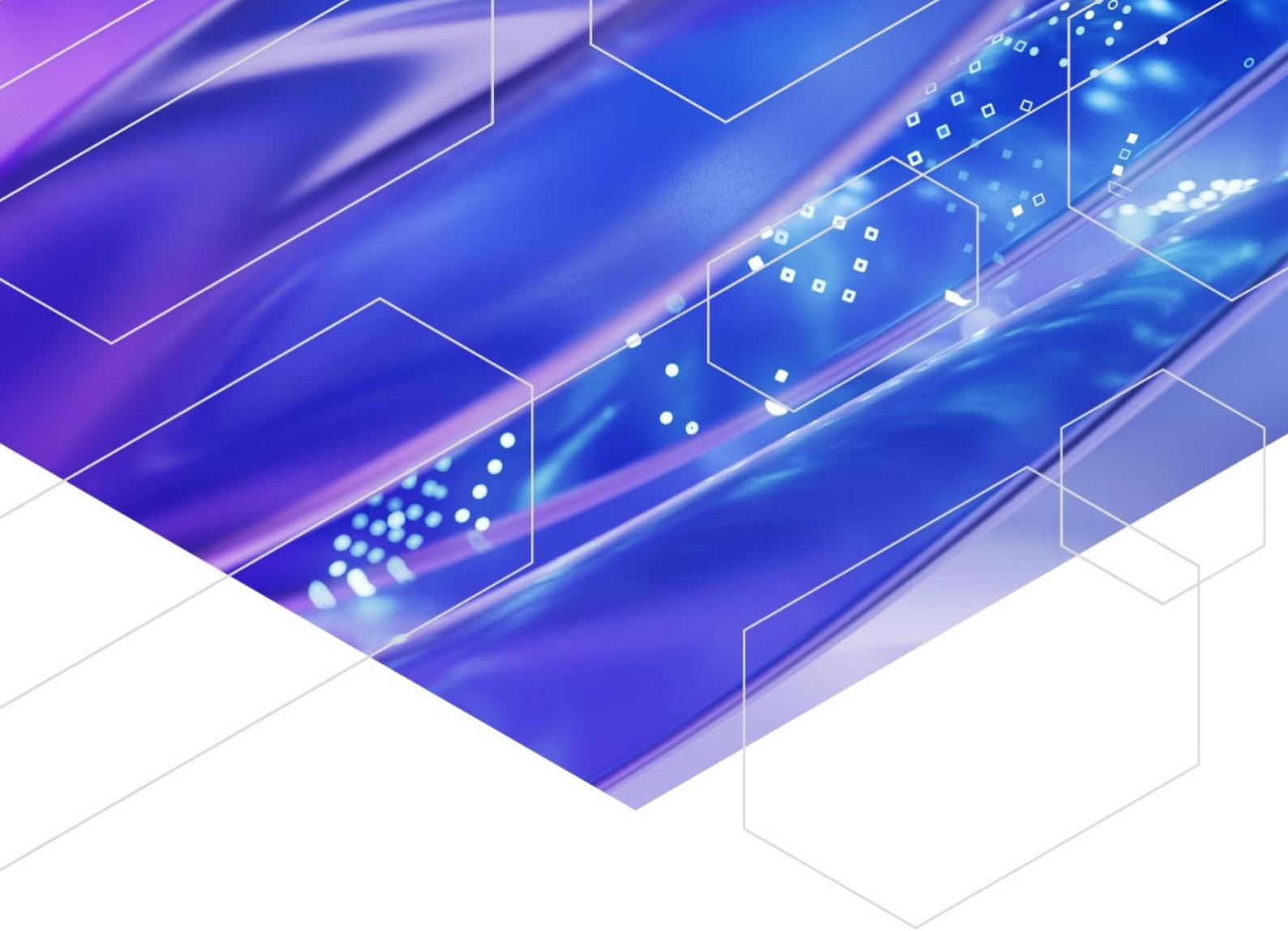

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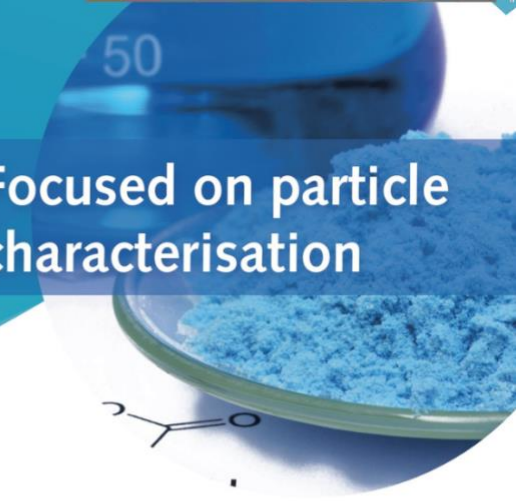

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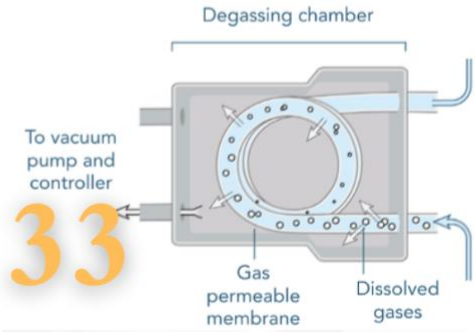

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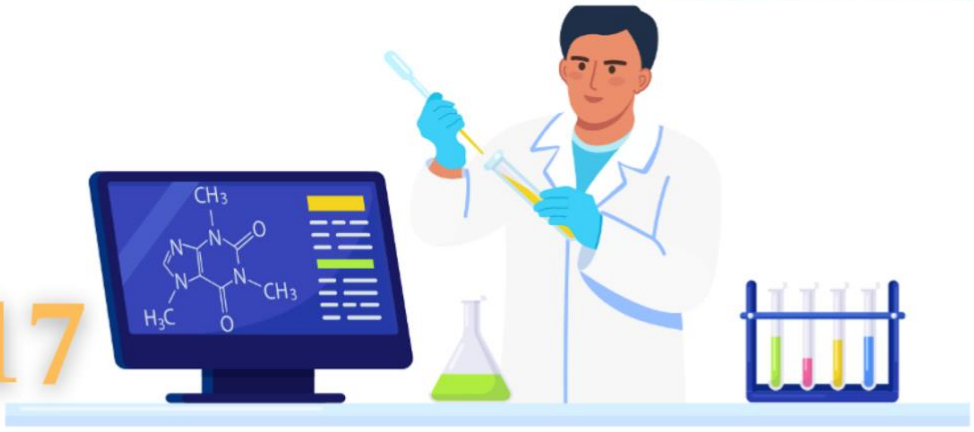

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Editor's Word

ear Readers,
Welcome to the latest issue of Microbioz India. As we delve into the pages of this edition, we are excited to bring you a collection of engaging stories, insightful features, and thought-provoking content that we believe will capture your imagination and enrich your knowledge.
In a world constantly in motion, Microbioz India remains steadfast in its commitment to delivering high-quality content that informs, inspires, and entertains. We take pride in curating content that reflects the diverse interests of our readers, and in this issue, you will find a wide range of topics to explore.
In our cover story, we shine a spotlight on "**SMARTER SCIENCE. BETTER PHARMA.: The Technologies Accelerating the Next Industrial Revolution**" delving deep into its intricacies and uncovering the stories and people that make it an intriguing subject. Additionally, you'll find articles **Silicone Breast Implants: Advances in Manufacturing, Quality Control & Regulatory Compliance**" contributed by Dr. Priyabrata Pattnaik Chief Executive Officer, Ami Polymer, that we hope will pique your curiosity.
As we embrace the digital age, Microbioz India continues to evolve to provide you with fresh, interactive experiences. Be sure to check out our website for additional content, multimedia features, and ways to connect with us through social media.

We value your feedback and insights, which drive us to continually improve and innovate. Your voices shape the direction of Microbioz India, and we appreciate the trust you place in us to be your source for Pharma, Bio-Pharma, Laboratory and Analytical Industry news and product launches.
Thank you for your continued support and loyalty. We look forward to embarking on this journey with you, exploring the worlds within the pages of Microbioz India, and sharing the stories that make our world so captivating.
Enjoy the read!

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From intelligent laboratories and AI-driven discovery to connected manufacturing and advanced analytics, the pharmaceutical industry is entering an era where data, automation and human expertise are converging to redefine how medicines are discovered, developed and manufactured.

For over 100 years, the major public health advances have been the result of major scientific discoveries. The ways in which new medicines are discovered and manufactured is undergoing as major a change as occurred during the discovery and development of the first medicines.

The increased use of automation, artificial intelligence, big data and the digitalization of laboratory sciences and of pharmaceutical manufacturing will change the pharmaceutical industry as much as have the various scientific discoveries on which the pharmaceutical industry has been built.

The pharmaceutical industry is rapidly adopting integrated systems, both within the laboratory and the manufacturing facilities.

The goal of all of these innovations is to enhance the quality and integrity of pharmaceutical products while increasing the speed with which new medicines can be developed and produced. This is far more than the digitization of pharmaceutical industry.

This is the pharmaceutical industry's next revolution. Traditionally, pharmaceutical manufacturing has been driven by a sequential flow. The flow has been from research to the development of active pharmaceutical ingredients (APIs) to the manufacture of a pharmaceutical product. Each of these has relied on the input of a different team or work group.

Now the focus of innovation has shifted to use the full potential of automated, data driven and integrated systems. The goal is to obtain actionable intelligence from data.

This enables what has been coined, the Intelligent Pharma Enterprise.

Artificial Intelligence Is Moving From Experiment To Enterprise

What was once a relatively obscure area of research has now arrived in the pharmaceutical industry. AI-based innovations are helping to transform the pharmaceutical industry across the entire drug life-cycle, from target identification to clinical development. And the impacts of AI-based innovations extend well beyond drug development.

AI is helping to optimize formulation and manufacturing processes. It is also assisting with the analysis of complex types of real-time data for quality control and investigations into deviations. AI is even finding applications in environmental monitoring and supply chain management. AI-based innovations are helping to digitalize and transform various areas of the pharmaceutical industry. In many cases, the focus of pharmaceutical companies has shifted from replacing workers with AI to integrating AI in order to enhance workers' skills.

2. The Rise of the Intelligent Laboratory

Digital transformation is now impacting the laboratory more than any other part of a pharmaceutical company.

The integration of advanced digital and analytics technologies in laboratories is shifting them from an isolated, fragmented state to a connected and integrated platform. This evolution from Lab 2.0 to Lab 3.0 and, ultimately, to Lab 4.0 is well underway.

1. New opportunities are available.
2. Tracking samples digitally is now possible.
3. Work flows can be automatically assigned.
4. Results from instruments can be communicated to lab equipment.
5. Data can be accessed in real time.
6. Exceptions can be defined and notified.
7. Imported data can be used to create a rule.
8. Mechanical systems can perform lab tasks.

With the aforementioned technologies, lab automation can be expanded and processes can be monitored in real time.

3. Robotics can automate numerous lab tasks.

With recent advancements in automation, lab systems have evolved to a level where numerous processes can be fully automated. These systems can perform tasks including sample preparation, liquid handling, and high throughput assays.

4. Further changes in the pharma industry can be simulated using digital twin technologies.

Simulating lab processes can help evaluate and improve the efficiency of lab workflows. Digital twin technologies can also be used to improve and optimize lab processes before capital expenditures are made.

A digital twin is a virtual representation of a physical process or product that is augmented with real world data.

Digital twins have the potential to revolutionize pharmaceutical manufacturing and provide significant benefits to the industry.

Digital twins can be utilized to model and improve:

1. Methods and equipment used for pharmaceutical production
2. Energy and resource consumption
3. Production output
4. Variability of production processes
5. Equipment and facility performance

Pharmaceutical manufacturers are now able to digitally test various change scenarios before they are physically implemented. This testing may help to minimize the number of changeover events required for optimization, improve throughput, identify bottlenecks, and support decision making.

This capability may provide a significant competitive edge to pharmaceutical companies. The data available to pharmaceutical manufacturers is considerable. The challenge is interpreting this data in a useful and timely manner.

The use of advanced analytics can help pharmaceutical manufacturers and other related service providers to shift their focus from purely describing and reporting business activities to helping inform and make decisions on future business actions.

Actions to be taken to achieve a particular business outcome can be informed by the intersection of multiple data sets. It is used for predicting future events.

6. Continuous Manufacturing and Process Intelligence

Flexible and data-rich pharmaceutical manufacturing is evolving with continuous manufacturing. Continuous pharma manufacturing focuses on processes where the active pharmaceutical ingredients (APIs) and intermediates are continuously flowed, mixed and/or transformed.

When integrated with

PAT, real-time process control and/or automation, Artificial Intelligence, Digital Twin Technology, and/or automated quality systems, continuous manufacturing can help pharma achieve advanced and intelligent real-time process and/or quality control. Continuous manufacturing also enables the removal of the final and/or intermediary quality controls. From a pharma manufacturing perspective, it's a shift from focus on end-of-the-line quality control (or assessment) to real-time control and/or assessment of quality throughout the manufacturing process.

7. The Connected Instrument Is The Intelligent Instrument

Similar to other areas of pharma, laboratory instruments are also taking a shift toward connectivity and intelligence. Instrument manufacturers are incorporating advanced electronics, computing, networking and software in their instruments. Data and analytics are at the core of the next evolution of instruments. The focus of future instrumentation will be on capturing data, performing analytics, and helping in making scientific or medical decisions.

Traditionally, a decision was made after performing an analysis and interpreting the results.

8. Cloud Technology Is Transforming The Pharmaceutical Industry

Digital transformations in the pharmaceutical industry increasingly rely on cloud computing technology.

Rather than work within the confines of closed, disconnected systems, companies can link data from multiple locations (e.g. laboratories and manufacturing sites) and cross-functional business processes (e.g. quality).

Cloud computing enables:

1. Workers in different locations to collaborate
2. Company personnel to access and work with data residing elsewhere in the company
3. Flexibility to increase or decrease the company's computing power based on demand
4. Employees to work and monitor operations off-site
5. Integration of different software
6. Innovative data analysis
7. Artificial Intelligence

In global pharmaceutical companies with multiple facilities, cloud computing can optimize and integrate a variety of business processes. Integrating the cloud to facilitate business operations raises legal and ethical concerns including protection of data, cybersecurity, and IT system validation.

There is a need to strike a balance between improving the company's business operations and processes and protecting legal and ethical concerns.

9. Quality and Cybersecurity are One and the Same

There are numerous advantages to integrating a company's business operations. Each integration creates new cybersecurity risks. One of the most significant competitive advantages is protecting data. Data can include patient information and data generated during the course of research and/or clinical studies as well as manufacturing and/or quality data.

It is imperative to protect data and cyber systems to ensure the security of supply chains. Risks associated with protecting a company's cyber systems should be integrated into business operations and processes.

10. All Systems Still Depend on Human Interaction

While an increase in automation may decrease the need for human labor in a scientific laboratory, scientists will always be necessary. In fact, they will be at the heart of scientific operations.

Technology can quickly analyze and find patterns in data. It can perform activities that require little to no creativity and critical thinking. There are many skills in pharmaceutical sciences that cannot be replaced by technology.

These skills include:

1. Understanding and recognizing ethical issues related to research and clinical trials.
2. Designing and performing experiments.
3. Critically appraising and analyzing scientific information.
4. Making and interpreting findings in the context of science, medicine, and laws.

Pharmaceutical sciences will always integrate skills that technology cannot perform. The focus will always be on the integration of technology and human skills. The organizations that will thrive in the future will possess state-of-the-art technology and people that can question and interpret findings generated by the technology.

11. From Automation to Autonomy

Automation is widely implemented in industries. The next phase will include systems that can think and act on their own. These systems will remain within predefined limits and constraints. An automated laboratory will perform a series of tasks to arrive at a result.

An intelligent laboratory of the future will be able to arriving at a different series of result based on the constraints of a given situation.

Thus the progress of a pharmaceutical organization can be as follows:

Organization	Examples of organizations
Manual	1950s-Present
Automated	1980s-1990s
Connected	1990s-2000s
Intelligent	2000s-2010s
Autonomous	2010s-?

The goal of an organization should not be to adopt the most recently available technology. It should identify opportunities where technology can generate scientific and business outcomes.

12. The Future is Here. The Data will Determine the Outcome

The quality of data will determine the limits of AI. This will determine the outcomes of digital transformations.

Data integrity, standardization, and interoperability are essential for pharmaceutical businesses. This is especially true for metadata, traceability, and governance. These elements help improve the accessibility of pharmaceutical data while maintaining security. Pharmaceutical businesses need to effectively integrate AI to better utilize large datasets.

The foundation for pharmaceutical AI is data. The focus on AI has obscured this reality. Data needs to be trusted for it to be useful. The intersection of sustainability and automation and the connection of pharmaceutical systems provides greater visibility into resource utilization.

This, coupled with improved analytics, can foster greater facility resource utilization. This improves sustainability while maintaining quality. Pharmaceutical businesses can improve their competitiveness and strengthen their positions by focusing on the rate of improvement and learning.

This is in addition to infrastructure, IP, and other traditional pharmaceutical business foci. Data is a catalyst for organizations to realize their greatest potential for improvement. The intersection of Data and Pharma 5.0 can positively transform the pharmaceutical industry.

More broadly, the change that is taking place can be described as part of Industry 5.0, in which the integration of various technologies enables human sensitivity and resilience in an efficient and sustainable manner.

Pharmaceutical companies may choose to develop their operations to incorporate the following features:

1. Intelligence
2. Through the use of learning technology and systems.
3. Connectivity
4. Across diverse business functions and units.
5. Human-centricity
6. Through the use of technology and systems to extend the reach and capacity of scientists.
7. Resilience
8. To absorb and recover from disruption.
9. Sustainability
10. To optimize the use of available resources.

Pharmaceutical companies may wish to pursue the above in their efforts to transform their businesses. One of the consequences of these developments will be the emergence of a digital pharmaceutical ecosystem.

We refer to this as Building the Pharmaceutical Enterprise of Tomorrow. In summary, a variety of technology building blocks have been developed.

Each can be connected to other technology building blocks, as well as to scientists.

Because of these developments, scientists can focus more on discovery and less on routine tasks. Of particular interest is the fact that numerous innovations in pharmaceutical and life science technology have reached a degree of maturity that allows for their convergence and integration.

These enable laboratories to become more connected, and manufacturing to become more responsive, intelligent and data-driven.

THE FINAL EQUATION

This equation describes the future of drug development:

SMARTER SCIENCE
+
ADVANCED TECHNOLOGY
+
human experience
=
IMPROVED PHARMA

Innovations are already transforming the field. Leaders in the pharmaceutical industry have stopped debating whether different forms of technology would change the ways drugs are discovered and developed.

The more constructive debate is about how various technologies will be integrated into drug discovery.

The most important element will be the integration of human expertise and scientific knowledge in order to leverage technology to create innovative, safe and effective pharmaceutical products. The future of the pharmaceutical industry will be defined by the integration of knowledge, and the combination of various technologies.

This is the race that will determine the industry's future.

Precision, Performance & Productivity: The New Paradigm in Pharma & Laboratory Technology

How intelligent instruments, automation, advanced analytics and connected workflows are redefining the standards for pharmaceutical manufacturing, analytical science and modern laboratories

Pharmaceutical science has always demanded precision. Small differences in a product can have major consequences, and identifying or preventing these differences often requires extensive and sophisticated efforts by the pharmaceutical industry.

However, the requirements on pharmaceutical and other laboratory services are changing.

Merely achieving a desired level of precision will not be sufficient to meet these requirements.

For example, consider the services needed to carry out laboratory testing or to manufacture pharmaceutical products. It is not enough to achieve a desired level of precision; these services must also enhance performance and increase the throughput of services offered while continuing to meet quality and compliance requirements.

This is the environment in which pharmaceutical and laboratory services find themselves today. To address this situation, services must be designed to incorporate the three key elements of precision, performance, and productivity.

This is particularly the case for services related to research and development, and clinical trials.

The concept of precision is wider and more encompassing than the concepts of repeatability and reproducibility.

Precision in pharmaceutical sciences includes, among others:

1. Precise control of a process
2. Precise delivery of a dosage form
3. Precise control of a system
4. Precise monitoring of an environment
5. Precise capture of data
6. Precise assessment of quality
7. Precise forecasting
8. Precise judgment

The extent to which services provided to the pharmaceutical industry have embraced the concept of precise judgment is open to conjecture. It is clear, however, that certain services, such as analytical testing, have embraced the concept of precise forecasting.

Having a baseline measurement is good, but to really know and understand the details and insights that drive the measurement is valuable. Looking at performance from a system perspective is becoming more pervasive.

A piece of lab equipment can be designed to have a high degree of performance but if it is incorporated into the lab in a way that is not efficient, it will not improve the lab's overall performance.

Like equipment in a lab, the tools and equipment in a facility can be sophisticated, but if the overall process is not integrated and if there are discontinuous systems, the facility can be inefficient and unproductive.

Because of this, the systems and processes in a facility need to be analyzed and performance assessed at the system level.

When analyzing and assessing performance it is important to evaluate:

1. Instrument Performance
2. Reliability, sensitivity and other performance characteristics.
3. Workflow Performance
4. How samples and data are transported and moved.
5. Data Performance
6. How quickly data is stored and analyzed.
7. Performance of the Process
8. How effectively the resources are utilized.
9. Quality Performance
10. How far the process deviates from the desired outcome.

From a business and entrepreneurship perspective, the best products and services facilitate and improve a process.This is especially true for products and services for the research, development, and pharmaceutical industries.

A true competitive edge will come from designing products that embrace intelligent productivity while also improving process control and integrating quality and safety throughout.

It means eliminating rote work, automatically performing tasks, enhancing information and processing it to produce useful business insights, while adhering to regulations.

Laboratory automation has evolved to encompass more than simple liquid handling. Today, automation can comprise of more complex, multistep procedures. One consequence of these advances is a shift from a labor-intensive to a more automated work environment in which the laboratory scientist's role is transformed to focus more on the review and evaluation of data and less on routine, mundane tasks. Laboratory automation not only allows for improvement in repeatability, traceability and integrity of samples, it can facilitate standardization and integration of a multitude of interconnected laboratory workflows and processes.

In addition to the benefits listed above, standardization and integration of a laboratory's work processes and procedures enable data to be collected in a repeatable and reliable manner to facilitate applications of artificial intelligence and advanced analytics.

The automation of scientific work processes and instrumentation allows integration of numerous diverse scientific and analytical instruments and equipment to form a cohesive and interoperable ecosystem. These integrated systems allow scientific and analytical equipment to be extended to and interfaced with a variety of enterprise systems and services. Today's science and analytical instruments have the potential to transform science and engineering work by collecting, collating, analyzing and interpreting scientific data and preparing scientific reports.

4. Advanced analytics turn information into insight.

Artificial Intelligence (AI) is rapidly progressing and providing opportunities for automation across different fields. The collaborative efforts between the pharmaceutical and AI industries have increased, allowing better opportunities and advancements in laboratory services and related fields.

AI is an influential and valuable resource that can change and evolve laboratory services and related fields. Deep learning has strong potential to positively disrupt and revolutionize the pharmaceutical, life sciences, biotech and chemistry sectors. AI will allow for the automated, prioritized and intelligent design and execution of scientific experiments.

AI and related advanced technologies will allow for safe and improved prediction, enhanced automated data analysis, process optimization and quality control, as well as automated laboratory scheduling and supply chain optimization.

The quality and volume of data will largely influence the intelligence and decisions derived from AI. Therefore, it is imperative to improve data and operational intelligence. AI will extend and amplify human intelligence.

Traditional pharmaceutical processes consist of lengthy, time consuming and labor intensive operations, including collecting, analyzing and interpreting data. Recent advancements have disrupted and enhanced traditional processes and allowed for the concurrent or real time analysis and execution of processes and related services. Continuous, real time process analytics and control will allow for the collaborative and concurrent efforts of laboratories, processes and services to better identify and understand process anomalies and enhance quality and related services.

Process Analytical Technology (PAT)

It is commonly understood that pharmaceutical manufacturing requires an extensive understanding of the processes used, as opposed to an overreliance on finished product testing. PAT enables real time processing and/or automation of actions to adjust or correct processing based on predefined constraints or parameters. Other multidisciplinary technology enablers, such as artificial intelligence and advanced sensing/analytical technology, can complement PAT to provide supershopm, real time processing and/or automation.

Through the application of PAT to pharmaceutical manufacturing processes, quality can be designed and ensured throughout the process. This philosophy is consistently aligned with the overall direction of advanced and/or intelligent manufacturing.

Predictive Maintenance

Downtime in pharmaceutical manufacturing and laboratory facilities can be costly. Traditional maintenance strategies do not always ensure equipment availability and serviceability. Achieving adequate maintenance strategies relies on the equipment failing and then taking corrective action.

Predictive maintenance shifts the focus from equipment failure to degradation. The goal of predictive maintenance is to identify equipment degradation and failure. This can be accomplished through analysis of equipment performance and/or utilizing real time and historical data.

The goal of Predictive Maintenance is:

Detect, Predict and Act upon equipment degradation to ensure continued equipment availability and serviceability.

Interconnected Systems for Faster SciDes

Effectively managing increasing and more complex sample throughput is a challenge for many laboratories. Productivity in these situations can be greatly improved with the assistance of automation.

The main advantage of automation is the reduction in error and increase in speed for repetitive tasks.

Some tasks that can be automated include sample preparation and liquid handling for high throughput screening. Other tasks include the automation of cell culture and microbiology.

Reducing the manual intervention in laboratory processes improves data integrity. Although data integrity and quality are important for regulations and compliance, the data can also improve laboratory productivity and throughput. The data in a laboratory should be accurate, complete, consistent and readily available to the end users.

One of the most valuable resources in a laboratory is the time of the scientists and quality staff. Time spent dealing with and correcting data errors is time lost productivity.

If automation is integrated with laboratory information systems, data integrity and productivity would be improved.

The next lab will use technology to move data between diverse systems. These systems will provide the following:

Context + Traceability + Security + Integrity

It's important to note the difference between meaningfully connecting various technologies and just indiscriminately connecting everything to everything.

Edge and Cloud provide a range of options.

Cloud provides an infrastructure where data, software, and services can be integrated and analyzed. Edge provides the means to process data where the generating equipment or apparatus is located.

Typically, these can be integrated to provide a hybrid architecture. Instrument or equipment data can be processed at the edge, and securely uploaded to the cloud for advanced data analytics and other activities.

Edge and Cloud architectures can support Meaningful Connectivity. For pharmaceutical companies, this can mean integrating and connecting labs, manufacturing sites and other facilities across the globe.

Pharmaceutical companies can use digital twins to optimize and improve various facets of their business from equipment and process to facilities.

Digital twins help companies understand how a particular equipment or process will perform under a range of scenarios or conditions before those changes are implemented.

Combining data and insights from the real world with digital and virtual modeling is becoming commonplace. As such, companies can digitally test and validate a myriad of scenarios and leverage data to determine the best possible course of action.

Scientists and researchers will still need to exercise their judgement to interpret the insights gained from data and other technology.

The pharmaceutical industry faces a Scientific, Ethical, and Legal (SEL) environment that is complex and requires experience and judgement that cannot be easily captured and transferred.

Hence, we can expect that:

1. Scientists will design more innovative experiments.
2. Scientists will interrogate complex data and formulate hypotheses.
3. Scientists will analyze and interpret data and identify knowledge gaps.
4. Scientists will challenge the parameters and assumptions set by artificial intelligence.
5. Scientists will identify new opportunities and evaluate and make complex trade-off decisions.

In the pharmaceutical industry of the future, many tasks will be performed by machine intelligence; however, human beings will be charged with developing new,, valuable and useful, ideas and making complex decisions.

The intersection of Pharmaceuticals and Technology brings an opportunity to improve efficiency of laboratories and other research facilities.

The Laboratories of the Future will be characterized by the use of innovative technologies and instruments that collect, exchange, and analyze data; and will allow members of a research team to be in different geographical locations.

Digital and advanced analytics will integrate sample and workflow data to allow researchers and scientists to focus on high-level, cognitive activities and away from routine, repetitive tasks.

10. The laboratory of the future will be evaluated by the extent of integration of technologies, not the presence of technologies.

11. Therefore, determining the extent of integration of technologies in the laboratory of the future will be very crucial.

A Pharmaceutical Technology Architecture

The pharmaceutical technology system can be represented in a format of a layered ecosystem. The layers are as shown below.

Layer 1: Physical Infrastructure

This layer consists of the hardware of the system e.g. instruments and manufacturing equipment.

Layer 2: Connectivity

This layer defines the communication systems that integrate the hardware of the technology.

Layer 3: Data

This layer represents the information produced by the system e.g. the quality of the product and the services offered by the system.

Layer 4: Intelligence

This layer represents the intelligence of the system e.g. machine learning and artificial intelligence.

Layer 5: Decision

This layer consists of the key decision makers in an organization e.g. scientists, engineers, quality personnel and management.

The New Standard of Performance

The pharmaceutical industry is moving towards measuring the performance of its technologies based on the results achieved rather than specified performance.

Results achieved rather than specified performance raises a lot of questions, for example,

How much faster can we perform our tasks?

1. How quickly can we transform our results to useful knowledge?
2. How extensively can we collect data?
3. How thoroughly can we analyze data?
4. What Does the Future Hold?

AI, automation, robotics, analytics, and other technologies will be continuously interconnected and integrated. The growth of these technologies will be outpaced by the growth of the systems built around them.

There will be a strong demand within the pharmaceutical industry for integrated systems and technologies that enable:

Precision

Improved accuracy and control with consistency in the outcome of a given process.

Performance

Improved equipment and system performance with respect to speed and volume of work.

Productivity

Improved output, especially if work is less repetitive and releases employees to perform other, more value-added activities. These will be the norm in the pharmaceutical industry.

The Pharmaceutical Industry's focus on better and more reliable outcomes will depend on continuous improvement in technologies that integrate Precision, Performance, and Productivity. There will be significant improvements in the systems that pharmaceutical and other research laboratories use to analyze and understand the impact of various interventions on patients and the overall health of the population.

Silicone Breast Implants: Advances in **Manufacturing, Quality Control & Regulatory Compliance**

Dr. Priyabrata Pattnaik
Chief Executive Officer
Ami Polymer

Biomedical engineering of silicone breast implants allows for a range of complex designs to be utilized in medical devices for long-term, implantable use. The convergence of science, engineering and technology enabled the development of sophisticated raw materials and methods to manufacture advanced medical devices. While a number of factors influence the in-use performance of a medical device (e.g. the skill of the surgeon and the raw materials used in the device), ongoing regulation and oversight of the medical devices is also critical.

The Choice of Materials:

Silicone breast implants are made of medical-grade polydimethylsiloxane (MMS), also known as PDMS. PDMS is a Siloxane-based elastomer which consists of long, repeating backbones with methyl side groups. Unlike organic polymers, PDMS retains its mechanical properties over a broad range of temperatures and is resistant to environmental stress cracking and degradation. Its biocompatibility and relatively low toxicity allow PDMS to be used in a number of biomedical applications. In addition, high purity fumed silica is used in PDMS-based breast implants to enhance mechanical properties and impart resistance to failure, and a platinum-based addition curing system is used to further improve purity of the implant.

Current-generation silicone breast implants have a multilayer elastomer shell structure with a filled gel or saline core. Most high-end implants have a core of highly cohesive gel, also known as "form stable" or "gummy bear" gel. High cross-linking of the gel enhances shape and stability of the implant and minimizes gel dispersal in the event the implant shell ruptures. Cross-linking is balanced with other variables to achieve the desired stiffness and stability of the implant.

Precision Manufacturing Technology

High purity, medical grade silicone is compounded and sterilized in controlled clean room conditions (ISO Class 7 or better). The shell is formed by dip-molding with an aluminum mandrel. Each layer of the shell is cured prior to the next layer being deposited. This allows the shell to be controlled within +/- tolerances.

The surface of the shell may be textured or left smooth based on the clinical indication. Texturing is produced by a variety of methods including salt-loss molding. Smooth implant shells have gained market predominance due to the increased incidence of Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) with textured implants. After filling the shell with silicone gel, the fill port is vacuum-oded to expel any trapped air and gel is held under partial vacuum to ensure complete filling.

The fill port is then sealed with silicone elastomer and a secondary cure is performed. The implants are washed to remove impurities, and then sterilized using ethylene oxide to provide a safe and secure product for end-use.

Quality control is performed at all stages of manufacturing and final product testing. The raw materials are evaluated to determine conformance to medical device standards, and the manufacturing processes are validated to comply with cGMP. Statistical process control and risk management are implemented to reduce process variation.

In addition to the physical and chemical testing mentioned in the previous chapters, implants also undergo microbiological and biological testing.

Representation of the intended use of the implant (long-term) is accomplished by performing durability tests on the implant shell, and analyses of the silicone gel to determine the coefficients of adhesion of the gel to the shell. It is also necessary to test the implant shell to determine the tensile strength, elongation at break, and resistance to tearing. Fatigue testing is performed to assess the durability of the implant to withstand millions of load cycles. The shell may also be tested to determine burst pressure and resistance to compression.

In addition to the mechanical and chemical testing described above, many of the biological tests performed on implants are mandated by the International Organization for Standardization (ISO) to determine the safety of a medical device. Biological testing of medical devices may also include genotoxicity testing. Clinical studies of medical devices may also be mandated. Manufacturers of medical devices are also obligated to perform post-market studies of implantable devices to assess device performance and determine the occurrence of infrequent, adverse events.

Breast implants are considered to be one of the highest risk, Class III, medical devices in the U.S. As such, they are required to undergo premarket approval by the Food and Drug Administration. In addition to the testing and reports specified in the Quality System (21 CFR 820) regulation and guidance, the FDA also requires breast implant manufacturers to validate the manufacturing processes and perform clinical studies for a period in excess of 5 years.

Bio-medical Performance, Benefits and Limitations

The use of breast implants can bring several clinical benefits. High-cohesive gel implants, for example, have improved shape and volume retention by reducing gel mobilization when compared to other implant types. Implant design can take into consideration the shape and proportions of the human body in order to provide aesthetic outcomes in reconstructive and cosmetic surgery. Other clinical benefits include improved tactile qualities of the implant, biocompatibility, resistance to fatigue and chemistry.

As with all prosthetic devices, complications can occur. Capsular contracture, rupture and infection are common. MRI and Ultrasound may be necessary to evaluate a possibly ruptured implant. It has been reported that textured implants can be associated with BIA-ALCL.

Considering the benefits and disadvantages of current breast implant technologies, further research and advancements in breast implant reliability and safety is expected.

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How Automation Is **Transforming HTE and HTS Reaction** Sample Preparation

While there is a need for accuracy in pharmaceutical research, there is even a greater need for speed. Recent advancements in research have focused on methods for maximizing speed while still allowing for sufficient accuracy. High-throughput experimentation (HTE) and high-throughput screening (HTS) allow researchers to conduct hundreds of chemical or biological transformations and evaluations, respectively, in a parallel fashion. The major limitations of these methods are sample preparation.

Historically, sample preparation has been achieved by laboriously performing hundreds of identical manipulations of chemical or biological samples. These manipulations are tedious and error-prone. Inconsistencies in sample and reagent preparation can greatly affect experiment outcome and alter the overall reaction.

It has been shown that the implementation of automation and robotics within the field of chemistry and biological research has significantly reduced preparation and process errors.

In addition, researcher productivity and overall throughput of a laboratory has also increased. Undoubtedly, these positive trends will continue, and ultimately researchers will be liberated from mundane sample manipulations and preparation.

Why HTE and HTS Need Reliable Sample Preparation

High-Throughput Experimentation (HTE) and High-Throughput Screening (HTS) are methods to quickly perform many experiments and analyze the results. The challenges occur during the sample preparation.

Each individual reaction may contain many different ingredients (e.g. chemicals, solvents, catalysts, etc.) which may not be easily identifiable to the researcher.

Prior to HTE, the manual nature of research limited the number of compounds that could be screened to 20-50 compounds per week. A research initiative to screen 3000 compounds would take about 1 to 2 years, and delays in research often negatively impact the competitiveness of a lab.

With HTE and automated sample preparation, thousands of reactions can be performed in a week. At this rate, a research backlog to screen 3000 compounds would only take a few weeks.

As thousands of reactions can be performed with HTE, the focus of research can be on the fundamental chemistry as opposed to the variability which can be introduced by sample preparation.

The Hidden Challenges of Manual Powder Dispensing

Preparing samples manually is relatively simple when only a small number of samples are involved. However, things quickly become difficult and time consuming when many samples are being processed. Preparing samples can be frustrating, especially when the sample is a powder and has properties which make it stick to surfaces and/or carry an electrostatic charge.

Manipulation of toxic and hazardous powders by hand increases the risk of exposure of sample powders to the laboratory personnel. Containment devices, such as glove boxes, greatly reduce exposure risk, but can restrict movement and make weighing powder samples even more difficult.

Using devices which require the repeated movement of the arms and/or hands for long periods of time increases the risk of injury and makes awkward movements fatiguing. Decreased concentration increases the likelihood of sample loss and transcription errors.

Use of automation for sample preparation moves personnel away to other activities and reduces the risk of sample loss and transcription errors. In addition, automation can provide better control over the laboratory processes and reduce the amount of sample utilized, all while reducing the strain placed on the personnel.

How Robotic Powder Dispensing Improves Efficiency

The CHRONECT XPR system from **METTLER TOLEDO** combines an XPR Automatic Balance with a 6-axis robotic arm to automate powder weighing and dispensing. Instead of requiring a scientist to remain at the balance throughout the process, the system supports unattended operation after the samples and method have been set up.

ITS can perform 288 sample preparations in one run using a set of three, 96-well vial plates. It can work with vials of 1 mL to 8 mL, which allows flexibility in choosing a reaction volume. Depending on the dimension of sample containers, the reaction volumes can be larger.

The system can load and store up to 32 different powders. This is ideal for simultaneous screening of multi-component reactions.

The dispensing technology can measure and dispense as low as 1 mg of a powder, which supports minimize the use of lab reagents.

The system is designed to support, and accelerate a wide range of laboratory activities. The infographic suggests the system can dose 900 or more compounds in a 24 hour period.

Saving Reagents Without Sacrificing Accuracy

Automating HTS and HTE reduces the amount of sample needed to process a given assay. Manual methods typically use a minimum of 1 µL of sample. Automated methods can reduce this to 100 µL (90% reduction). Various advantages of automation and reducing the volume of a sample become apparent.

Less sample is required for a given assay and reagents are used more efficiently. It may allow testing of sample types that were previously too costly or unavailable.

Of course, reducing the volume of a sample provides fewer opportunities to make up for sampling errors. Variability in a sample dispensing step that may not affect the final concentration of a 1mL sample may significantly impact concentration of a 100 µL sample.

The CHRONECT XPR and other automated sample preparation systems use a combination of automated weighing and sample handling to provide a means to prepare and process samples in small volumes. The overall goal of METTLER TOLEDO is to bridge the automation gap that currently exists between formulation and sample preparation.

Better Data, Traceability, and Process Control

Automation should enhance both the performance and the data of a given laboratory process. Automated systems should track what they have dispensed and how they have prepared a sample. Linking automated systems to experimental design provides the laboratory personnel with a means of track sampling in the course of an experiment.

The CHRONECT XPR offers a laboratory system to design and perform experiments using the CHRONOS software. Scientists can determine the experimental design and take control of their experiments. The software also provides scientists with the opportunity to analyze the data and track the experiment. The data flow is structured and documented in an automated format.

Process automation improves data by 18% according to the infographic. Traditionally, omissions and mix-ups occur during the formation and documentation of processes. Laboratory personnel must perform numerous tasks to document their processes. Automation reduces the requirement of laboratory personnel to document processes.

The process of documenting an experiment and sampling can be automated. The history of process documentation can be used to analyze and understand process variability. This information can be used to troubleshoot processes to ensure the sample being prepared is sampled and processed correctly.

Giving Scientists More Time for Science

The best part of automation is freeing up scientists to do more valuable work. Designing syntheses, analysis of promising comports, elucidation of mechanisms, and interpretation of data are intellectual activities that cannot be meaningfully performed by machines.

Routine laboratories tasks, such as weighing and preparation of samples, are activities that can be standardized and automated. The infographic shows that the automation of laboratories tasks can lead to a reduction in time to perform an assay by 30%, and reduced time for the development of pharmaceutical and chemical compounds from weeks to days.

Reducing time for assays allows researchers to evaluate a greater number of conditions and perform more experiments. It also speeds up the progression of advanced candidates to the next step.

Many scientists agree that, in order to gain better control over research activities and increase reproducibility of scientific work, research activities should be automated. Automation of research processes becomes especially necessary to address the overwhelming demand for new, innovative products. METTLER TOLEDO has developed CHRONECT XPR, a system integrating automation and digital controls for lab activities, to help the scientific community achieve better controls and more effective means for automating research.

Conclusion: A More Scalable Future for Reaction Preparation

HTS and HTE have raised expectations of what is achievable in automated reaction screening. Although sophisticated instruments can test thousands of conditions, the sample preparation step may limit throughput. For example, delays may be introduced if samples are weighed manually. In addition, variability and inefficiency may be introduced if an incorrect mass is assigned to a sample due to weighing errors.

The robotic automation of sample preparation can overcome these problems. High-throughput robotic systems can process hundreds of samples in a single cycle and can work with tiny sample amounts. In addition, these systems can work with a large variety of chemical samples and a large number of different powders.

Featured Article

Relying on robotic systems to perform sample preparation can lead to significant improvement of laboratory work. For example, errors can be decreased by 50% and the time needed to attain a final result can be reduced by 30%.

These improvements can be particularly beneficial for the sample preparation step required prior to automation of reaction screening. Thus, researchers can concentrate on less routine and more interesting activities.

More information can be found here:
www.mt.com/chronect-xpr

About METTLER TOLEDO –

METTLER TOLEDO is a global leader in precision instruments and services. We are renowned for innovation and quality across laboratory, process analytics, industrial, product inspection, and retailing applications. Our sales and service network is one of the most extensive in the industry. Our products are sold in more than 140 countries, and we have a direct presence in approximately 40 countries.
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Avantor® ACE®
Exclude SEC Column

Reliable, High-Resolution Size Exclusion Chromatography for Biotherapeutic Development

INTRODUCING THE NEXT GENERATION OF SEC PERFORMANCE

The Avantor® ACE® Exclude SEC Column delivers robust, cost-effective mAb aggregate analysis with excellent resolution and consistency, offering up to 3× longer lifespan, ~66% fewer replacements and minimal secondary interactions without high-salt buffers.

Built for Biopharmaceutical Workflows

- Clear separation between monomer and dimer/trimer for aggregate identification
- Seamless transitions to new batches
- Extended column lifetime
- Lower salt concentrations can be used in mobile phase
- Good peak shape even at low NaCl concentrations

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Advancing Biotherapeutic Analysis with **Avantor® ACE®** Exclude **SEC Columns**

The development of biotherapeutics requires the purification of proteins from numerous impurities. Size Exclusion Chromatography (SEC) is a powerful method of purification and analysis of biotherapeutics. During analysis of biotherapeutics, the method of choice is often SEC. The ACE Exclude SEC column is made for separation of biomolecules and offers reproducible and repeatable separation.

Challenges in Conventional SEC Analysis:

Despite its importance, conventional SEC methods often face limitations such as:

- Inconsistent separation between monomer and aggregates
- Variability between column batches affecting method robustness
- Limited column lifetime under high-throughput conditions
- Secondary interactions requiring high salt concentrations

This causes increased costs, late answers to validation questions, and hesitation to trust analytical results.

Solution Overview:

Avantor® ACE® Exclude SEC columns were developed with features intended to address these limitations through optimized particle and pore technology. With a selectivity of 100-800 kDa, the column has been shown to be lot-to-lot reproducible with different manufacturing lots. The column is used to separate mAbs, antibody-drug conjugates (ADCs) and other therapeutic proteins.

Key Benefits and Value Proposition:

Based on internal testing, the Avantor® ACE® Exclude SEC demonstrated:

- Fewer column replacements
- Reduced downtime
- Lower cost per analysis
- Improved laboratory productivity

Technical Performance:

Robust Across Conditions

The column demonstrated consistent chromatographic performance
under both low and high salt mobile phase conditions, providing flexibility in method development.

Optimized Design Specifications

- Particle size: 3 µm
- Pore size: 250 Å
- Selectivity: 100–800 kDa
- pH stability: 2–8
- Compatible with standard phosphate buffer systems

Application Example: mAb Aggregate Analysis:

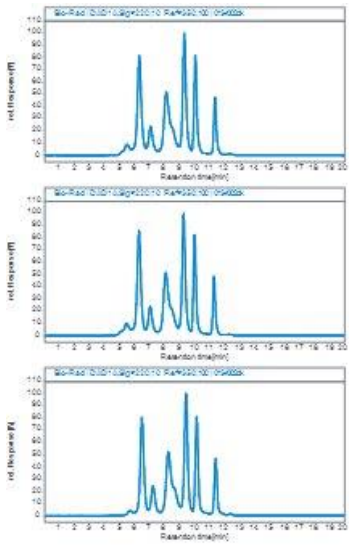
SEC plays a critical role in:

- Protein purity assessment
- Aggregate detection
- Structural integrity monitoring
- Supporting regulatory compliance

In a demonstrated application, the ACE® Exclude SEC column successfully separated NISTmAb monomer from induced aggregates, confirming its suitability for demanding biopharmaceutical analyses.

Figures 1 shows that the Avantor ACE Exclude SEC columns provide consistent separation of protein standards across different lots.

Figure 1



Test Conditions

- **Mobile phase:** 20 mM Na_2HPO_4 (pH 7.0) with NaCl
- **Flow rate:** 0.35 mL/min
- **Temperature :** 25 °C
- **Injection volume:** 0.5 µL

Sample:

- Thyroglobulin
- γ-Globulin
- Ovalbumin
- Myoglobin
- Vitamin B_{12}

mAb Aggregate Separation Application

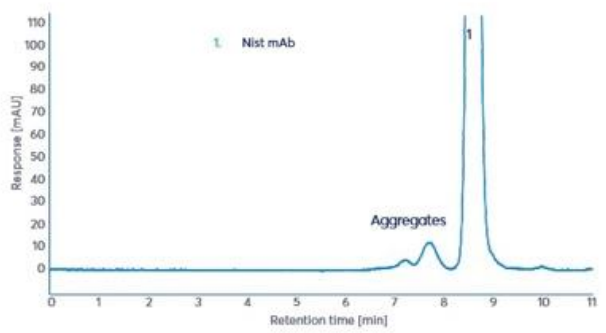
In biopharmaceutical development, SEC plays a critical role in:

- Assessing protein purity
- Detecting aggregates
- Monitoring structural integrity
- Supporting quality control and regulatory compliance

SEC is widely applied in the characterization of monoclonal antibodies (abs), antibody–drug conjugates (ADCs), and other therapeutic proteins, supporting quality control and regulatory compliance throughout the drug development lifecycle.

In this example application, NISTmAb at 1 mg/mL was diluted 1:9 in mobile phase and heated to 65 °C for 30 minutes with agitation to induce aggregate formation. As shown in Figure 2, the Avantor ACE Exclude SEC column successfully separated the NISTmAb monomer from the aggregates.

Figure 2



Test Conditions

- **Column:** Avantor ACE Exclude SEC
- **Particle size:** 3 µm
- **Dimensions:** 300 × 4.6 mm
- **Mobile phase:** 100 mM Na_2HPO_4 (pH 7.0) with 200 mM NaCl
- **Flow rate:** 0.35 mL/min
- **Temperature:** 25 °C
- **Injection volume:** 1 µL
- **Detection:** UV (220 nm)
- **Sample:** 1 mg/mL NISTmAb, diluted 1:9 in mobile phase

Conclusion

The Avantor® ACE® Exclude SEC column provides a reliable SEC platform to analyze biotherapeutics. SEC methods often suffer from poor reproducibility and subpar column lifetime. The ACE® Exclude SEC column provides resolution and reproducibility to enhance your SEC methodology. The column is designed to accelerate analysis of monoclonal antibody (mAb) aggregates, providing an opportunity to increase analysis throughput while reducing analysis cost. The ACE® Exclude SEC column can also be utilized to analyze other biotherapeutics in addition to mAbs.

Prolonging the operational lifespan of inline **vacuum degassers**

Authored By: Anders Grahn and Fritiof Pontén

Features of inline degassers

Inline degassing is the silent guardian of precision and reliability in fluidic systems. Installation of an inline vacuum degasser (see Figure 1) will drastically diminish the concentration of dissolved gases in the liquids propelled through the apparatus. This reduces variations, improves baseline stability, shortens startup times, and ensures more consistent results. By reducing the concentration of dissolved gases beyond the level where outgassing can occur, bubble formation will not be an issue despite changes in temperature, pressure, or compositions of the liquid managed throughout the flow path.

Construction outline

Degassers are important equipment components in laboratory analysis equipment such as liquid chromatography, HPLC, UHPLC, ion chromatography and mass spectrometry. Machines for semi-conductor manufacturing or assembly will also typically deliver more consistent results with a degasser included in the fluid path. The same is true for instruments in immunology, haematology, and in vitro diagnostics.

An inline degasser assembly contains a purposedly designed vacuum pump connected to one or several degassing chambers through which each liquid with dissolved gases flows. Inside the degassing chamber (see Figure 2) there is an inert gas-permeable membrane that must be compatible with the liquid to be degassed.

A control board with a vacuum sensor ensures that the vacuum level is kept at a constant level to minimize fluctuations in degassing performance and wear on the vacuum pump.

Measures to extend degasser lifetime

Modern inline degassers incorporated into instruments handling liquids with high precision and accuracy, are fortunately essentially maintenance-free.

However, there are a few things to keep in mind not to shorten the lifetime of your inline degasser.

Firstly, one should always use a degassing chamber compatible with the solvents that will be used. Organic solvents such as hexane, heptane, toluene, tetrahydrofurane (THF), and dichloromethane (DCM), typically demand specially designed degassing chambers. These degassing chambers are often labelled GPC to highlight their suitability in gel permeation chromatography, but they are equally suitable for normal phase and flash chromatography applications where such organic solvents are also employed. In addition, there are degassing chambers explicitly designed for hexafluoro isopropanol (HFIP) that are required when this aggressive organic solvent is used.

As with any fluidic component, it is advised to never leave your degassing chamber with liquid inside when disconnected from use for more than a moment.

This is especially important when there are dissolved salts or buffer components within the liquid since they may precipitate. Precipitates will block the flow path and are notoriously problematic to wash out again. In addition, buffered aqueous solutions exposed to open air may constitute an attractive environment for microbial growth, which can constrict the flow path.

Finally, it is strongly recommended to always suck solutions through the degassing chambers, rather than pumping or pushing liquids through them. The internal gas-permeable membrane material that allows gases to penetrate while blocking liquids, is designed to withstand a certain pressure difference. That limit may accidentally be exceeded if liquids are pumped too fast into the degassing chamber, which may cause irreparable damage.

Figure 1. Example of a stand-alone inline vacuum degasser from the DEGASi® NG family, suitable for aqueous liquids and organic solvents at flow rates from 5 µL/min up to 1 L/min, depending on model and configuration.

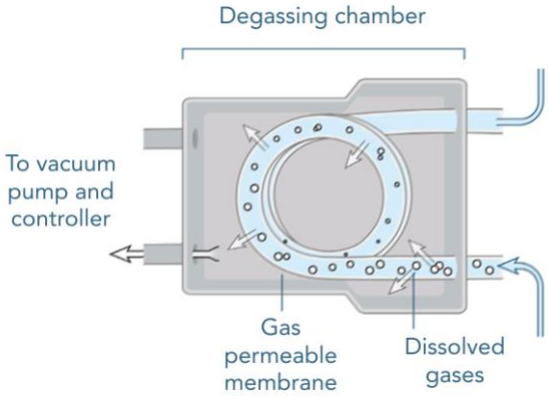


Figure 2. Schematic sketch of a degassing chamber containing a gas permeable tubular membrane, connected to a vacuum pump with constant vacuum controller.

Figure 3. Picture of a modern degassing vacuum controller incorporating fifth-generation vacuum pump and standardised error output that can be retrofitted to legacy constructions for extension of their product lifecycle.

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✓ Certified
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- Homogeneity & stability established as per ISO guidelines
- Designed for high-precision titrimetric and analytical applications
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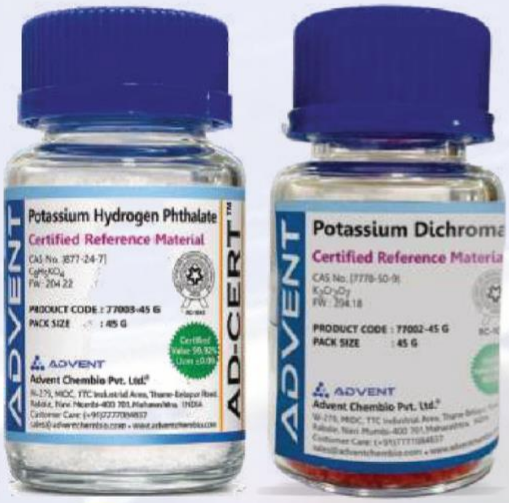
NIST Traceable

PRODUCT PORTFOLIO

CRM	Application	Pack Size
Potassium Hydrogen Phthalate	**Acid-base titration**	45 g
Sodium Carbonate	**Acid-base titration**	45 g
Sodium Chloride	**Argentometric titration**	45 g
Potassium Chloride	**Conductivity / Calibration**	45 g
Potassium Dichromate	**Redox titration**	45 g

APPLICATION AREAS

- Pharmaceutical Quality Control
- Research & Development Laboratories
- Analytical Method Validation
- Environmental & Chemical Testing etc..
- Calibration of Volumetric Solutions



ADVENT

Potassium Hydrogen Phthalate

Certified Reference Material

CAS No. [877-24-7]
$C_8H_5KO_4$
FW : 204.22

PRODUCT CODE : 77003-45 G
PACK SIZE : 45 G

RC-1043

Certified Value 99.92% Ucrm ±0.09

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AD-CERT™

Storage : Store at 15.0-35.0 °C in original packing at a clean, dry and well-ventilated place.
Keep the container tightly closed away from source of ignition; handle at inert atmosphere.

Purpose : Use as a Primary standard for testing, calibration and method validation.

Warning : It may cause skin and eyes irritation. If exposed, rinse repeatedly with water.

Batch No.	: G26B0015
Mfg. Date	: 09 February 2026
Exp. Date	: 08 February 2029

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NABL

CERTIFICATE OF ACCREDITATION

QUALITY CONTROL LABORATORY, ADVENT CHEMBIO PRIVATE LIMITED

has been assessed and accredited in accordance with the standard

ISO/IEC 17025:2017

"General Requirements for the Competence of Testing & Calibration Laboratories"

for its facilities at

W-279, MIDC, TTC INDUSTRIAL AREA, THANE-BELAPUR ROAD, RABALE, NAVI MUMBAI, THANE, MAHARASHTRA, INDIA

in the field of

TESTING

Certificate Number: TC-11230

Issue Date: 21/12/2024 Valid Until: 20/12/2028

This certificate remains valid for the Scope of Accreditation as specified in the annexure subject to continued satisfactory compliance to the above standard & the relevant requirements of NABL.
(To see the scope of accreditation of this laboratory, you may also visit NABL website www.nabl-india.org)

Name of Legal Entity: ADVENT CHEMBIO PRIVATE LIMITED

Signed for and on behalf of NABL

Anita Rani
Director

N. Venkateswaran
Chief Executive Officer

ISO 17034:2016 (NABL) Accredited Reference Material Producer (RMP)

Demonstrating Competence in Production of Certified Reference Materials

National Accreditation Board for Testing and Calibration Laboratories

NABL

CERTIFICATE OF ACCREDITATION

ADVENT CHEMBIO PRIVATE LIMITED - RMP DIVISION

has been assessed and accredited in accordance with the standard

ISO 17034: 2016

"General Requirements for the Competence of Reference Material Producers"

for its facilities at

W-279, MIDC, TTC INDUSTRIAL AREA, THANE - BELAPUR ROAD, RABALE, NAVI MUMBAI, THANE, MAHARASHTRA, INDIA

in the field of

REFERENCE MATERIAL PRODUCER

Certificate Number: RC-1043

Issue Date: 12/03/2026 Valid Until: 11/03/2030

This certificate remains valid for the Scope of Accreditation as specified in the annexure subject to continued satisfactory compliance to the above standard & the relevant requirements of NABL.
(To see the scope of accreditation of this RM Producer, you may also visit NABL website www.nabl-india.org)

Name of Legal Identity: ADVENT CHEMBIO PRIVATE LIMITED

Signed for and on behalf of NABL

Anita Rani
Director

Dr. Ramanand N. Shukla
Chief Executive Officer

Representative Certificate of Analysis (CoA)

Each AD-CERT™ CRM is supplied with a comprehensive and traceable CoA.

ADVENT

Certificate of Analysis

POTASSIUM HYDROGEN PHTHALATE - CERTIFIED REFERENCE MATERIAL

Product Code	: 777003-45 G
Lot Number	: G2680015
Appearance of CRM	: White crystals or crystalline powder
Expiry date	: 08 February 2029
Storage Conditions	: 15 °C to 35 °C
Certificate version	: G2680015.00
Chemical Formula	: $C_8H_5KO_4$
Molecular Mass	: 204.22
CAS No.	: 877-24-7

	CERTIFIED VALU...	
Assay of Potassium Hydrogen Phthalate	99.92 %	± 0.09 %

Metrological Traceability Metrological traceability to SI units is established through the characterization of Potassium Hydrogen Phthalate using validated measurement procedures and calibration against corresponding primary standard NIST SRM 84L. Traceability is ensured through an unbroken chain of comparisons with stated measurement uncertainty.

Measurement Method The certified value was established through purity determination by potentiometric titration, performed in accordance with ACS Reagent Chemicals (11th Edition). The method has been validated and demonstrated to be suitable for the intended use of the material.

Intended Use As a Reference Material for standardization of volumetric solutions used in titrimetric analysis as well as for verification and validation of standard analytical methods.

Instruction for Handling and Correct Use

Sample Preparation:
The material is in anhydrous form. Prior to use, it is recommended to dry the material at 105 °C for 2 hours and allow it to equilibrate in a desiccator.

Handling:
Due to potential differences between internal container pressure and ambient atmospheric pressure, open the container slowly and carefully to prevent dispersion of the material.

Storage:
To maintain the integrity of the certified values, the container should be tightly closed immediately after use and stored under the recommended conditions (15 °C to 35 °C). Protect from direct sunlight and moisture.

Health and safety information This material should be handled as a potential skin, eye, and respiratory irritant. It is intended for use by qualified laboratory personnel using appropriate personal protective equipment (PPE), including gloves and safety glasses.

Avoid dust generation and inhalation. In case of contact, rinse thoroughly with water. For detailed hazard information and emergency procedures, refer to the Safety Data Sheet (SDS).

Accreditation ADVENT CHEMBIO PRIVATE LIMITED is accredited by the National Accreditation Board for Testing and Calibration Laboratories (NABL) as a Reference Material Producer in accordance with ISO 17034:2016.

Certificate Issue Date 30 March 2026

Packaging The material is supplied as 45 g in a transparent glass bottle.

Advent Chembio Pvt. Ltd. ®
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ADVENT

Certificate of Analysis

POTASSIUM HYDROGEN PHTHALATE - CERTIFIED REFERENCE MATERIAL

Measurement Uncertainty (Expanded Uncertainty) The uncertainty values in this certificate are expressed as expanded uncertainty (Ucrm) corresponding to a confidence level of 95 % (coverage factor k = 2).
Ucrm is obtained by multiplying the combined standard uncertainty by the coverage factor k, determined using the Student's *t*-distribution based on the effective degrees of freedom.
The components of combined standard uncertainty include the uncertainties due to characterization, homogeneity, and stability including both long term and short term (transport) stability. All relevant components have been evaluated through rigorous testing and incorporated into the uncertainty budget, though they may be considered negligible if within the limits of the measurement method.

$$U_{Crm} = \left(\sqrt{u^2_{Characterization} + u^2_{Homogeneity} + u^2_{Stability}} \right) \times k$$

Measurement Method The assay was determined by potentiometric titration using 1 N sodium hydroxide solution as the titrant. The procedure follows the methods specified in ACS Reagent Chemicals (11th Edition) for Potassium Hydrogen Phthalate.

Homogeneity Assessment Homogeneity was evaluated in accordance with ISO Guide 35 using a stratified random sampling plan. The assessment was performed by chemical analysis, and the resulting data were processed using Single-Factor analysis of variance (ANOVA). No statistically significant between-bottle variation was observed, and the associated uncertainty contribution due to homogeneity has been included in the combined standard uncertainty.

Stability Assessment Stability studies have been initiated and are being conducted in accordance with ISO Guide 35. Based on available characterization data and short-term stability studies, the material is considered suitable for its intended use within the stated uncertainty, provided it is stored under the recommended conditions and used within the stated expiry date.
Long-term Stability:
An ongoing long-term stability study has been initiated, with a planned evaluation period of 5 years from the date of release. The study will continue to monitor the stability of the material under recommended storage conditions.
Short-term (Transport) Stability:
Short-term stability has been evaluated under simulated transport conditions, including exposure to elevated temperature and humidity. The results indicate that no significant effect on the certified values was observed under the tested conditions.

Certificate of Analysis Revision History

Certificate Version	Date of Issue	Reason of Version
00	30 March 2026	New product.

Mr. Swapnil Patil
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Malfunctioning components

Should a degasser chamber malfunction, it is most often either related to use with incompatible organic solvents, or a blocked flow path. If this happens, the chamber needs to be replaced. Fortunately, this is a straightforward and quick procedure in most systems. Note however, that in cases where there has been a leakage from the fluidic line into the vacuum line, there is a high risk that the vacuum sensor on the control board has been impaired. In these situations, there are often so many damaged components that one should consider exchanging the entire degasser.

Since modern inline degassers are highly robust equipment with a long lifetime, it may well be that if their internal vacuum pumps eventually fail, there is a risk the original part is no longer available from the manufacturer. The stepper motor driven vacuum pumps, with sensor and control boards to ensure constant vacuum, come in a range of variants for different degasser assemblies. These pumps may differ in capacity for various flow rate ranges, or in the vacuum setpoint, or in the control board design, or in the mounting orientation. Without proper guidance it might thus take quite some effort to find most suitable components.

Retrofitting modern parts

Lately, development of new degasser vacuum controller technologies with retrofit capabilities have emerged (see Figure 3). This enables extension the lifecycle of legacy constructions without replacement of the entire degasser. The result is a more sustainable and economically favourable manoeuvre to achieve improved degassing performance.

The physical replacement process of a vacuum pump and controller board is rather simple and can be completed within a few minutes by an instrument technician once the degasser unit has been opened.

Procuring the correct parts may actually be a more complex task. Conveniently however, Biotech Fluidics upholds an online vacuum pump replacement finder [1] that facilitates exchange of obsolete pumps and control boards in inline degassers from many different brands.

Conclusions

Inline degassers are robust equipment that require minimal maintenance to continuously safeguard precision in fluidic systems by reducing dissolved gases and eliminating troubles from bubbles.

With proper handling, the user can ensure that their degasser will keep performing for many years, and if it eventually fails, replacements of parts will be rather simple procedures.

References

[1] https://biotechfluidics.com/products/degassing-debubbling/degasi-inline-degassers/degasser-spare-parts/ (accessed September 7th 2026).

Authors

Anders Grahn, Chairman & Founder, Biotech Fluidics AB, Onsala, Sweden

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Alembic Pharma Gets USFDA Closure for Vadodara Facility

Shares of Alembic Pharmaceuticals Ltd soared 3% on September 17 after the US Food and Drug Administration (USFDA) closed its inspection of the company's bioequivalence facility in Vadodara, Gujarat.

The regulator issued an Establishment Inspection Report (EIR), formally communicating the closure of the inspection. The latest development relates to an unannounced onsite USFDA inspection conducted at the facility from August 31 to September 10, 2026.

According to the company's regulatory disclosure, the inspection concluded without any Form 483 observations.

The Vadodara facility conducts bioequivalence studies, which are an important part of the generic drug development process. These studies help establish whether a generic medicine performs similarly to its reference drug and are required as part of regulatory submissions for generic medicines in markets such as the US.

The clean inspection outcome provides regulatory clarity for the facility and supports the company's ongoing generic drug development activities. The closure also comes after a July 2026 USFDA warning letter issued to an associated clinical investigator, making the latest inspection outcome relevant to the company's regulatory monitoring.

Alembic Pharmaceuticals has also been managing other business and regulatory developments. The company recently redeemed commercial papers worth ₹150 crore on their September 11 maturity date, reducing its short-term debt obligations.

It also incorporated a wholly owned subsidiary, Alembic Pharmaceuticals Global FZCO, in Dubai in August 2026. The US remains an important market for Alembic Pharmaceuticals, particularly for its generic drug business. Maintaining compliance at facilities involved in bioequivalence testing is therefore important for

supporting future product filings and approvals.

The EIR closure and zero-observation outcome mark a positive regulatory update for the Vadodara facility. Investors will now track the company's further regulatory developments and progress in its US generic drug pipeline.

At 11:50 am, the shares of Alembic Pharmaceuticals were trading 1.19% higher at Rs 835.20 on NSE.

Tired of missing hot stocks? Tradz by EquityPandit provides powerful tools like stock scans and more help you make informed trading decisions.

Aurobindo Pharma Gets US FDA Approval for Asthma Inhaler

Aurobindo Pharma has received final approval from the US Food and Drug Administration (US FDA) to manufacture and market Beclomethasone Dipropionate HFA Inhalation Aerosol, a generic equivalent of Teva's QVAR RediHaler. The inhaler is approved for long-term preventive maintenance treatment of asthma in patients aged five years and above.

$301 Million Market Opportunity

As per ETPharma, the US market for the approved product and newer versions of QVAR RediHaler was estimated at $301 million for the 12 months ended July 2026, according to IQVIA estimates.

The company expects to launch the product in the upcoming quarters. It will manufacture the inhaler at its Raleigh facility in North Carolina, owned by its wholly owned step-down subsidiary Aurolife Pharma LLC.

Expanding Respiratory Portfolio

Importantly, this approval marks Aurobindo Pharma's first metered-dose inhaler (MDI) product. The company is expanding into complex respiratory therapies and recently launched another asthma treatment, Advair, in the US.

With the latest approval, Aurobindo Pharma's cumulative US FDA ANDA approvals have reached 596, including 571 final and 25 tentative approvals.

Strides Pharma Receives 3 USFDA Observations For Alathur Formulations Facility

Strides Pharma's Alathur formulations facility in Chennai underwent a routine 10-day USFDA inspection ending on September 11, 2026. The inspection concluded with the issuance of Form 483 containing three observations, which represents a slight increase from the two observations received in the previous April 2024 cycle. The company is preparing its official response to address the findings, and no material impact on current commercial operations is expected.

Market snapshot: Strides Pharma Science Limited has announced that its formulations manufacturing facility in Alathur, Chennai, has received three observations from the USFDA. This follows a routine current Good Manufacturing Practices (cGMP) inspection conducted at the site between September 2 and September 11, 2026. The company intends to submit a comprehensive response to the regulator within the stipulated timeframe.

Data Snapshot The USFDA routine cGMP inspection of the Alathur formulations facility concluded with the issuance of a Form 483 containing three observations.

The regulatory audit was conducted over a period of 10 days, starting on September 2, 2026, and ending on September 11, 2026.

The Alathur formulations facility received two observations during its previous inspection cycle conducted in April 2024.

The Alathur formulations facility received 3 observations in the current cycle, compared to 2 observations issued during the previous USFDA audit in April 2024.
The previous April 2024 inspection eventually resulted in a 'Voluntary Action Indicated' (VAI) classification, which was successfully concluded with an Establishment Inspection Report (EIR) in August 2024.

Key Takeaways

Routine Inspection: The 10-day inspection at the Chennai-based formulations facility was a routine cGMP audit.
Form 483 Issued: The USFDA concluded the audit with three observations, requiring the company to submit corrective actions.

Resolution Plan: Strides Pharma plans to respond to these observations within the stipulated timeline to ensure compliance.

Operational Continuity: The observations are procedural and do not disrupt current commercial production or existing export channels from the facility.
SAHI Perspective

For export-oriented Indian pharmaceutical firms, minor Form 483 observations are a standard part of regulatory oversight. Strides Pharma has a consistent track record of resolving these observations, as demonstrated by their recent clearance of five observations at their Bengaluru site. The increased observation count from two in 2024 to three in 2026 is minor and unlikely to cause severe operational hurdles, provided the corrective actions are accepted by the US regulator.

Market Implications
The announcement of three observations may lead to mild short-term volatility in the stock price as investors assess the severity of the findings. However, since this is a routine inspection and the facility has historically maintained manageable VAI statuses, the overall impact on the long-term outlook remains stable. Prompt submission and approval of the corrective and preventive action (CAPA) plan will be key to removing regulatory overhang.

Market Bias: Neutral
The regulatory audit concluded with standard Form 483 observations. While there is a minor increase to 3 observations compared to 2 in the previous cycle, the routine nature of the inspection and lack of immediate operational disruption supports a neutral near-term outlook.

Overweight: Pharmaceuticals
Trigger Factors:
USFDA classification of the inspection (e.g., Voluntary Action Indicated vs. Official Action Indicated).
Submission of the corrective action plan by Strides Pharma within the standard 15-day window.
Status of current commercial export shipments from the Alathur facility.

Time Horizon: Near-term (0-3 months)
Industry Context
Indian generic drug manufacturing facilities face frequent USFDA audits due to their heavy reliance on the US market. Standard inspections often yield procedural observations under Form 483, which are typically resolved through robust CAPA filings.

Corrective actions aligned with quality guidelines help domestic producers maintain export eligibility to the US, preventing disruptive regulatory actions like import alerts.

Key Risks to Watch
Escalation Risk: If the corrective actions are deemed inadequate by the USFDA, the inspection status could be classified as Official Action Indicated (OAI), which could delay new product approvals from this site.

EIR Timeline: Any prolonged delay in receiving the Establishment Inspection Report (EIR) could prolong regulatory uncertainty.

Recent Developments
In August 2026, Strides Pharma received the Establishment Inspection Report (EIR) for its flagship manufacturing facility in Bengaluru.

This successfully closed the inspection conducted from May 12 to May 20, 2026, which had originally concluded with five Form 483 observations, demonstrating the company's capability to resolve regulatory findings.

Closing Insight
While USFDA observations initially cause cautious sentiment, Strides Pharma's robust regulatory history and recent successful closure of the Bengaluru inspection suggest that the company is well-equipped to resolve these three observations without operational impairment.

Aurobindo Pharma receives final USFDA approval for generic Beclomethasone inhalation Aerosol

Aurobindo Pharma Limited has received final approval from the US Food & Drug Administration (USFDA) to manufacture and distribute its generic Beclomethasone Dipropionate HFA Inhalation Aerosol in 40 mcg and 80 mcg doses. The approved product serves as a generic alternative to Teva Branded Pharmaceutical Products' QVAR Inhalation Aerosol.

This represents Aurobindo's first metered-dose inhaler (MDI) product, marking a significant milestone in the Company's expansion into complex respiratory therapies and strengthening its capabilities in the inhalation segment. The product will be manufactured at Aurobindo Pharma's Raleigh facility in North Carolina, owned by its wholly owned step-down subsidiary Aurolife Pharma LLC. The product is expected to be launched in upcoming quarters.

The US market for the approved product and newer versions of the reference product, QVAR RediHaler, was estimated at US$301 million for the twelve months ended July 2026, according to IQVIA.

With this approval, Aurobindo Pharma's cumulative USFDA ANDA approvals stand at 596, comprising 571 final approvals and 25 tentative approvals, further strengthening the Company's portfolio of complex and differentiated products.

Beclomethasone Dipropionate HFA Inhalation Aerosol is indicated in the maintenance treatment of asthma as prophylactic therapy in patients 5 years of age and older. Indicated for asthma patients who require systemic corticosteroid administration, where adding Beclomethasone Dipropionate HFA Inhalation Aerosol may reduce or eliminate the need for the systemic corticosteroids.

Biocon's Pertuzumab Biosimilar Pebrilzo Gets Positive EMA Recommendation for Breast Cancer

Biocon Biologics has achieved a significant regulatory milestone after the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) issued a positive opinion recommending marketing authorisation for its pertuzumab biosimilar, **Pebrilzo®**, for the treatment of HER2-positive breast cancer. The development strengthens Biocon Biologics' position in the global biosimilars market and represents another important step in expanding access to complex biologic therapies.

Pebrilzo is being developed as a biosimilar to pertuzumab and is intended for use in several treatment settings involving HER2-positive breast cancer. The recommended product is a **420 mg concentrate for solution for infusion**, adding another potentially accessible option within an important area of oncology care.

The regulatory recommendation is particularly notable because Biocon describes Pebrilzo as the first biosimilar to receive a positive CHMP opinion under the EMA's newer tailored clinical development approach. The approach places increased emphasis on robust analytical and clinical pharmacology evidence to establish biosimilarity.

The positive CHMP opinion is not yet the final European Union marketing authorisation. The application will now proceed to the **European Commission**, which is responsible for making the final decision regarding authorisation across the European Union.

For Biocon Biologics, the development further demonstrates the company's focus on complex biologics and biosimilars as a major component of its international growth strategy.

Biosimilars are increasingly becoming an important part of efforts to broaden access to biologic medicines while supporting healthcare systems facing high treatment costs.

The development also highlights the growing sophistication of India's biologics industry, with Indian companies increasingly participating in the development, regulatory approval and global commercialisation of complex therapies. If ultimately authorised, Pebrilzo could further strengthen Biocon Biologics' presence in the global oncology biosimilars market.

Aragen Plans Major Expansion in Complex Drug Modalities and 500-KL CDMO Capacity

Hyderabad-based **Aragen Life Sciences** is stepping up investments in complex drug modalities as demand for specialised development and manufacturing services continues to increase globally. The company is expanding its capabilities across areas including antibody-drug conjugates, peptides, oligonucleotides and high-potency active pharmaceutical ingredients.

As part of the expansion, Aragen is planning to add approximately **500 kilolitres of new CDMO capacity**, reinforcing its manufacturing infrastructure for pharmaceutical customers. The investment reflects the growing demand for advanced development and manufacturing platforms capable of supporting increasingly complex therapeutic products.

The company's strategy extends beyond traditional small-molecule manufacturing. Advanced modalities such as ADCs, peptides and oligonucleotides require specialised process development, analytical capabilities, containment systems and manufacturing infrastructure, creating opportunities for specialised Indian CDMOs.

Aragen's expansion comes at a time when pharmaceutical companies globally are reassessing their development and manufacturing networks. Demand for integrated partners capable of supporting projects from development through commercial manufacturing has created additional opportunities for Indian CRDMOs.

The move also illustrates the evolution of India's pharmaceutical outsourcing industry. Indian companies are increasingly investing in specialised technologies rather than relying solely on conventional generic-drug manufacturing and API production.

With investments in complex modalities and additional manufacturing capacity, Aragen is positioning its platform to participate in higher-value segments of the global pharmaceutical development ecosystem. The expansion could also strengthen India's role as a strategic destination for complex pharmaceutical development and manufacturing services.

Dr. Reddy's to Bring Takeda's QDENGA Dengue Vaccine to India

Dr. Reddy's Laboratories has entered into an exclusive agreement with Japanese pharmaceutical company **Takeda** to promote and distribute **QDENGA®,** Takeda's dengue vaccine, in India's private market. The agreement follows the recent approval of the vaccine by India's drug regulator and marks a major development in the country's dengue-prevention landscape.

Under the agreement, Dr. Reddy's will be responsible for promoting and distributing QDENGA in the private market, covering vaccination for both children and adults. Takeda will retain responsibility for manufacturing and importation, while continuing to commercialise the vaccine in the public market.

QDENGA recently received approval in India for individuals between **4 and 60 years of age**. The approval makes it the first dengue vaccine authorised for use in India and represents a significant regulatory milestone for dengue prevention. The vaccine is administered as a **two-dose schedule**, with the second dose given three months after the first. According to the companies, prior dengue infection screening is not required before vaccination.

Dr. Reddy's said the vaccine is expected to become available in India during the **first half of 2027**, subject to completion of the required regulatory and local processes.

The agreement therefore establishes an important foundation for the future private-market availability of dengue vaccination in India.

The development comes against the backdrop of dengue remaining a significant public-health challenge across India and other tropical countries. The introduction of an approved dengue vaccine through a major Indian pharmaceutical distribution network could represent an important addition to the country's preventive healthcare ecosystem.

India's CRDMO Sector Accelerates Investment in Advanced Pharmaceutical Manufacturing

India's pharmaceutical development and manufacturing sector is witnessing increased investment in advanced capabilities as global drugmakers seek more integrated and specialised partners. Recent investments by Indian CRDMOs highlight a shift from traditional outsourcing toward complex drug development, advanced manufacturing and end-to-end pharmaceutical services.

Companies such as **Aragen Life Sciences** are increasing their focus on complex modalities, including antibody-drug conjugates, peptides, oligonucleotides and high-potency APIs. These areas require sophisticated technologies, specialised facilities and stringent process controls, creating a higher-value opportunity for India's pharmaceutical manufacturing ecosystem.

The shift is being supported by the broader transformation of pharmaceutical supply chains. Global drug developers increasingly require partners capable of handling multiple stages of the product lifecycle, from early development and analytical testing through clinical manufacturing and commercial-scale production.

India already has an established base in generic pharmaceuticals, APIs and contract manufacturing. However, investments in biologics, complex formulations, high-potency compounds and emerging modalities are expanding the country's capabilities into more technically demanding areas.

This transition could have implications across the wider pharmaceutical supply chain, including laboratory technology, analytical instrumentation, process equipment, containment systems and quality-control infrastructure. As manufacturing complexity increases, demand for advanced analytical and process technologies is also expected to grow.

The latest expansion plans therefore point toward a broader transformation of India's pharmaceutical industry—from a predominantly volume-driven manufacturing base toward a more integrated ecosystem supporting **drug discovery, development, analytical science, advanced manufacturing and global commercial supply**.

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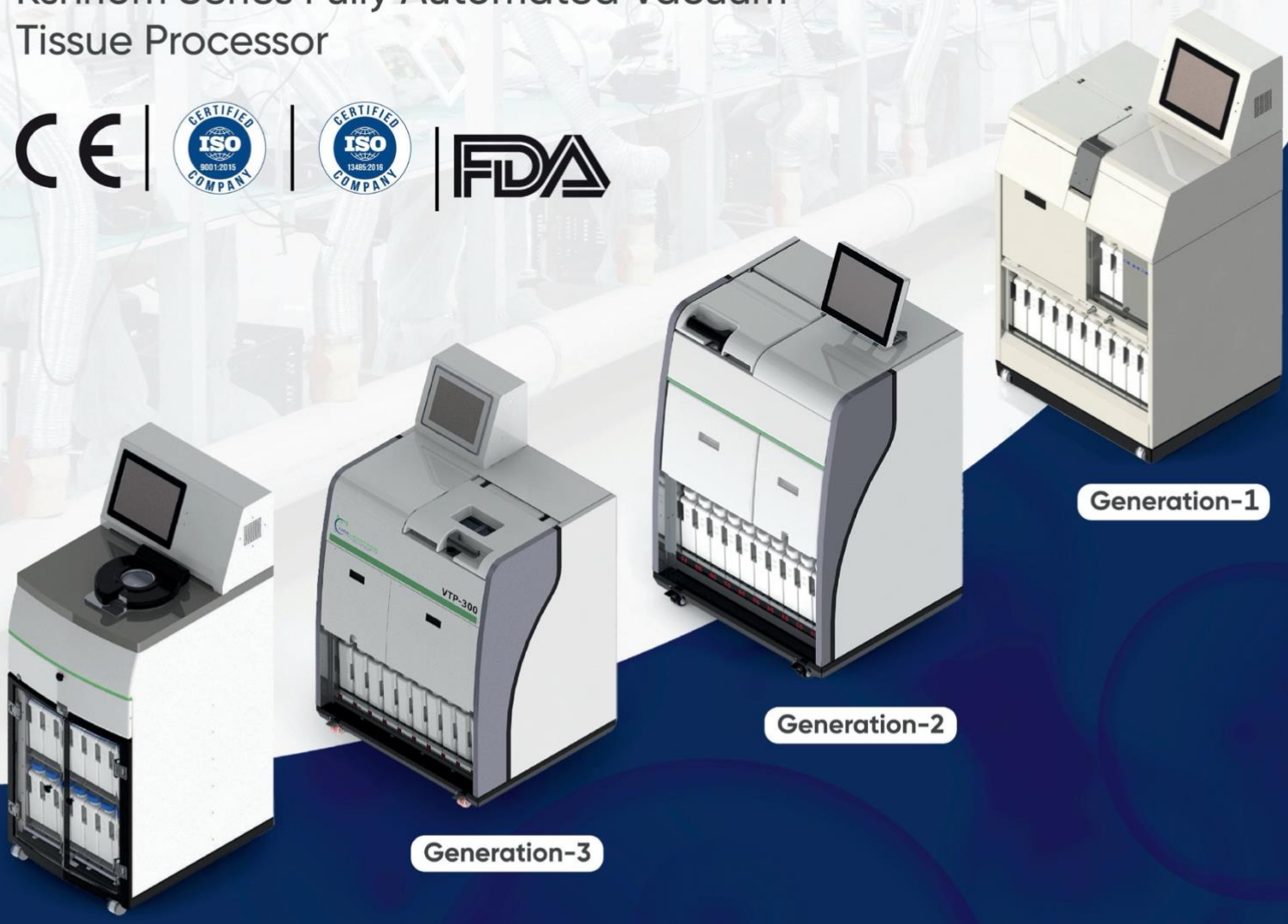

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BSE Healthcare Index Hits Record High as Pharma Stocks Gain Momentum

India's pharmaceutical and healthcare sector attracted strong market attention on September 21, with the **BSE Healthcare Index reaching a new lifetime high** during Monday trading. The index was reported to be among the strongest-performing sectoral indices during the session.

According to market data reported by *Business Standard*, the BSE Healthcare Index was up around **1.2% at 11:45 a.m.**, while the broader BSE Sensex had gained approximately 0.62% at that point in the session. The healthcare index had also significantly outperformed the benchmark during financial year 2026–27 to date.

Several pharmaceutical companies contributed to the sector's positive momentum. **Laurus Labs and Aurobindo Pharma**, among others, touched new highs during the trading session, reflecting continued investor interest in selected Indian pharmaceutical companies.

The sector's performance comes amid a period of continued investment in pharmaceutical manufacturing, contract development and manufacturing, complex therapies and international markets. Indian companies are simultaneously expanding domestic capabilities and strengthening their global pharmaceutical operations. Beyond stock-market performance, the developments illustrate the increasing diversity of India's pharmaceutical sector.

The industry now encompasses generic medicines, APIs, biosimilars, specialty products, complex drug modalities, CDMO services and advanced manufacturing platforms.

For the pharmaceutical ecosystem, continued investment and expansion could have a wider impact on laboratories, analytical testing, quality control, process development and manufacturing technology. The sector's latest market performance therefore comes alongside broader structural changes taking place across India's pharmaceutical value chain.

Singapore Strengthens Regulatory Reliance with Malaysia to Accelerate Medicine Access

Singapore's **Health Sciences Authority (HSA)** has expanded regulatory cooperation with Malaysia as part of a broader effort to reduce duplication in medicine assessments and support faster access to health products. Malaysia's National Pharmaceutical Regulatory Agency (NPRA) began a pilot on **September 1, 2026**, to reference HSA's assessments when reviewing medicines.

The pilot is designed to examine how regulatory reliance can reduce duplicated assessment work while maintaining each authority's requirements for safety, quality and efficacy. Under a reliance model, one regulator can make use of assessments or regulatory work already conducted by another trusted authority.

Singapore said the initiative forms part of a broader expansion of regulatory cooperation with international agencies. HSA has also announced new or strengthened collaborations involving the African Medicines Agency, Saudi Food and Drug Authority and the UK's Medicines and Healthcare products Regulatory Agency.

For pharmaceutical companies operating across Southeast Asia, regulatory reliance could potentially reduce repetitive regulatory processes when products are submitted in multiple markets. Greater regulatory cooperation may also improve coordination between agencies and support more efficient product evaluation.

The Malaysia initiative is particularly relevant to the ASEAN pharmaceutical environment, where companies frequently operate across multiple regulatory jurisdictions. Harmonisation and reliance mechanisms have the potential to simplify aspects of regional market access while preserving national regulatory oversight. The development highlights a broader regional trend toward **regulatory collaboration, reliance and digitalisation**, as Southeast Asian regulators seek to improve efficiency while maintaining rigorous standards for pharmaceutical quality, safety and efficacy.

Sun Pharma's $11.75 Billion Organon Deal Moves Closer to Completion

Sun Pharmaceutical Industries continues to advance its proposed **US$11.75 billion acquisition of Organon & Co.**, one of the largest overseas acquisitions undertaken by an Indian pharmaceutical company. The transaction, announced earlier this year, is expected to significantly expand Sun Pharma's global commercial footprint and diversify its portfolio across innovative medicines, women's health and established pharmaceutical products.

The proposed transaction involves Sun Pharma acquiring **100% of Organon** at an enterprise value of approximately US$11.75 billion. The deal remains subject to customary regulatory and closing conditions and is currently expected to close by **March 2027**, according to reporting on the transaction.

The scale of the proposed acquisition has attracted attention from international credit-rating agencies. **Moody's Ratings and S&P Global Ratings** have assigned investment-grade ratings to Sun Pharma following the company's binding bid, while maintaining stable outlooks.

According to S&P, the acquisition could substantially strengthen Sun Pharma's business position and potentially almost double its revenue base to approximately **₹1.3 trillion**, or around US$14 billion. The transaction would also provide Sun Pharma with a significantly larger international commercial platform.

The acquisition is strategically important because Indian pharmaceutical companies are increasingly looking beyond traditional generic medicines toward specialty pharmaceuticals, innovative products and established global brands. Sun Pharma has already been expanding its specialty business internationally, particularly in the US.

If completed as planned, the Organon transaction would represent a major milestone in the international expansion of an Indian pharmaceutical company and further demonstrate the growing scale and global ambitions of India's pharmaceutical industry.

Aragen Announces Major Investment in Complex Drug Modalities and 500-KL CDMO Capacity

Aragen Life Sciences is stepping up investments in advanced pharmaceutical development and manufacturing as demand for complex drug modalities continues to increase. The Hyderabad-based CRDMO is expanding its capabilities in **antibody-drug conjugates, peptides, oligonucleotides and highly potent APIs**, strengthening its position across the global pharmaceutical value chain.

As part of its expansion strategy, Aragen plans to establish approximately **500 kilolitres of additional CDMO capacity**. The new capacity is intended to support increasing demand from pharmaceutical and biotechnology companies seeking specialised manufacturing partners for complex molecules and advanced therapies.

The company's investment reflects a broader shift in the outsourcing model. Pharmaceutical companies are increasingly looking for CRDMO partners capable of providing integrated services covering process development, analytical development, clinical manufacturing and commercial-scale production.

Complex modalities such as ADCs and oligonucleotides require specialised manufacturing environments, advanced analytical capabilities and sophisticated process-development expertise. Investment in these areas can therefore create higher-value opportunities than conventional contract manufacturing.

Aragen's expansion also reflects the continuing evolution of India's pharmaceutical outsourcing industry. Indian companies are increasingly moving beyond traditional API and generic-drug manufacturing into advanced development platforms and specialised therapeutic technologies.

The planned capacity addition positions Aragen to participate in the growing global demand for complex pharmaceutical manufacturing while supporting India's broader ambition to become an integrated hub for pharmaceutical research, development and manufacturing.

Dr. Reddy's Signs Global Licensing Deal for Gilead's Once-Yearly HIV Prevention Drug

Dr. Reddy's Laboratories has entered into a licensing agreement with **Gilead Sciences** covering the investigational once-yearly HIV prevention medicine **lenacapavir**. The agreement represents another major step in Dr. Reddy's strategy of expanding its global healthcare portfolio through strategic licensing and international partnerships.

Under the agreement, the partnership will support manufacturing and supply planning for the medicine across **120 countries**. The arrangement gives Dr. Reddy's an opportunity to participate in the global expansion of a potentially important long-acting HIV-prevention technology.

Lenacapavir belongs to a new generation of long-acting medicines designed to reduce the frequency of administration compared with conventional prevention approaches. A once-yearly dosing model could have implications for treatment adherence and the delivery of HIV prevention programmes, subject to regulatory approvals.

The agreement also highlights the increasing importance of Indian pharmaceutical companies in global access strategies. Indian manufacturers have extensive experience in large-scale production and distribution of medicines across emerging and lower-income markets.

For Dr. Reddy's, the licensing arrangement adds another strategic component to its international portfolio while providing a pathway to participate in the commercialisation and supply of an innovative medicine across multiple markets.

The transaction demonstrates how licensing partnerships between multinational innovators and Indian pharmaceutical companies are increasingly being used to combine innovative drug development with global manufacturing, supply-chain and market-access capabilities.

Gujarat Themis Completes ₹1,300 Crore Acquisition of Japan's MicroBiopharm

Gujarat Themis Biosyn Limited (GTBL**)** has completed its acquisition of Japan-based **MicroBiopharm Japan Co., Ltd. (MBJ)** for approximately **¥21.5 billion, or around ₹1,300 crore**. The acquisition gives the Indian pharmaceutical company access to established Japanese manufacturing infrastructure, specialised technologies and long-standing relationships with international pharmaceutical customers.

The transaction was completed through GTBL's wholly owned Japanese subsidiary, **Themis Biosyn Japan**, after receiving the required regulatory approvals and satisfying closing conditions. GTBL funded the acquisition through approximately ₹475 crore of capital contribution and ₹745 crore of loans to its Japanese subsidiary.

MicroBiopharm operates **three GMP-compliant manufacturing facilities** and has a history of inspections by regulators including the US FDA and Japan's PMDA. The company reported revenue of approximately ¥9.5 billion in FY26, with around 40% generated outside Japan.

The acquisition significantly expands GTBL's technological capabilities beyond its traditional fermentation-focused business. MBJ brings a proprietary **P450 enzyme platform**, along with capabilities in plasmid DNA, recombinant proteins and antibody-drug conjugate conjugation.

The deal also provides GTBL with access to APIs and intermediates used in areas including oncology, immunosuppressants, peptides and antibiotics. The company plans to combine MBJ's technology and customer relationships with India's cost-efficient manufacturing base.

GTBL has described the acquisition as an important step in its ambition to become a **globally integrated CDMO**. The transaction illustrates the increasing willingness of Indian pharmaceutical companies to use overseas acquisitions to gain specialised technologies, regulated manufacturing capacity and access to established international customers.

Shilpa Biologicals Signs Strategic PD-1 Biosimilar Licensing Deal for MENA Markets

Indian biologics developer and manufacturer **Shilpa Biologicals** has entered into an exclusive strategic licensing and commercialisation agreement with Saudi Arabia-based **SPIMACO Bio** covering a portfolio of PD-1 inhibitor biosimilars for the Middle East and North Africa (MENA) region.

Under the agreement, Shilpa Biologicals will retain intellectual-property ownership and act as the developer and manufacturer of the products. SPIMACO Bio will lead regulatory execution, commercialisation and market-access activities across the targeted MENA markets.

The partnership also includes a phased technology-transfer programme aimed at establishing local manufacturing capabilities in Saudi Arabia. Such arrangements are becoming increasingly relevant as countries seek greater pharmaceutical manufacturing resilience and domestic access to advanced medicines.

PD-1 and PD-L1 inhibitors are an important class of cancer immunotherapies, and the market for these medicines is expanding as oncology treatment increasingly incorporates immune-based approaches. Biosimilar competition could potentially broaden access as more biologic therapies face patent expiry and competition.

For Shilpa Biologicals, the agreement creates an international commercialisation pathway while allowing the company to leverage its biologics development and manufacturing capabilities. For SPIMACO Bio, the partnership provides access to additional biologic technologies and supports its regional manufacturing ambitions.

The transaction highlights the growing role of Indian biotechnology and pharmaceutical companies as technology and manufacturing partners for international markets. It also demonstrates how strategic licensing and technology-transfer agreements can help Indian companies expand beyond domestic markets into specialised global healthcare segments.

RPG Life Sciences Expands API Portfolio Through ₹135 Crore Raghava Life Sciences Acquisition

RPG Life Sciences **has completed** the acquisition of the API business of **Raghava Life Sciences**, adding significant manufacturing capacity and new molecules to its pharmaceutical portfolio. The transaction forms part of the company's broader strategy to strengthen its API capabilities and build an integrated pharmaceutical business.

The acquisition was completed on **September 15, 2026**, and reportedly adds approximately **300 kilolitres of manufacturing capacity** and **29 molecules** to RPG Life Sciences' portfolio. The transaction was valued at around **₹135 crore**.

The integration provides RPG Life Sciences with additional infrastructure and product capabilities within the API segment. APIs remain an important component of India's pharmaceutical supply chain, supporting both domestic formulations and international pharmaceutical manufacturing.

The transaction also comes as RPG Life Sciences continues to strengthen its domestic formulations business. The company's domestic formulations reportedly recorded **14.8% year-on-year growth in Q1 FY27**, contributing to its progress within India's competitive pharmaceutical market.

The addition of manufacturing capacity and molecules could provide opportunities for greater vertical integration between API production and finished pharmaceutical products. It also reflects the continuing importance of scale, manufacturing efficiency and portfolio breadth in India's pharmaceutical business environment.

For the Indian pharma sector, the acquisition is another example of consolidation and capacity expansion within the API and formulations ecosystem. As companies seek greater control over supply chains and access to specialised molecules, strategic acquisitions are increasingly becoming an important growth tool.

Edmund **Bühler Shakers**: Precision Shaking for Modern Laboratories

Modern laboratories demand equipment that can deliver precision, consistency, and reliable performance across a wide range of applications. **Edmund Bühler shakers** are designed to meet these demands, offering versatile solutions for applications ranging from gentle cell culture and biological sample handling to intensive mixing and homogenization.

Advanced Shaking Technology for Modern Laboratories – Edmund Bühler Sets the Standard

In laboratories where accuracy, efficiency, and reliability are non-negotiable, Edmund Bühler provides the ideal shaking solutions for a wide range of applications. From gentle cell culture cultivation to intensive mixing tasks, Bühler shakers are engineered to deliver consistent performance across research, pharmaceutical, and industrial environments.

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Edmund Bühler offers the right laboratory shakers for mixing or shaking different media or for culturing cell cultures with or without a CO2 Atmosphere. Whether orbital shakers or horizontal shakers, for incubation or homogenization – From **mixing and homogenization** to **culturing sensitive biological samples**, Bühler devices are optimized to handle diverse laboratory protocols—safely, reliably, and with repeatable results.

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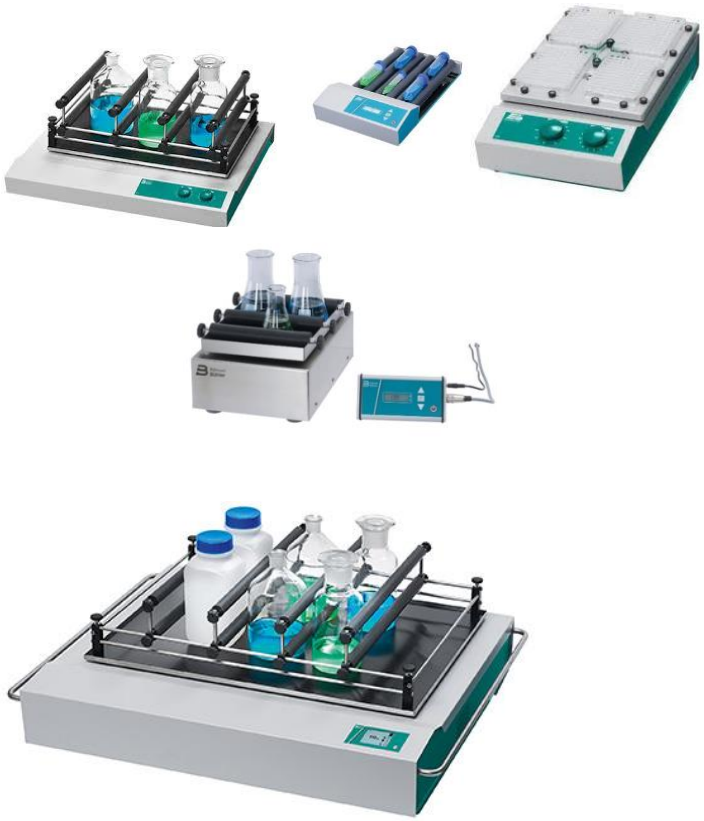
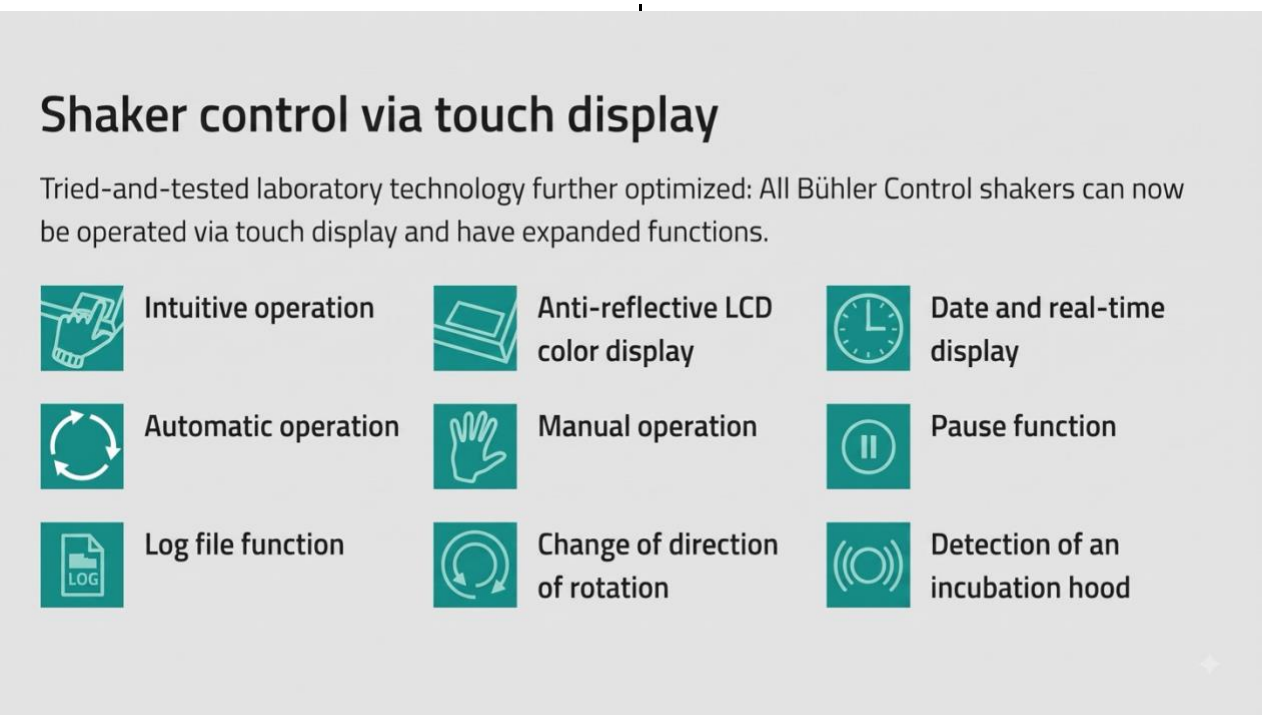


Not Just Shakers – Complete Thermal Processing Solutions

Beyond shaking technology, Edmund Bühler is a leading provider of **metal melting plants** for demanding thermal processes.



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With a long-standing legacy in laboratory innovation, Edmund Bühler combines German engineering with forward-looking design. Whether you need robust shaking equipment or specialized melting systems, Bühler delivers solutions that support progress in science and industry.

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Agilent Launches 9500 ICP-MS, New GC Systems and OpenLab Sync in India

Agilent Technologies **has introduced a new portfolio of analytical and digital** laboratory solutions in India, targeting laboratories facing increasing testing volumes and growing requirements for productivity, data quality and regulatory compliance. The portfolio includes the **Agilent 9500 Triple Quadrupole ICP-MS**, the **8890B and 8860B Gas Chromatography Systems with GC Assist**, and **OpenLab Sync**, a new Laboratory Execution System designed to bring guided digital workflows directly to the laboratory bench.

Agilent Technologies

The **Agilent 9500 Triple Quadrupole ICP-MS** is designed for elemental analysis across complex sample matrices. Its potential applications span pharmaceutical testing, food safety, environmental analysis and advanced materials, where laboratories increasingly require sensitive and reliable measurement of trace elements.

The new **8890B and 8860B GC systems** introduce GC Assist capabilities designed to help laboratories manage instrument operation, monitoring, diagnostics and maintenance. The systems are aimed at supporting laboratories seeking greater instrument availability and more consistent analytical workflows.

Agilent has also introduced **OpenLab Sync**, a laboratory execution system that digitises procedures traditionally managed through paper-based workflows. By bringing guided instructions and workflow management to the laboratory bench, the system is intended to improve consistency, traceability and audit readiness.

The launch addresses three connected requirements in modern laboratories: **analytical performance, instrument productivity and workflow execution**. This combination reflects the industry's broader movement from standalone instruments toward integrated laboratory environments where equipment, software and data work together.

For India's pharmaceutical, food, environmental and industrial laboratories, the launch represents a move toward more connected analytical operations. As testing requirements become more demanding, technologies combining advanced instrumentation with digital workflow management are becoming increasingly important for efficient and compliant laboratory operations.

Eppendorf Launches New Centrifuge 5811 R with Sustainable Refrigeration Technology

Eppendorf **has launched its new** Centrifuge 5811 R**, a** refrigerated multipurpose benchtop centrifuge designed for laboratories handling a broad range of tube-, bottle- and plate-based workflows. The new system succeeds the established 5810 R and combines a refreshed design and user interface with updated cooling technology.

One of the key features of the new centrifuge is its use of **R290 propane refrigerant**, which has a very low global warming potential of 0.02 and zero ozone depletion potential. The cooling technology forms part of Eppendorf's broader focus on reducing the environmental footprint of laboratory equipment.

The Centrifuge 5811 R offers a capacity of up to **3 litres** and speeds of up to **20,913 × g**, or 14,000 rpm. This enables the instrument to support a wide variety of sample-processing requirements within a benchtop configuration.

The system is compatible with a portfolio of **15 rotors and multiple adapters**, including swing-bucket and fixed-angle configurations. Mixed bucket loading allows laboratories to accommodate different vessel form

ats within a single run, increasing flexibility when applications and protocols change.

Energy-conscious features include **ECO shut-off, FastTemp temperature control and aerodynamic bucket designs** intended to support efficient operation. These features demonstrate how sustainability is increasingly being incorporated directly into laboratory equipment design rather than treated as a separate consideration.

The launch is particularly relevant for pharmaceutical, biotechnology, academic and research laboratories where centrifugation remains an essential sample-processing step. With increasing attention on laboratory sustainability, equipment combining established performance with lower-impact cooling technologies is becoming an important part of modern laboratory infrastructure.

Thermo Fisher Introduces Multiskan Ease Microplate Reader for Routine Biological Assays

Thermo Fisher Scientific **has launched the** Thermo Scientific Multiskan **Ease Absorbance Microplate Reader**, a compact instrument designed for routine absorbance-based laboratory assays. The new platform is aimed at academic, biotechnology, pharmaceutical and quality-control laboratories that require straightforward measurement workflows for frequently performed biological assays.

The Multiskan Ease is designed to support applications including **protein quantification, ELISA, cell-viability studies, enzyme activity assays, endotoxin testing and microbial growth monitoring**. By focusing on commonly performed absorbance applications, the instrument targets laboratories looking for accessible and streamlined plate-based analysis.

Microplate readers are increasingly used across pharmaceutical development, biotechnology research and quality-control workflows because they allow laboratories to process multiple samples in parallel. Compact systems can also help laboratories make better use of available bench space.

The new platform emphasises simplified operation and dependable absorbance measurements. This makes it relevant to laboratories where routine testing needs to be performed repeatedly while maintaining consistent analytical workflows.

The instrument also reflects a broader laboratory-equipment trend toward **application-specific systems that simplify routine analysis**. Rather than requiring highly complex instrumentation for every assay, laboratories can deploy dedicated systems for frequently performed measurements.

For pharmaceutical and life-science laboratories, the Multiskan Ease provides another option for routine microplate-based testing and research. Its application range positions the instrument across research, bioprocessing and quality-control environments where reliable absorbance measurements are routinely required.

Waters and BD Launch FACSDiscover A7 Cell Analyzer for Advanced Spectral Flow Cytometry

Waters Corporation and **BD** have announced the commercial launch of the **BD FACSDiscover A7 Cell Analyzer**, expanding access to advanced spectral flow cytometry. The platform is designed to enable researchers to analyse more than **50 cellular characteristics**, supporting increasingly complex cell-analysis workflows in research and biopharmaceutical laboratories.

Spectral flow cytometry enables researchers to analyse multiple fluorescent signals simultaneously and extract detailed information about heterogeneous cell populations. Such capabilities are increasingly important in immunology, cell biology, drug discovery and biopharmaceutical research.

The FACSDiscover A7 is designed with an emphasis on standardisation and accessibility in advanced flow-cytometry workflows. The commercial launch expands availability of the technology beyond specialised research environments.

The platform is particularly relevant to laboratories working with complex biological samples where multiple cellular parameters need to be characterised within a single experiment. These capabilities can support research programmes involving immune-cell profiling, disease biology and therapeutic development.

The launch also reflects the growing convergence between **advanced instrumentation, data analysis and biological characterisation**. As pharmaceutical research increasingly focuses on complex biological systems, laboratories require analytical platforms capable of generating richer datasets from limited samples.

For biopharmaceutical laboratories, the FACSDiscover A7 adds another advanced tool for high-dimensional cellular analysis. Its commercial availability illustrates the continuing evolution of flow cytometry toward more information-rich and standardised laboratory workflows.

Agilent Introduces Cary 635 FTIR Spectrometer for Advanced Molecular Analysis

Agilent Technologies has introduced the **Cary 635 FTIR Spectrometer**, adding a new Fourier-transform infrared spectroscopy platform to its analytical instrumentation portfolio. The launch comes as laboratories increasingly seek analytical technologies capable of delivering rapid molecular information across pharmaceutical, chemical and materials applications.

FTIR spectroscopy is widely used for identifying chemical compounds, characterising materials and investigating molecular structures. In pharmaceutical laboratories, infrared spectroscopy can support raw-material identification, formulation analysis, process monitoring and quality-control activities.

The Cary 635 expands Agilent's spectroscopy offering and reflects the continuing importance of infrared analysis in modern analytical laboratories. FTIR systems are valued for their ability to provide molecular fingerprints with relatively rapid analysis and limited sample preparation.

The launch also comes at a time when pharmaceutical and industrial laboratories are placing greater emphasis on analytical efficiency. Faster identification and characterisation of materials can help laboratories support quality-control decisions while maintaining established analytical procedures.

For laboratories operating under regulated environments, analytical instruments must also fit into broader quality and data-management workflows. This makes integration, usability and reproducibility increasingly important considerations when laboratories evaluate new analytical technologies.

The introduction of the Cary 635 therefore adds another option for laboratories requiring infrared-based molecular analysis. Its applications span pharmaceutical development, chemical analysis, materials research and other analytical environments where rapid molecular characterisation is required.

CRAIC Updates 508PV Microscope Spectrophotometer for Life-Science Research

CRAIC T**echnologies** has introduced significant technology updates to its **508PV Microscope Spectrophotometer**, expanding the platform's capabilities for biological, medical and pharmaceutical research. The system combines microscopic imaging with spectroscopic analysis, allowing researchers to obtain spectral information directly from microscopic specimens.

The updated 508PV can perform measurements including **absorbance, reflectance, fluorescence, photoluminescence and polarization spectra** when integrated with an appropriate optical microscope. This enables researchers to investigate both the physical appearance and optical characteristics of microscopic samples.

The platform provides spectral coverage from approximately **250 nm in the deep UV to 2100 nm in the near-infrared**, with sub-micron spatial resolution possible in suitable configurations. These capabilities can be valuable when researchers need detailed information from very small sample areas.

Potential applications include protein and nucleic-acid research, fluorescence analysis, pharmaceutical development, histology, pathology, biomaterials and biosensor research. The combination of imaging and spectroscopy can provide additional information beyond conventional microscopy alone.

CRAIC's updated platform also works with its **Lambdafire software** for data acquisition, analysis and reporting. This software component supports the conversion of complex spectral measurements into usable analytical information for researchers.

The launch demonstrates the growing convergence between **microscopy and spectroscopy**, particularly in life-science research. For pharmaceutical and biomedical laboratories investigating drug crystals, biological specimens, tissues or advanced materials, integrated imaging and spectral analysis can provide a more detailed view of sample characteristics.

Waters Launches Spectral Flow Cytometry Analyzer for High-Parameter Research

Featuring up to five lasers and 78 detectors, the instrument enables analysis of more than 50 single-cell characteristics with under 10% variation.

Waters Corp has announced the commercial launch of the BD FACSDiscover A7 Cell Analyzer, expanding its spectral flow cytometry portfolio to academic, pharmaceutical, and contract research organization laboratories.

The system incorporates BD SpectralFX Technology, which is also utilized in the BD FACSDiscover A8 Cell Analyzer. The instrument supports up to five lasers and 78 fluorescence detectors, enabling laboratory researchers to measure more than 50 characteristics on a single cell.
The analyzer also includes FACSTruQ Technology, which provides automated setup, calibration, and quality control. Internal company data indicate that this system achieves reproducible results with a coefficient of variation below 10% across more than 50 dyes, supporting data consistency across different users, instruments, and laboratory sites.

The instrument is paired with an integrated autoloader and BD FACSChorus Software, which provides guided workflows to support experimental standardization.

"The FACSDiscover A7 Cell Analyzer lowers the barrier to advanced spectral flow cytometry and will open up new possibilities for immunology research, enabling our core facility to help scientists uncover deeper biological insights with greater standardization and confidence," says Cheryl Kim, senior director of the flow cytometry core at La Jolla Institute for Immunology, in a release. "We look forward to the FACSDiscover A7 Cell Analyzer being an integral instrument for our core, allowing our researchers to get the most out of spectral data to advance our important work of improving human health through the development of treatments and cures for immune system disorders."

Expanding Spectral Capabilities and Standardization

According to Waters, the platform builds on technology first introduced with the BD FACSDiscover S8 Cell Sorter, which demonstrated a 50-color flow cytometry panel.

"The FACSDiscover A7 Cell Analyzer couples advanced spectral performance and leading standardization with a compelling price-to-performance balance, bringing spectral flow cytometry within reach of more researchers than ever before, for applications from biomarker discovery to drug development," says Steve Conly, senior vice president of Waters Biosciences at Waters Corp, in a release. "Just two years after the world's very first 50-color flow cytometry panel was developed on the BD FACSDiscover S8 Cell Sorter, the FACSDiscover A7 Cell Analyzer extends these transformative capabilities, helping labs meet their increasingly critical needs for reproducibility within our connected ecosystem of instruments, reagents, and informatics."

The BD FACSDiscover A7 Cell Analyzer is available globally through local representatives, according to the release. Following Waters Corporation's acquisition of the BD Biosciences and BD Diagnostic Solutions units, Becton, Dickinson and Company serves as the legal manufacturer of the instruments until regulatory transfers are finalized.
Photo caption: BD FACSDiscover A7 Cell Analyzer
Photo credit: Waters Corp

Wiley Launches Spectral Analysis API Portfolio for Laboratory Workflows

The new application programming interface tools provide access to spectral data and analytical intelligence directly within existing laboratory systems.

Wiley announced the launch of its spectral analysis application programming interface (API) portfolio, designed to provide laboratories with faster access to spectral data, analytical algorithms, and predictive models within their own workflows. The portfolio allows users to integrate spectral intelligence into modern, API-driven environments, reducing manual effort and increasing analysis speed, according to a press release from Wiley.

The tool is intended for **identifying unknown chemical compounds** in fields such as pharmaceuticals, forensics, environmental science, and materials.
"Speed matters when you're trying to identify an unknown substance; a delayed analysis can mean an assembly line sitting idle or a forensic lab holding up a case," says Armughan Rafat, Wiley senior vice president and chief AI and data services officer, in a release.

"We've spent decades building the reference data this industry trusts. Now, by making that spectral data and analytical intelligence available through APIs, we're setting the standard for how labs and vendors turn unknowns into answers faster and at scale."

Core API Capabilities

The portfolio features four specific capabilities: a spectral database search for compound identification, spectrum-structure validation to confirm chemical structures against experimental data, compound classification based on class, and spectra prediction to generate predicted spectra for research and validation.
These APIs support various analytical techniques, including **infrared (IR)**, **mass spectrometry (MS)**, **nuclear magnetic resonance (NMR)**, and **Raman spectroscopy**. By offering a vendor-neutral foundation, the system is designed to support multi-technique workflows, regulatory compliance, and cross-platform interoperability, according to Wiley.

Improving Laboratory Throughput

As sample volumes grow and **workflows become more automated**, the ability to identify and verify compounds quickly becomes critical for laboratory operations. The API portfolio aims to meet this need by providing a faster way to complete analysis, whether identifying an unknown compound in the field or catching a quality issue on a production line.
By integrating these tools, laboratories can potentially **increase throughput**, minimize downtime, and protect the value of existing instrumentation and data investments, according to Wiley.

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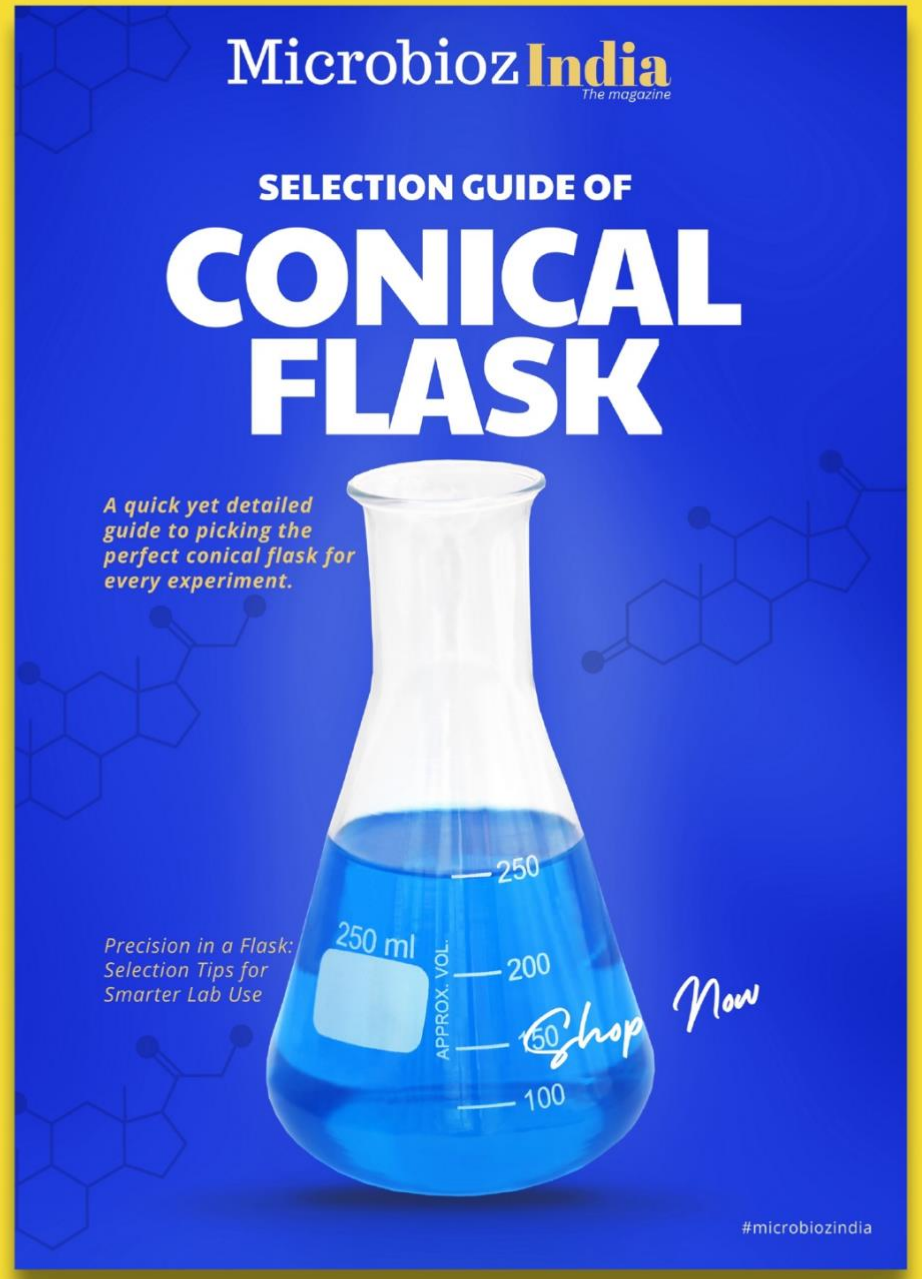

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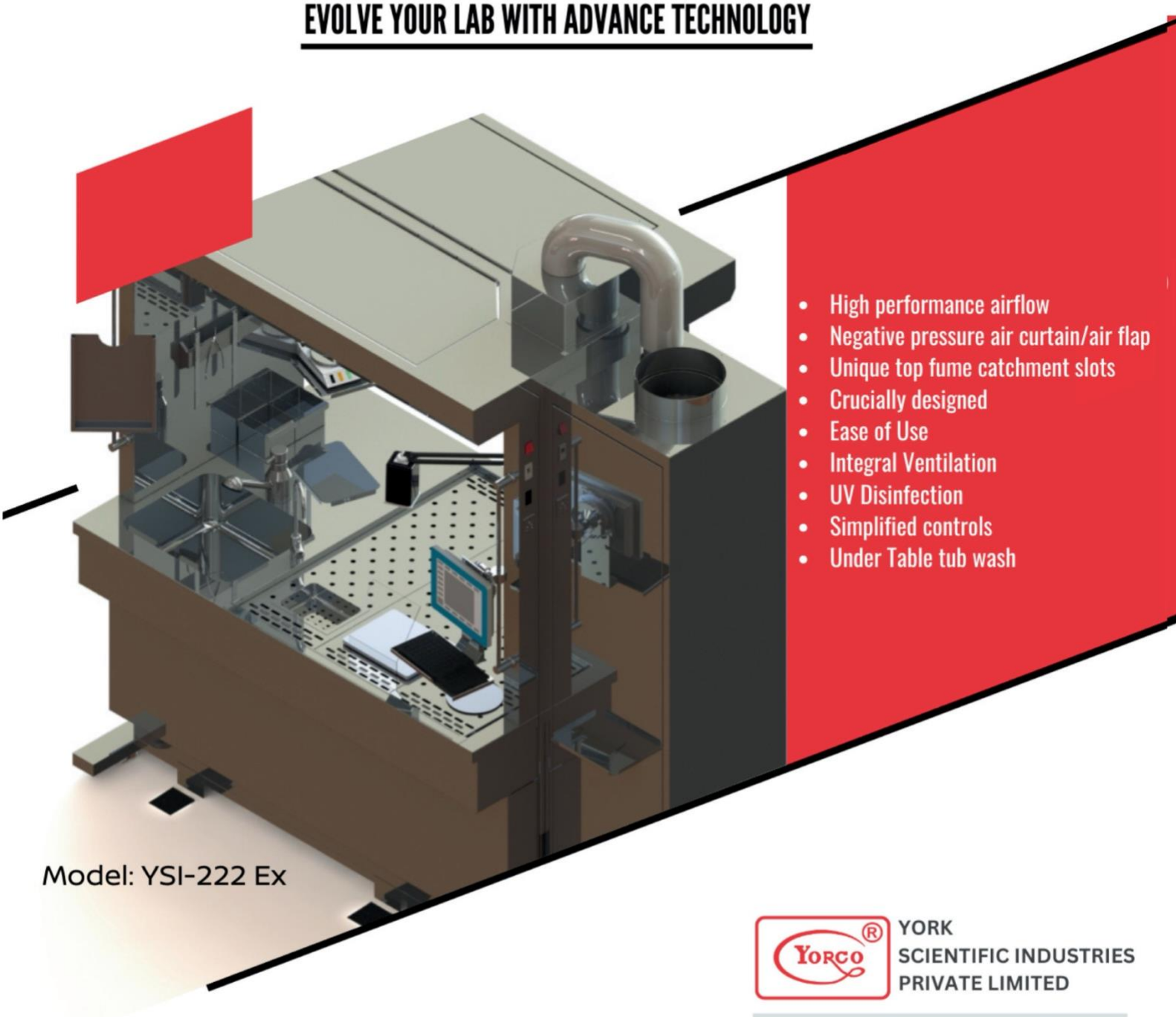

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