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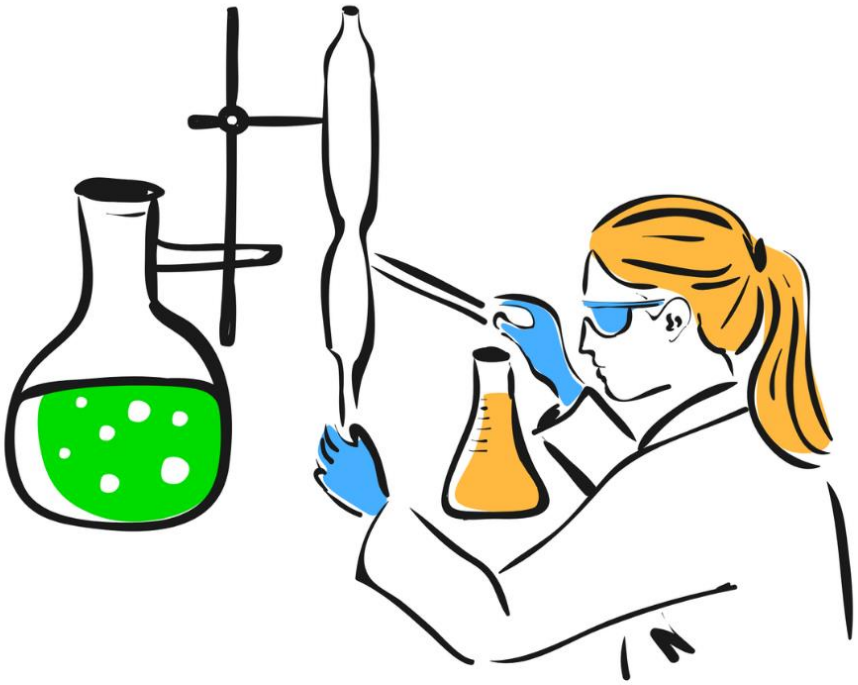

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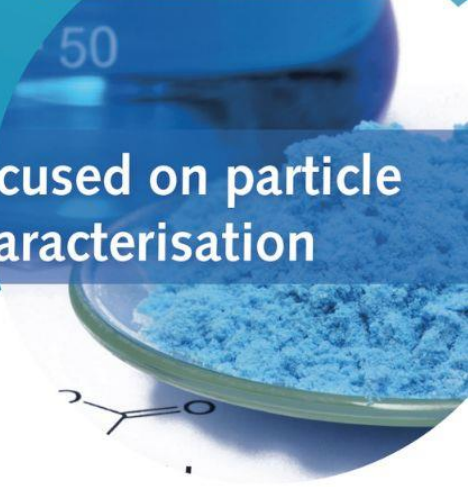

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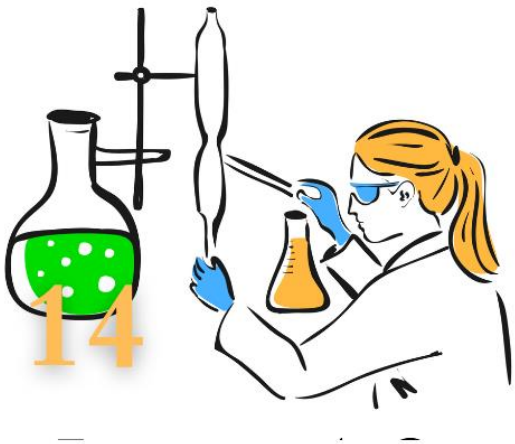

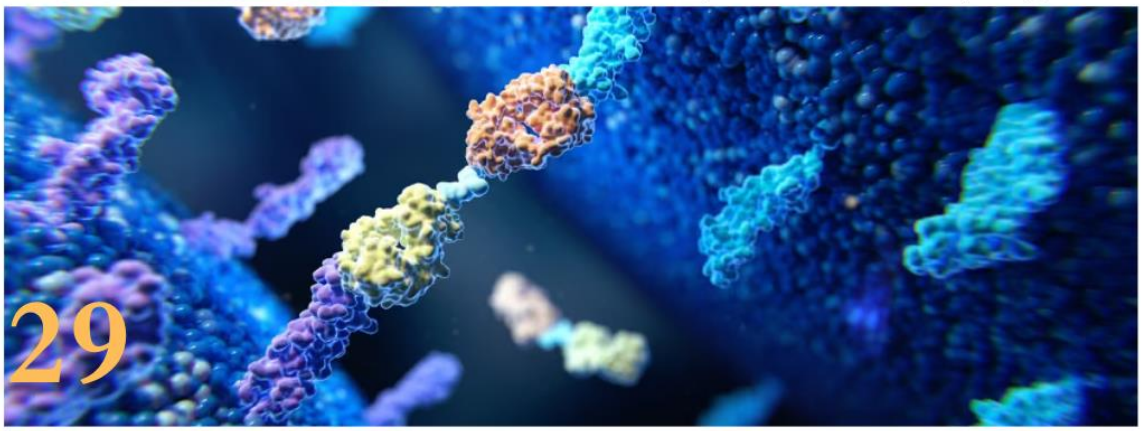

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Editor's Word

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 "**Lab 4.0: Building the Intelligent, Connected & Automated Laboratory**" delving deep into its intricacies and uncovering the stories and people that make it an intriguing subject. Additionally, you'll find articles "X-Ray Sterilization: Next-Generation Radiation Processing for Bioprocess Bags"contributed by Ami Polymer, authored 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.

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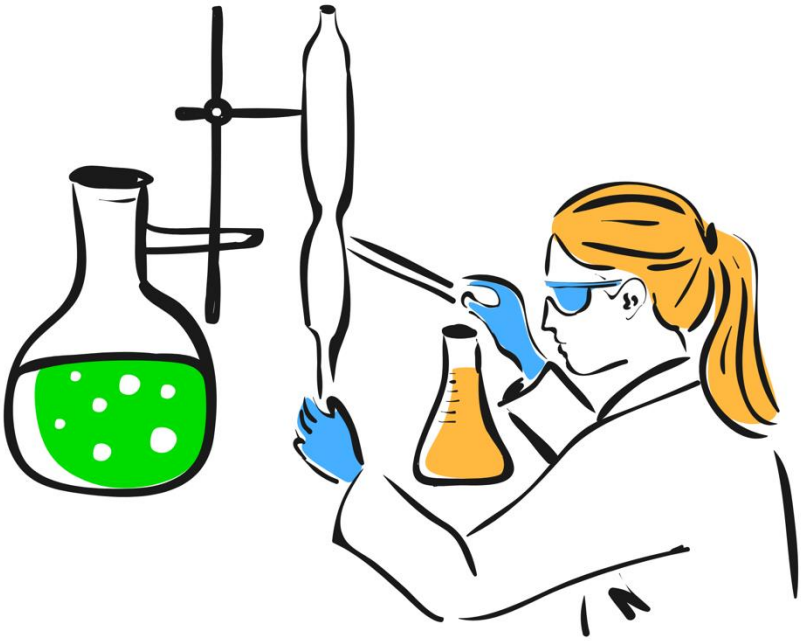

LAB 4.0

BUILDING THE INTELLIGENT, CONNECTED & AUTOMATED **LABORATORY**

The modern laboratory is evolving. For many years, laboratories have purchased equipment and software, such as instruments and laboratory information management systems (LIMS) and electronic laboratory notebooks (ELNs), without effectively addressing fragmented systems and data housed in disparate systems.

From Digital Transformation to Intelligent Laboratory Ecosystems

Lab 4.0 is the next chapter.

Lab 4.0 incorporates connected and intelligent automation using AI and robotic process automation (RPA) to create more adaptive and autonomous laboratories.

Pharmaceutical, biotechnology, clinical, food, chemical, and research laboratories are increasingly focused on accelerating research, improving data integrity and reducing errors, as well as maximizing effectiveness and efficiency.

What is Lab 4.0?

Lab 4.0 represents the merging of legacy laboratory infrastructure with digital intelligence.

Current laboratories rely on scientists to operate instruments, transfer results, analyze data, record findings, and formulate next steps, whereas Lab 4.0 integrates these steps with digital technologies.

The Lab 4.0 system is comprised of five layers. These include:

Connected Instruments → Digital Data → Automation → Intelligence → Decision-Making

Data generated by instruments is captured by digital technologies. Automation is used to process and execute ongoing instructions. With the aid of AI and advanced analytics, automation and data are integrated to simplify and accelerate the decision-making process. The goal isn't to take scientists out of labs. The goal is to eliminate the lower level work scientists do so they can focus on the higher impact science.

The Connected Laboratory: The Breakdown of Data Silos

Connectivity is one of the pillars of Lab 4.0.

The modern lab can consist of 100s of instruments, each with the potential to capture important data. Due to the nature of these systems, lab technologists need to manually move data between the different instruments, spreadsheets, software, and reports.
This leads to a number of issues:

1. Data entry errors
2. Inability to trace data
3. Delayed decision-making
4. Unclear operational status
5. Difficulty merging historical and current data

Lab 4.0 resolves these issues by creating a digital landscape where instruments, software, users, samples, and data are interconnected and communicate with each other.

The connectivity in Lab 4.0 can be supported by varying technologies such as LIMS, ELN, laboratory execution systems (LES), scientific data management platforms, integrator software for research instruments, application programming interfaces (APIs), and standard data formats.

In this lab, data can move from sample acquisition to analysis and interpretation, reporting, and archiving with zero manual intervention.

Automation: The Elevation of Science Beyond Manual Methods

Automation is another distinguishing feature of Lab 4.0.

Automation of lab processes expanded far beyond robotic liquid handlers and now includes automation of the following:

1. Automated sample handling
2. Automated liquid dispensing
3. Automated cell culture
4. Automated robotic plate movement
5. Analytical workflow automation
6. Environmental monitoring automation
7. Automation of smart storage & retrieval
8. Automation of data processing
9. Automation of digital workflow

Integration of multiple technologies typically allows more opportunities to streamline lab automation rather than implementing the technologies individually.

For example, in a pharmaceutical lab, sample registration, barcode identification, robotic sample preparation, analytical method selection, data collection and reporting, review of automated results, and reporting of findings could all be integrated into a streamlined workflow. Integration of these technologies can decrease the amount of tedious, repetitive work various laboratory personnel perform, while increasing consistency and traceability.

The Future of Lab Automation – Autonomous Workflows

The next step of lab automation is the ability of lab processes to operate autonomously.

An autonomous workflow can respond to the information that is generated throughout the process.

For instance, an intelligent system can identify a sample and can determine the most appropriate method of analysis; launch an automated workflow; monitor the results; identify an out-of-range result; and notify the scientist of the sample of interest in the automated workflow for result review.

This makes lab automation more intelligent and flexible in the way processes can be automated.

AI Gives the Lab a Brain

Of Lab 4.0 technologies, AI is likely the fastest evolving and potentially the most important.

AI combines the latest in automation and advanced analytics with state of the art technologies to mine lab data for latent relationships which may remain undetectable to humans.

Potential applications include:

Predictive Analytics

AI models use historical laboratory and manufacturing data to identify patterns and anticipate failures.

In analytical laboratories, predictive models may assist in maintenance of instruments, recognize abnormal analytical behavior, or anticipate deviations.

Intelligent Data Analysis

Processing, classification, comparison and interpretation of large data sets from analytical instruments are made easier with AI.

Image Analysis

Computer vision encompasses a broad range of applications, such as cell counting and colony identification, microscopy, pathology, particle analysis, and quality inspection.

Experimental Optimization

AI can help optimize an experimental design by evaluating parameters and suggesting potential combinations of variables that may reduce the required number of experiments.

Scientific Knowledge Discovery

AI is capable of analyzing scientific literature, experimental data, databases, and corporate repositories to provide relevant knowledge and help scientists develop new insights.

Given the above details, it can be foreseen that the laboratory of the future will progressively operate as a human-AI collaboration, where AI is expected to perform voluminous data analysis and scientists are expected to provide their scientific judgment, creativity, and oversight.

The Digital Thread: Connecting the Complete Laboratory Lifecycle

A key concept of Lab 4.0 is the Digital Thread.

A Digital Thread enables information generated along a process to be traced and kept in context throughout the lifecycle of the information.

Consider a pharmaceutical development workflow: Research, Formulation, Process Development, Analytical Testing, Scale-up, Manufacturing, Quality Control, and Release.

Each of these steps may have individually maintained data and documentation in the past.

Lab 4.0 aims at integrating these steps.

A formulation scientist could retrieve pertinent analytical data. An analytical scientist could know the sample's development history. Quality teams could trace results to original experiments. Development information may help manufacturing teams improve the performance of the process.

This is essentially an information continuum and not a series of disconnected information segments.

Smart Devices and the Internet of Laboratory Things

The Internet of Things (IoT) has been adopted in the laboratory environment.

Smart laboratory devices can capture information about the following:

1. Status of the instrument
2. Temperature and humidity
3. Instrument usage
4. Maintenance, calibration, error and sampling needs
5. Performance

With a connection to a laboratory management system, this information can provide complete real-time information about the operation of the laboratory.

Now, a laboratory manager can have real-time information about an instrument that is approaching a maintenance limit.

With predictive maintenance, laboratory productivity and instrument availability are enhanced.

Cloud and Edge Computing: Connecting Laboratories

The volume of data generated in a laboratory is increasing. Consequently, the need for on-demand computing resources is growing.

Cloud computing can offer a single accessible source of laboratory ready applications, data, servers, and computing resources.

Edge computing can provide on-site real time analytics and processing.

The combination can support real-time analytics and large data analysis.

Regulated laboratories adopt cloud service offerings with specific considerations for the following:

Data integrity | Cybersecurity | Access control | Validation | Compliance | Data residency | Backup and recovery

A goal beyond just cloud migration of lab data is necessary. Instead, the goal should be the creation of a secure, scalable digital infrastructure that meets all compliance requirements.

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Digital Twins: Replicating the Lab before Adjusting it
Digital twin technology is located within Lab 4.0 and is likely to be a significant part of that lab in the future.

Digital twins are digital replicas of physical assets, processes, or environments that are able to capture real world data.

In the field of laboratory science, digital twins have the potential to achieve virtually anything, including the following:

1. modeling the performance of instruments
2. optimization of lab workflows
3. capacity modeling
4. simulating processes
5. determining the best time for maintenance
6. optimization of lab spaces
7. simulating automation

Prior to developing any of these capabilities for a laboratory workflow, digital simulations may allow organizations to see the potential impacts of each workflow variation.

This has the potential to improve the effectiveness and decrease the risk of operational shifts.

Robotics and the Lights-Out Laboratory

One of the uses of robotics is processing a high volume of repetitive lab work.

Automated lab systems can perform tasks like pipetting, sample transfers, plate handling, reagent dispensing, and sample storage with high precision.

Eventually, one of the goals of laboratory science will be the "lights-out" lab, which is a highly automated lab that requires highly limited interaction with humans.

It is unlikely that this will completely replace human interaction in laboratory science.

However, it is likely that in the future lab work will be a combination of robots performing repetitive lab work, and humans interpreting and acting on the results.

This creates a new division of labor:

Machines execute. Algorithms analyze. Scientists decide.

Data Integrity and Cybersecurity: The Foundation of Lab 4.0

More connectivity in a system means more responsibility.

A highly connected lab has more access points to digital resources, more data crossing in and out, and more exposure to cybersecurity risks.

Laboratories must build security into their digital transformation strategies from the ground up.

This includes considerations for:

1. Access permissions
2. User identity
3. Encryption
4. Audit trails
5. Secure APIs
6. Backup and recovery
7. Network splits
8. Device protection
9. Active monitoring
10. Appropriate validation, change control and auditable checkpoints

Regulated industries require digital transformation to address data integrity, retention and auditing requirements.

Lab 4.0 must incorporate security.

The Human Factor: Scientists Remain at the Centre

Technology alone does not create Lab 4.0. The largest barrier to implementing Lab 4.0 is the organizational shift. Employees must understand how lab technologies impact their work on a daily basis.

Activities to support these changes include:

1. Digital skills
2. Data skills
3. Awareness of AI and automation
4. Change management
5. Inter-team connections

The laboratory professional and scientist's role is changing. The lab scientist of the future will need a much broader range of skills and knowledge to include an understanding of data, automation, AI, digital workflows and system integration.

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This does not require that every scientist learn to program. Scientists will need to learn skills that enhance their ability to flexibly work alongside intelligent systems and technologies.

Building a Lab 4.0 Strategy

Organizations should avoid thinking of Lab 4.0 as a single technology project.

Change should start with goals and key objectives.

1. Map Existing Workflows

Identify repetitive processes, manual data transfers, bottlenecks, and error-prone areas.

2. Establish a Digital Foundation

Ensure laboratory data is structured, accessible, secure, and governed appropriately.

3. Connect Instruments

Prioritize instrument integration and eliminate unnecessary data silos.

4. Automate High-Value Processes

Start with workflows where automation can deliver measurable benefits.

5. Introduce Advanced Analytics

Use data analytics to identify trends and improve operational visibility.

6. Deploy AI Where It Adds Value

AI should address clearly defined scientific or operational problems rather than being implemented simply because it is technologically fashionable.

7. Scale Through Integration

Connect individual digital initiatives into a broader laboratory ecosystem.

Measuring the Impact

A successful Lab 4.0 transformation should produce measurable improvements.

Organizations can track indicators such as:

1. Turnaround Time: How quickly are samples processed?
2. Throughput: How many samples or experiments can the laboratory handle?
3. First-Time-Right Rate: How frequently are processes completed without rework?

4. Instrument Utilization: How effectively are laboratory assets being used?
5. Manual Data Entry: How much transcription has been eliminated?
6. Data Review Time: How quickly can scientists review and approve results?
7. Unplanned Downtime: How often do instruments become unavailable?
8. Cost per Sample: Is automation improving laboratory economics?

These metrics help demonstrate that digital transformation is delivering tangible scientific and business value.

What Will the Lab of 2030 Look Like?

The laboratory of the future will not necessarily look dramatically different from today's laboratory.

There will still be scientists, instruments, samples, reagents, experiments, and analytical technologies.

What will change is how these elements interact.

A Lab 4.0 environment allows for the creation of sample digital identities over the course of the entire analysis process.

Instrument autonomous communication with lab software is possible. Samples might be moved by robots from one workstation to the next. AI may perform real-time data analysis. Predictive systems can identify imminent equipment failures. Scientists can focus on scientific data analysis if they can monitor experiments via digital dashboards. The laboratory will lose its identity as a collection of workstations and will become a single intelligent ecosystem.

The Future is Now

This is not just the next level of automation in the lab. Lab 4.0 is radically changing the way we do science.

AI, robotics, connected devices, clouds, advanced analytics, digital twins, and lab informatics are changing the speed and efficiency of science and lab operations, while improving data reproducibility and integrity.

Transforming the lab means more than technology.

Data integrity and intelligent process flow design are critical. So too are workforce skills and a solid understanding of technology's value in laboratory processes.

The future is not only about the best automation technologies. The future is about the best integration technologies.

The Laboratory Already Thinks

Lab 4.0 is moving the traditional lab devoid of automation to a connected, predictive, intelligent laboratory without losing its richness in data.

The goal is not a lab without people.

This laboratory integrates people and machines to rapidly discover, build, and make better decisions about science.

The future of the lab is here with the intelligent lab and old school labs are a thing of the past.

Next-Generation Analytical Technologies: Powering Faster, Smarter & More Reliable Testing

Analytical testing lies at the foundation of modern science and industry. Analytical labs are the bailiffs of science, pointing to the evidence to help make critical decisions about processes and the safety of finished products through methods like the identification of known substances, determining the presence of unwanted materials,characterizing biologics, monitoring a process, or assessing the safety of a product.

Present day analytical labs face new challenges.

Increased complexity of pharmaceutical and biotechnology products results in larger datasets, more stringent timelines, greater pressures from regulations, and more complex samples. Laboratories must do more with less by improving accuracy, reproducibility, and throughput, while also reducing the cost of testing.

All these complexities support the need for advanced analytical methods.

Modern analytical laboratories now transcend traditional tests and embed high resolution instrumentation, automation, artificial intelligence, advanced spectroscopy, mass spectrometry, chromatography, imaging, sensors, digital workflows, and real time analytics to analyze a sample.

This new era of analytical technologies seeks to test rapidly, understand comprehensively, detect the previously undetectable, and make decisions with greater confidence.

From Traditional Analytical Techniques to Intelligent Analysis

Traditional analytical procedures are characterized by a linear workflow that includes:

Sample → Preparation → Instrument → Data → Analyst → Report

This workflow, while still fundamental, is marked for change with the introduction of various new technologies.

Sample preparation is evolving to automated systems. Instruments are increasingly capable of producing high resolution, high dimensionality data. Software is available to interpret data in real time. AI systems are aiding the interpretation of data. Cloud-based systems are offering collaboration and centralized management of data.

The result is a transition toward:

Sample → Automated Preparation → Intelligent Instrumentation → Real-Time Data → Advanced Analytics → Actionable Insight

This transition is especially relevant for laboratories that work in heavily regulated environments; these laboratories need to produce accurate, reliable results quickly, while maintaining the integrity of their data.

High-Resolution Mass Spectrometry: Seeing More Than Ever Before

Mass spectrometry is one of the best tools that modern laboratories have at their disposal.

High-resolution mass spectrometry (HRMS) has pushed the boundaries even further on how scientists can characterize complicated samples.

Modern HRMS systems can provide extremely accurate mass values and can yield massive amounts of information to support the following uses cases:

1. Impurity characterization
2. Metabolite identification
3. Analysis of biopharmaceuticals
4. Proteomics
5. Analysis of biomarkers
6. Analysis of environmental pollutants
7. Structure elucidation
8. Characterization of small molecules

Even with the incredible amount of information that HRMS systems can provide, mass spectrometry's increasing complexity is producing even greater volumes of data.

In this time, advanced software and AI assistance in data analysis become critical.

As opposed to just producing spectra, next-generation systems tend to assist in data analysis by helping scientists find signal, prioritize data analysis, perform data comparison, and even interpret datasets.

Chromatography Gets Faster and More Intelligent

Chromatography is essential for analysis in the fields of pharmaceutical, biopharmaceutical, food, environmental, and chemical industries.

However, laboratories need to rely on chromatographic techniques that can help increase throughput and level of automation, all while maintaining resolution and reliability.

Improvements in:

1. Ultra-high-performance liquid chromatography (UHPLC)
2. High-performance liquid chromatography (HPLC)
3. Two-dimensional chromatography and other methods of multidimensional separations
4. Automated sample preparation
5. Automated sample introduction
6. Self- optimizing chromatography
7. Intelligent method development are helping laboratories do more with less.

The next generation of chromatography will focus more on connection.

Chromatography is an increasingly connected field within the software of its corresponding instruments. These systems are capable of monitoring system performance, and flagging anomalies within the system. Automated calculations and reporting of results within the laboratory information systems are all made possible by increasing levels of interconnectivity within chromatography.

Traceability and precision of results can be improved, while time spent "hands-on" with the system is actively reduced.

Spectroscopy: Faster Answers With Minimal Sample Preparation

Like chromatography, spectroscopic technologies are progressing rapidly.

In research, quality control, manufacturing, and process monitoring, Raman, NIR, FTIR, NMR, and UV-Vis spectroscopy are highly utilized.

Of the many spectroscopic methods, one of the major advances within the field is the ability to perform analysis with minimal or no sample preparation.

This is particularly useful for analysis with rapid demands.

Raman and NIR

Raman and NIR spectroscopy are excellent technologies for rapid identification and characterization of materials, and are easily adaptable for use in manufacturing.

With appropriate calibration models and chemometric tools, spectroscopic systems can provide real time information on the properties of the material, and process control information.

This facilitates the shift from the traditional concept of laboratory testing toward process-focused analytical science.

Process Analytical Technology: Bringing the Laboratory Into the Process

One of the most important advancements in analytical science is the focus on situ testing in a manufacturing context.

Process Analytical Technology (PAT) empowers manufacturers to determine process quality and attributes in a real-time, in-process context, as opposed to a traditional end-product testing context.

Sensors can be used to determine:

1. Concentration
2. Moisture
3. Particle Size
4. Chemical Composition
5. Temperature
6. Pressure
7. Process Dispersion

Phase variation during the manufacturing process can be recognized to help improve process consistency.

For pharmaceutical manufacturing, PAT (Process Analytical Technology) helps to implement Quality by Design (QbD), which is the concept of designing and controlling a manufacturing process.

Rather than wondering if the end product conforms to manufacturing specifications, a manufacturer can better understand and control how the manufacturing process impacts the product.

Artificial Intelligence Comes to the Analytical Lab

Integrating artificial intelligence into analytical science is perhaps the most significant change that has occurred.

Each analytical experiment may generate thousands of data points.

Human analysts are essential, but individually evaluating the results can be an overwhelming task.

The use of artificial intelligence (AI) and machine learning can be beneficial because they can:

1. Recognize patterns
2. Identify discrepancies
3. Identify classes of samples
4. Predict events
5. Perform routine interpretation
6. Determine possible contaminants
7. Assist in clarifying spectra
8. Refine techniques

Speed is not the only advantage of AI. AI can help laboratories enhance the information contained within their data.

Artificial Intelligence – Based Anomaly Detection

Anomaly detection is particularly useful and innovative.

Analytical workflows are typically designed to include criteria against which results are evaluated.
If a result falls outside of a criterion, a process is initiated to investigate the discrepancy.

AI can be used to determine discrepancy results that are not conventional failures, yet are also unusual.

Such a platform could analyze changes in:

1. Patterns of chromatographic peaks
2. Spectral signatures
3. The performance of instruments
4. Process parameters
5. Characteristics of samples

Laboratories could then shift to anticipatory testing from reactive testing.

Automated analytical laboratories rely on advanced instruments, but become less valuable with additional manual steps.

Therefore, automation is a key element of next generation analytical laboratories.

Automation applies to:

1. Registering samples
2. Locating samples
3. Preparing samples
4. Handling liquids
5. Inserting samples
6. Method execution
7. Data processing
8. Result computation
9. Report generation
10. Data storage

When these features are available as a complete unit, laboratories can devise a fully automated workflow.

Automated Sample Preparation: Approaching a Hidden Bottleneck

In most cases, the instrument is not the bottleneck in an analytical process.

In many cases sample preparation is the major time sink in a laboratory. Weighing, dilutions, extractions, filtrations, digests, and derivative conversions are a set of transformations that can add a lot of variability to a process.

Automated preparation of samples is necessary.

A robotic system can perform repetitive processes with high precision potentially reducing analysts' exposure to hazardous materials.

All the processes can substantially increase productivity in high throughput laboratories.

The Rise of Multimodal Analysis

More complex scientific questions require more than one analytical method. Sometimes, answers may only be partial with a single instrument.

For instance, some researchers may opt to use:

1. Chromatography + Mass Spectrometry
2. Raman + Chemometrics
3. Microscopy + Image Analysis
4. Spectroscopy + Machine Learning
5. Separation Science + High-Resolution Detection

Representing an integrated analytical approach, the combination of two or more methods provides a richer characterization of a sample.

This is especially true for complex biologics and advanced therapies, impurities, degradation products, and biological systems that may require more than an answer for molecular identity.

Single-Cell and Spatial Analysis

The analytical revolution is now penetrating the biological dimension as well.

Thanks to single-cell technologies, researchers are now able to describe biological systems with great detail.

Instead of examining a population of cells that are perceived as a single unit, disparities among cells that are inconspicuous can now be revealed.

In addition, spatial analysis provides a description of the localization of biomolecules, proteins, or cells in tissues.

A few of the many potential applications are:

1. Drug development and discovery
2. Cancer research
3. Design and development of therapies
4. Immunotherapy
5. Research and development of novel biomarker
6. Cell and gene therapy
7. Translational medicine and research

The understanding of biological systems is being revolutionized by the interplay of ultra-modern and highly advanced analytical technologies and computing systems.

Digitalization and the Analytical Data Explosion

Highly advanced and powerful analytical technologies are resulting in laboratories producing massive amounts of data.

A modern analytical ecosystem may contain data from:

1. Chromatographs
2. Mass spectrometers
3. Spectrometers
4. Microscopes
5. Plate Readers
6. Sensors
7. Automated Systems
8. Laboratory Information Systems
9. Electronic Laboratory Notebooks

It has become as important to manage this information effectively as it is to generate it.

Laboratories therefore need to develop robust strategies for:

Data integrity | Metadata | Traceability | Storage | Integration | Accessibility | Security

The future analytical laboratory will not be defined by the instruments it has.

It will be defined more by the manner in which it manages and uses its data.

Real-Time Analytics and Faster Decision-Making

Traditional laboratory testing has often caused delays in the time between a measurement and the making of a decision. This has been addressed with next generation systems.

Processing data in real-time has allowed laboratories to analyze data and identify patterns in the midst of an ongoing experiment or process.

This has been used in manufacturing for timely and efficient control and correction.

This has been used in research to allow scientists the ability to alter a given experiment while it is still in process.

This has been used in quality control to speed up the process of evaluating a given quality.

The goal of this technology is to change the function of historical analytical data from being a record of past events to a data resource that is actively utilized during the process of making a decision.

Miniaturization and Portable Analytical Technologies

Decentralization is becoming even more apparent in the realm of analytical testing.

Previously, the need for advanced analysis required the use of large, complex instrumentation only found in specialized laboratories.

This has been changed due to rapid advances in miniaturization, sensors, microfluidics, portable spectroscopy, and compact mass spectrometry.

Near-site and portable technologies can be applied for:

1. Testing in the field
2. Monitoring the environment
3. Verification of raw materials
4. Analysis at the site of care
5. Monitoring of processes
6. Screening of tests

There are numerous applications for portable technologies in testing and analysis. Decentralized testing will always have a role to play in reducing the time from sample collection to the delivery of actionable insights.

Sustainability and Environmental Impact

There is also a need to lessen the impact that analytical laboratories have on the environment. Certain analytical methods are based on the use of a large amount of solvents, water, energy, and disposables.

The use of next generation technologies will offer a laboratory:

1. Minimized use of solvents
2. Reduced size of analytical process
3. Lower energy analytical systems
4. More automated systems
5. Reduced need for testing
6. Electronic records
7. Simplified processes of sample preparation

The further development of Green Analytical Chemistry will also be a priority.

A laboratory of the future will be able to provide faster, more accurate, and more sustainable analysis.

Reliability

Speed and intelligence mean nothing if results are not reliable.

As laboratories leverage AI, Automation and other Disruptive Technologies, a primary focus must remain confidence in results.

There needs to be:

1. Protocols
2. Qualified and calibrated systems
3. Standards
4. Control measures
5. Integrity of the results
6. Robust processes
7. Competent staff
8. Regular upkeep

Automation should not mask variability, it should minimize it. AI should assist in answer formation, not eliminate guidance.

The Future of Analytical Testing

The future will bring a variety of changes to the way analytical laboratories operate as compared to how they function today.

In the future, instruments and software will utilize more automation and AI. Robotics will be used to prepare samples. Data generated by analytics will be able to be used across networks, rather than being confined to a specific instrument.

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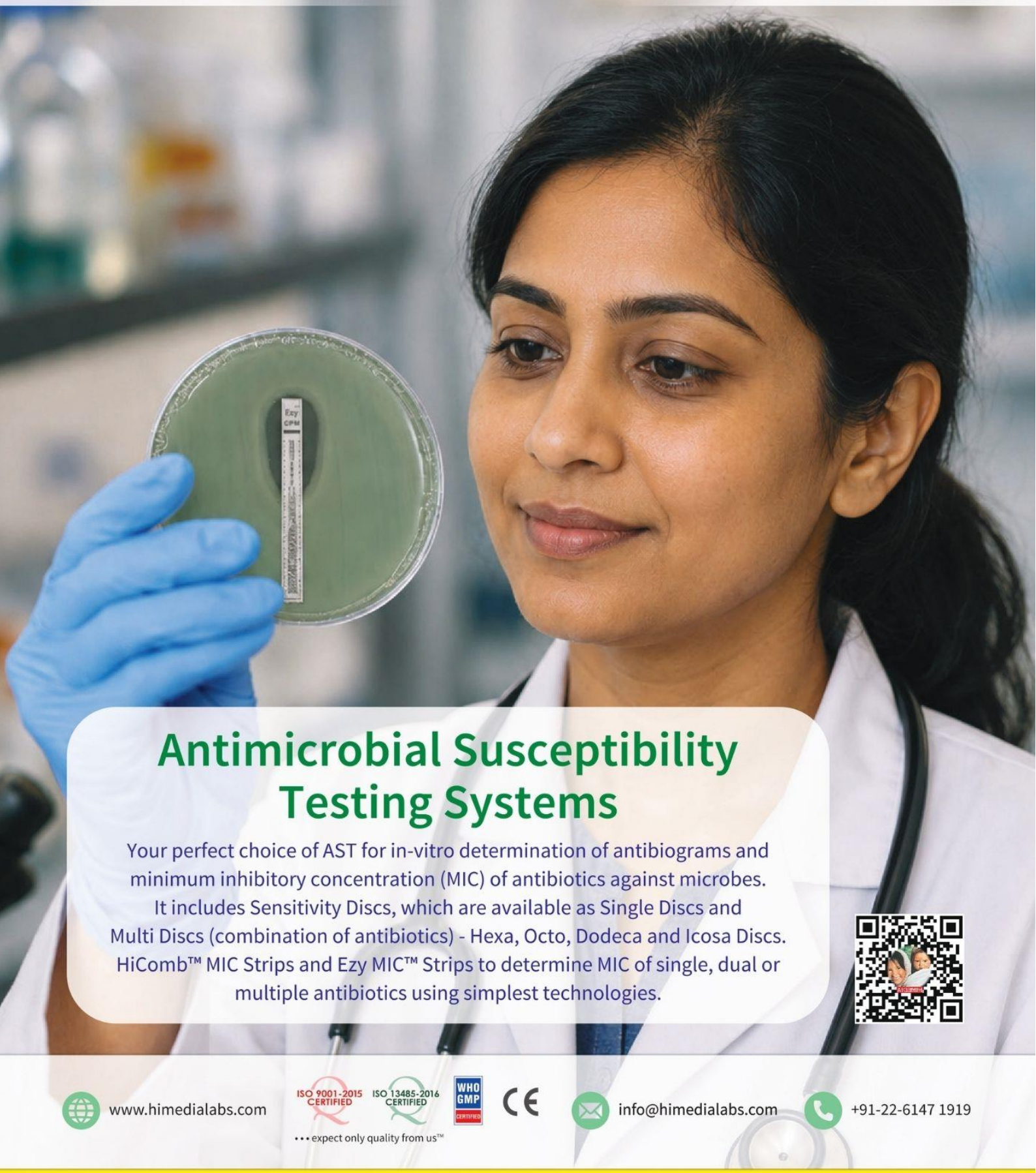

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The most significant change in the future will be the ability of analytics to be predictive, rather than simply descriptive.

Rather than simply asking,

"What is in this sample?" advanced analytics will provide answers to the more complex and descriptive questions, including:

1. "Why is it there?"
2. "What will happen next?"
3. "Is the system in flux?"
4. "What should we do?"

The next frontier of analytical science lies in these questions.

The Next Generation of Analytical Laboratories

A strategic, rather than a reactive, approach is needed when organizations attempt to modernize their analytical capabilities.

Begin with the Scientific Problem

The analytical problem, as opposed to the prevailing analytical technology, should dictate the choice of technology.

Integrate Instruments and Data

Value will only be derived from advanced analytics when systems are integrated.

Automate Repetitive Work

Automation will bring the most benefit in terms of increased speed and consistency.

Invest in Data Infrastructure

The future of analytics and AI will be based on the availability of quality data.

Develop Scientific and Digital Skills

The future of analytical science will require a new generation of scientists that possess an amalgamation of skills in instrumentation and automation as well as data science.

Build for the Future

Laboratory infrastructure should be able to undergo changes to support new technology.

Conclusion: From Measurement to Intelligence

Innovations in laboratory analytics are beginning to fundamentally shift the way organizations conduct laboratory analytics.

The lab is relocating from an area where samples undergo measurement to a zone where data is continuously generated, interpreted, integrated, and converted into scientific insights.

High-resolution instruments enhance measurement capabilities and exhibit greater depth of analyses. Automation allows for faster and more consistent analyses. Artificial Intelligence (AI) analyzes and interprets complex data sets.

Digital connectivity promotes and allows collaboration. Real-time data analyses describe and define the speed of underlying processes.

These science and technology advances exemplify the beginning of a paradigm shift in analytical sciences.

The future of the analytical laboratory will exemplify quicker analyses, more intelligent interpretations, increased reliabilities, and improved decisions.

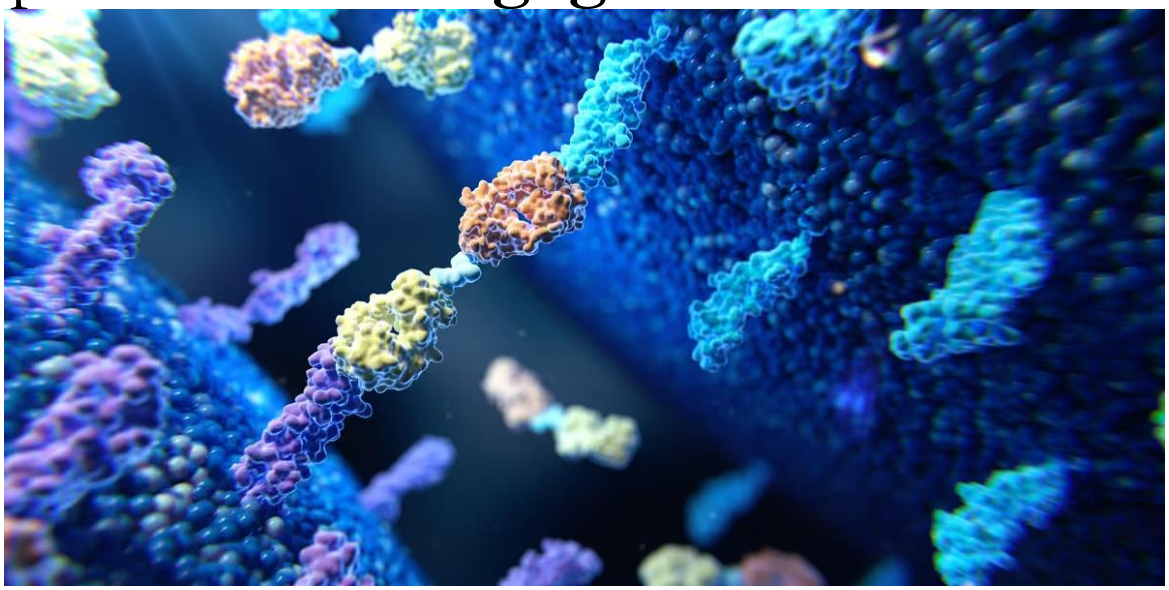
Tomorrow's advanced analytical laboratories will not be defined by a particular instrument.

Rather, the laboratories will be exemplified by the amalgamation of technologies, information, and automation, and by the integration of scientific and analytical intelligence.

As the complexities of science grow, the integration of technologies, information, and automation may be the most important analytical capability of all.

Featured Article

Innovations in cancer immunotherapy: Bi-specific **T cell engagers**



Authored By–
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Immunotherapy is one of medicine's most promising frontiers in cancer treatment by ingeniously transforming patients' own immune systems into personalized cancer-fighting arsenals. By eliminating malignant cells while sparing healthy tissues, this type of treatment achieves potency and precision — the twin pillars of successful cancer treatment.

While the initial wave of immunotherapies has already revolutionized oncology, a remarkable innovation is now emerging: Bi-specific T cell engagers (Bi-TCEs).

These engineered proteins represent perhaps the most elegant solution yet — molecular bridges that physically force cancer cells and immune cells together, creating an unavoidable deadly encounter from which cancer cells cannot escape.

Structurally, Bi-TCEs consist of two single-chain variable fragments (scFvs) connected by a flexible linker. One scFv binds to a tumor-associated antigen (TAA), while the other targets CD3, a key component of the T cell receptor complex. This dual specificity enables Bi-TCEs to physically link any CD3-expressing T cells with cancer cells, bypassing the need for peptide-MHC recognition.

Upon engagement, Bi-TCEs trigger a potent immunological cascade activating T cells, promoting their proliferation, and inducing the release of perforin and granzymes that mediate tumor cell lysis (see Figure 1).

This mechanism of action has proven effective in hematologic malignancies, positioning Bi-TCEs as a promising frontier in cancer immunotherapy.

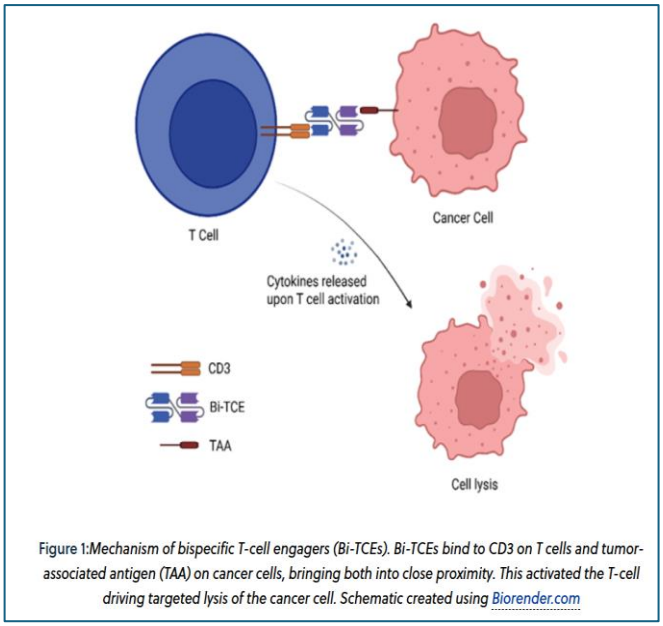

Figure 1:*Mechanism of bispecific T-cell engagers (Bi-TCEs). Bi-TCEs bind to CD3 on T cells and tumor-associated antigen (TAA) on cancer cells, bringing both into close proximity. This activated the T-cell driving targeted lysis of the cancer cell. Schematic created using Biorender.com*

Bi-specific T cell engagers in the cancer immunotherapy landscape

How do Bi-TCEs compare to the predominant cancer immunotherapy approach, CAR-T? One key difference is their production method — CAR-T therapies are developed by genetically engineering a patient's own T cells, whereas Bi-TCEs are produced by engineering proteins in antibodies from mammalian cell lines.

This makes Bi-TCEs an "off-the-shelf" type of drug that is simpler to produce than individualized CAR-T therapies.

There are other important comparisons, summarized below in Table 1:

Features	CAR-T cells	Bi-TCEs
Structure	Engineered patient T cells with a synthetic receptor, including a target antigen-binding domain (scFv), a hinge region, a transmembrane domain, and an intracellular signaling domain	A recombinant antibody with two connected scFv regions; one targeting a TAA and one targeting CD3, a part of the TCR complex in T cells
Recruitment of T cells	Active, redirect engineered T cells to kill tumor cells	Passive, dependent on endogenous T cells and redirecting them to kill tumor cells
Mechanism of cytotoxicity	Release of perforin and granzyme B from the CAR T cells	Release of perforin and granzyme B from endogenous T cells activated by the Bi-TCE
Lymphodepletion treatment before therapy	Required (drugs like fludarabine and cyclophosphamide)	Not required
Half-life	Long (weeks to months)	Short (hours) – requires repeated infusions
Production	Genetic engineering of patient's T cells *in vitro*	Protein engineering of antibodies from mammalian cell lines
Availability	Individual production process for each patient	"Off-the-shelf" drugs with relatively simple production processes
Indications	Mainly hematological malignancies, early clinical stage development ongoing for solid tumors	Mainly hematological malignancies, early results from solid tumors suggest that compared to CAR-T, Bi-TCEs may have slight advantages in solid tumors

Publication trends show increasing opportunities in cancer research and beyond

We examined the CAS Content Collection™, the largest human-curated repository of scientific information, to better understand the research landscape of Bi-TCEs.

There has been a significant increase in the number of journal and patent documents in the last 10 years. Interestingly, patents hold a 44% share of the total number of documents, suggesting sustained commercial interest in this area (see Figure 2).

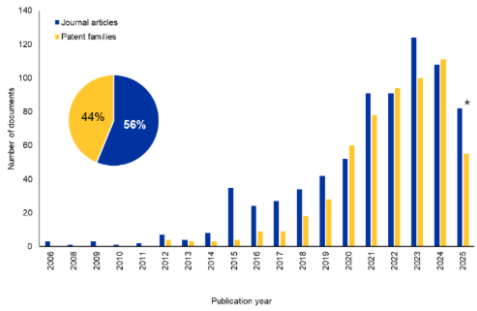

Figure 2: *Yearly trend journal and patent publications related to Bi-TCEs. *Data for 2025 is partial through September. Source: CAS Content Collection.*

We analyzed the patent data to find the top 10 commercial patent assignees (see Figure 3). Amgen was the first to develop a globally approved Bi-TCE molecule in hematology and continues to be the leader in this field with their proprietary BiTE® technology.

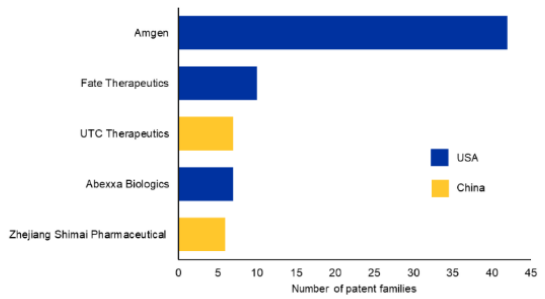

Figure 3:*Top five commercial entities with patents assigned related to Bi-TCEs. Source: CAS Content Collection.*

We also explored the leading therapeutic areas in the context of Bi-TCEs using the CAS indexed concepts accessed through CAS STNext®. Our landscape analysis shows that the development of Bi-TCEs is predominantly concentrated in solid tumors, with the highest documents on lung, breast, pancreatic, prostate, and ovarian cancers. Hematological malignancies form the second major focus area, driven largely by programs targeting multiple myeloma and acute leukemias (see Figure 4).

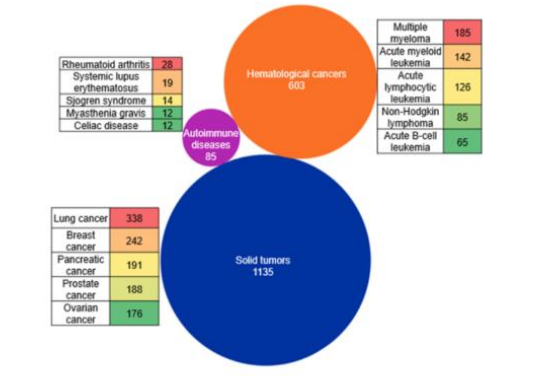

Figure 4: *Major therapeutics areas from publications related to Bi-TCEs. Data from 2006-2025. Source: CAS Content Collection.*

In contrast, autoimmune diseases represent a smaller emerging area of exploration, with interest distributed across conditions like rheumatoid arthritis, systemic lupus erythematosus , and Sjögren syndrome. Noteworthy is the majority of FDA-approved Bi-TCEs so far are for hematological indications. However, in our analysis, we see that the number of documents is highest for solid tumors. This is probably due to the increased ongoing efforts to efficiently utilize Bi-TCEs for solid tumor indications. The first FDA-approved Bi-TCE, blinatumomab, was approved in 2014. It targets CD19 and CD3 and is indicated for relapsed or refractory B-cell acute lymphoblastic leukemia.

Many more Bi-TCE therapeutics have gained accelerated approval from FDA since then for various cancer types, including two solid tumor indications. The details are summarized in Table 2 below:

Bi-TCE name	Approval year	Disease indication	Target on tumor cells
Blinatumomab (Blincyto)	2014	Acute lymphoblastic leukemia	CD19 on B cells
Mosunetuzumab (Lunsumio)	2022	R/R follicular lymphoma	CD20 on B cells
Tebentafusp (Kimmtrak)	2022	Unresectable or metastatic uveal melanoma	gp100 peptide-HLA-A on uveal melanoma cells
Teclistamab (Tecvayli)	2022	R/R multiple myeloma	BCMA on myeloma cells
Elranatamab (Elrexfio)	2023	R/R multiple myeloma	BCMA on myeloma cells

Bi-TCE name	Approval year	Disease indication	Target on tumor cells
Epcoritamab (Epkinly)	2023	R/R diffuse large B-cell lymphoma	CD20 on B cells
Glofitamab (Columvi)	2023	R/R diffuse large B-cell lymphoma, not otherwise specified; large B-cell lymphoma	CD20 on B cells
Talquetamab (Talvey)	2023	R/R multiple myeloma	GPRC5D on myeloma cells
Tarlatamab (Imdelltra)	2024	Small cell lung cancer (SCLC)	DLL3 on SCLC cells

Table 2:*Overview of Bi-TCEs approved by FDA (including accelerated approvals, as of November 2025). CD: cluster of differentiation; gp100, glycoprotein 100; HLA-A, human leukocyte antigen-A; BCMA: B-cell maturation antigen; GPRC5D: G-protein coupled receptor family C group 5 member D; DLL3: Delta-like ligand 3, R/R: Relapsed or refractory. Source: U.S. Food and Drug Administration*

Limitations of Bi-TCEs as a cancer cure

Bi-TCEs are considered transformative in hematologic cancers but still face several limitations. Classical Bi-TCEs (e.g., BiTEs like blinatumomab) are small antibody fragments (~55 kDa) lacking an Fc domain. This means they are rapidly cleared by renal filtration, resulting in a plasma half-life of only a few hours. Continuous intravenous infusion is required to maintain therapeutic concentrations, which increases the burden on patients and healthcare resources.

Bi-TCEs induce polyclonal T cell activation by crosslinking CD3 with tumor antigens, leading to massive cytokine secretion (IL 6, IFN γ, TNF α) known as cytokine release syndrome (CRS). CRS manifests as fever, hypotension, and multi-organ dysfunction.

Bi-TCEs are also associated with a risk of neurotoxicity, specifically an immune effector cell-associated neurotoxicity syndrome (ICANS). These toxicities can be life threatening and require hospitalization, corticosteroids, or IL 6 receptor blockade (e.g., tocilizumab).

Bi-TCEs exhibit strong activity in hematologic malignancies but have shown limited clinical success in solid tumors. Barriers include tumor penetration, antigen heterogeneity, and immunosuppressive microenvironment.

Another critical limitation of Bi-TCEs is the on-target, off-tumor toxicity phenomenon. Many tumor-associated antigens (e.g., CD19, BCMA, EpCAM) are also expressed at low levels on normal tissues.

Consequently, Bi-TCEs can redirect T cells to attack healthy cells, leading to collateral tissue damage and limiting antigen selection.

Recent developments in cancer research with Bi-TCEs

Recent advances in Bi-TCEs reflect a concerted effort to address the above-mentioned challenges and drive greater clinical impact with these treatments.

Ongoing innovations are enhancing their precision, safety, and durability, positioning Bi TCEs as a rapidly evolving class of immunotherapies with expanding potential across diverse cancer types. Some of the most notable approaches include:

Half-life extended Bi-TCEs (HLE Bi-TCEs):

Canonical Bi-TCE molecules have a short half-life of two to four hours due to the absence of an Fc domain, requiring continuous intravenous infusion.

To address this, HLE Bi-TCEs are being developed which fuse the Bi-TCE to an Fc domain, enabling FcRn recycling and prolonged circulation.

Preclinical and early clinical studies show HLE Bi-TCEs maintain activity with CD19 and BCMA HLE Bi-TCEs achieving half-lives of up to 210 hours, supporting once-weekly dosing.

CD3 tuning and 2:1 formats:

CD3 tuning in Bi-TCEs involves adjusting the affinity of the CD3-binding arm to control T cell activation. Lower-affinity CD3 binding reduces excessive cytokine release while still enabling effective tumor cell killing, thereby improving safety.

The 2:1 format places two binding domains for the tumor antigen and one for CD3, increasing tumor selectivity and potency by ensuring stronger engagement with cancer cells before activating T cells.

Together, CD3 tuning and the 2:1 format are key engineering strategies to balance efficacy with tolerability in next generation Bi-TCE therapies.

Dual-targeting and tri-specific engagers:

To address antigen heterogeneity and escape, researchers are advancing dual- and tri-specific engagers that co-target two tumor antigens to increase specificity and coverage or add a costimulatory arm to boost T cell fitness in immunosuppressive settings. Dual-specific T-cell engagers have two binding sites: one for CD3 on T cells and one for a tumor-associated antigen, forcing immune synapse formation and cytotoxicity.

Tri-specific engagers (TriTEs) expand this design with a third binding site, which can target a second tumor antigen to prevent escape or engage a co-stimulatory receptor such as CD28 to enhance T cell activation.

This added domain increases selectivity and potency, ensuring stronger tumor recognition before T cell engagement. "AND-gate" approaches that leverage dual tumor antigen targeting are helpful in reducing the on-target, off-tumor toxicity of Bi-TCEs.

Novel delivery systems:

New delivery systems for Bi-TCEs aim to overcome the limitations of short half-life and continuous infusion. AAV-based gene therapy enables *in vivo* expression of Bi-TCEs, allowing sustained production from the patient's own cells and potentially supporting single-dose treatment.

Additionally, other approaches like extracellular vesicles are being explored to deliver Bi-TCEs directly into the tumor microenvironment for enhanced local immune activation.

Other strategies include targeting novel tumor antigens to expand their efficacy in solid tumors. Some Bi-TCEs use microenvironment-mediated activation, binding only under tumor-specific conditions to reduce off-target toxicity.

Albumin-binding domains are being added to Bi-TCEs to extend half-life and improve pharmacokinetics by leveraging natural albumin recycling. Bi-TCEs are also being combined with checkpoint inhibitors, cytokines, or cell therapies to enhance immune activation and overcome resistance mechanisms.

Clinical trials suggest future directions for Bi-TCE therapies

We analyzed data from Clinicaltrials.gov for insights on the current landscape of clinical trials in this field. As seen in Figure 5, most trials with status "Active, recruiting" are for well-established and FDA-approved candidates, which dominate the hematological cancer domain (196 trials).

A smaller but meaningful proportion is directed toward solid tumors (33 trials) with limited efforts in autoimmune diseases, amyloid light chain amyloidosis (AL amyloidosis), and kidney disorders.

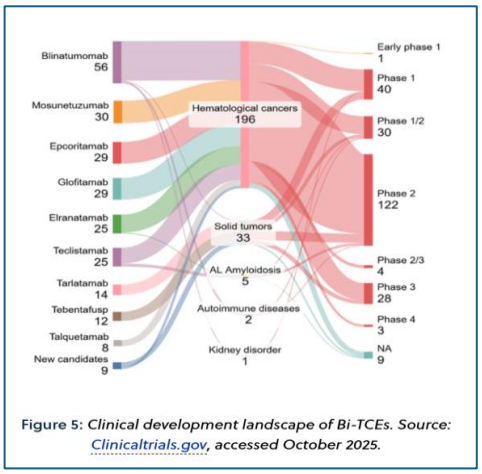

Figure 5: *Clinical development landscape of Bi-TCEs. Source: Clinicaltrials.gov, accessed October 2025.*

Across indications, the highest concentration of trials is in phase 2 (122), followed by phase 1 (40) and phase 1/2 (30), indicating a clinical pipeline that is maturing but still focused on early- to mid-stage activities.

Only a few candidates have reached phase 3 (28 trials), reflecting the challenges of translating T cell redirecting therapies beyond hematological settings. Our analysis highlights two major trends — strong clinical momentum in B-cell malignancies and a gradual expansion of Bi-TCEs into solid tumors and non-oncology diseases.

Some of the phase 3 clinical trials for solid tumors involve approved drugs in combination with other chemotherapy or immune checkpoint inhibitors (e.g., Tebentafusp + Pembrolizumab).

The newer candidates, which the FDA has not approved yet, and their details are summarized in Table 3:

Bi-TCE candidate (Company)	Indication	Target on tumor cells	Clinical trial ID, Phase	Innovation highlight
AZD0486 (AstraZeneca)	B-cell malignancies	CD19	NCT06564038, Phase 1/2	Low-affinity CD3 for reduced CRS
XmAb541 (Xencor, Inc.)	Ovarian cancer, Endometrial cancer, Germ cell tumor	CLDN6	NCT06276491, Phase 1	2+1 format for selectivity
BI764532 (Boehringer Ingelheim)	Small cell lung carcinoma, Neuroendocrine tumors	DLL3	NCT05882058, Phase 2	Solid tumor Bi-TCE with DLL3 targeting
BA3182 (BioAtla, Inc.)	Advanced adenocarcinoma	EpCAM	NCT05808634, Phase 1	Conditionally active binding, only in the tumor microenvironment
CLN-049 (Cullinan Therapeutics Inc.)	R/R AML, MDS	FLT3	NCT05143996, Phase 1	Novel tumor antigen (FLT3)
AMG 509 (Amgen)	Prostate cancer	STEAP1	NCT04221542, Phase 1	2+1 format, novel solid tumor antigen (STEAP1)
AMG 305 (Amgen)	Advanced solid tumors	CDH3/ MSLN	NCT05800964, Phase 1	Dual targeting Bi-TCE
VNX-202 (Vironexis Biotherapeutics Inc.)	HER2 expressing solid tumors	HER2	NCT07192432, Phase 1/2	AAV gene therapy for in vivo Bi-TCE delivery
VNX-101 (Vironexis Biotherapeutics Inc.)	B-cell malignancies	CD19	NCT06533579, Phase 1/2	AAV gene therapy for in vivo Bi-TCE delivery

Table 3: *Summary of notable Bi-TCE candidates in clinical development. Abbreviations: R/R: Relapsed/Refractory; AML: Acute myeloid leukemia; MDS: Myelodysplastic Syndrome; EpCAM: Epithelial cell adhesion molecule; CLDN6: Claudin-6; FLT3: fms like tyrosine kinase 3; STEAP1: Six transmembrane epithelial antigen of the prostate 1; CDH3: cadherin-3; MSLN: mesothelin; HER2: human epidermal growth factor receptor 2; AAV: Adeno-associated virus.*

These new Bi-TCEs have demonstrated considerable potential and favorable results in early clinical studies.

They show that the field is rapidly evolving, and the development of next-generation Bi-TCEs aims to enhance efficacy while improving safety profiles.

Bi-TCEs are carving out a crucial niche in oncology treatment and are poised to offer improved outcomes for patients.

They may also play an important role in treating conditions other than cancer. As research expands, they could soon drive new breakthroughs and more hope for patients everywhere.

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X-Ray Sterilization: Next-Generation Radiation Processing for **Bioprocess Bags**

Dr. Priyabrata Pattnaik
Chief Executive Officer
Ami Polymer

The modern landscape of biopharmaceutical manufacturing is dominated by the rapid introduction of single-use technologies (SUT) and their associated components. Disposable bioprocessing bags, mixing systems, tubing assembly, filtration systems, connectors, and fluid transfer components are utilized to manufacture monoclonal antibodies, vaccines, cell therapies, gene therapies, and recombinant proteins. Highly complex and sophisticated polymers utilized in biopharmaceutical manufacturing require the final sterilization of these SUTs. Gamma irradiation has been the dominant technology for over four decades; however, that may be changing. High-energy X-ray sterilization technologies may provide competitive advantages from a manufacturing and logistics point of view for ensuring the same level of sterility assurance as gamma irradiation.

Radiation Sterilization Technologies

All technologies for radiation sterilization employ damage to cellular and DNA structures from ionization to kill microorganisms.

Gamma rays and X-rays share this mechanism of DNA damage and cause sterilization without leaving a radioactive residue.

Gamma irradiation is delivered from radioisotopes of cobalt-60. ISO 11137 standard defines the range of sterilization doses as 25 to 40 kGy. High-energy X-ray sterilization systems utilize electron accelerators in the range of 5 to 7.5 MeV for sterilization. When high-energy electrons strike a metallic target, high-energy bremsstrahlung X-ray similar to cobalt-60 gamma radiation is produced.

The equivalence in the biological effectiveness of both technologies allows sterilization dose validation to be transferred over with minor modifications to the process.

Regulatory Acceptance

Acceptance of X-ray sterilization by global regulatory agencies has grown substantially in the last ten years.

International standards ISO 11137 Parts 1 - 3 recognize gamma, electron beam (E-beam), and X-ray as equivalent radiation sterilization modalities. Both the U.S. FDA and European regulators have accepted X-ray sterilization providing manufacturers demonstrate adequate dose mapping, bioburden determination, process controls, and validation of a sterility assurance level (SAL) of 10^{-6}.

Leading global biopharmaceutical suppliers have qualified numerous single-use assemblies sterilized by X-ray irradiation demonstrating increasing acceptance of the technology by global regulatory agencies.

Impact on Biomedical Polymers

The major components of bioprocess bags include polyethylene (PE), ethylene vinyl acetate (EVA), ethylene vinyl alcohol (EVOH), ultra-low-density polyethylene (ULDPE), polypropylene (PP), thermoplastic elastomers (TPE), and silicone elastomers. During radiation sterilization polymer chain scission, cross-linking, and oxidation may occur. The extent of these changes may depend on the chemistry of the polymer used, the stabilizer system, the presence or absence of oxygen, and the dose absorbed.

There are many studies in the literature that have compared the effects of X-ray irradiation to gamma irradiation, and these reveal that there are similar effects. Polymer modifications due to X-ray sterilization do not appreciably impact mechanical properties of the materials and polymer films up to 50 kGy.

One benefit of X-ray over gamma irradiation, is that X-ray systems deliver radiation faster, therefore reducing the length of time the polymer multilayer films are exposed to an oxidative environment. This has the potential of decreasing the oxidative degradation of polyethylene.

Extractables, Leachables and Sealing Performance

Extraction studies on biopharmaceutical systems have been conducted to identify and better understand the migration and potential degradation of materials in contact with therapeutic proteins.

Evidence seems to indicate that, in terms of extractable profiles, X-ray sterilization parallels gamma sterilization. The production of a number of compounds following X-ray treatment have been documented. These include: organic oxidation products, antioxidants, oligomers, and low-molecular-weight degradation compounds, which are for the most part, similar to, or less than, for gamma irradiation. Variability in formulation is the main contributor to differences in these compounds.

The integrity of the heat sealed bag also must be considered. The strength of the seal is primarily determined by the polymer and the parameters of the sealing process and is not related to the choice of the sterilization method. Several studies have shown that properly optimized X-ray sterilization process maintains seal peel strength, burst pressure, and weld integrity that are equivalent to assemblies of gamma treated products.

Manufacturing Economics

The differences in manufacturing economics of X-ray and gamma sterilization are significant. Gamma plants require the secure handling of radioactive sources of cobalt-60, massive shielding, continual oversight by the regulation agencies, and long, expensive commissioning periods. The construction of one of these plants is generally in the range of US$20–40 million.

The X-ray sterilization systems make no use of radioactive sources, and therefore have less economic burden and more flexible licensing, and lower operating costs since there are no isotopes to replace. However, these systems still have a significant cost due to the capital expenditure on the high energy electron accelerator. The primary limitation is the efficiency of X-ray conversion which is approximately 8–15% versus direct electron beam systems.

Though there is a high disadvantage of electricity consumption versus E-beam sterilization due to the conversion efficiency, improvements in accelerator technologies are slowly diminishing this disadvantage.

Quality Control and Process Validation

Quality assurance for X-ray sterilization is the same as for gamma irradiation. Manufacturers perform dosimeter calibration, dose mapping, routine monitoring, microbial validation, equipment qualification and periodic revalidation per ISO 11137.

Newer X-ray sterilization units include digital control systems for real time beam monitoring and dose, and electronic batch records to improve process traceability and provide automated dose verification.
There is no radioactive decay for the X-ray source and so there is no decrease in radiation output over time, making dose consistency easier to control throughout the lifespan of the equipment. This also simplifies dose consistency in gamma sterilization equipment.

Looking Forward

Constrained supplies of cobalt-60 and increasing scrutiny on the use of radioactive materials is likely to increase interest in X-ray sterilization in the life science industry.

It is particularly valuable for high value single-use bioprocess assemblies and biomedical polymer components due to its favorable regulation, polymer compatibility, and increasing microbial efficacy.

Though gamma irradiation is anticipated to remain a key sterilization technology, over the coming years, improvement in the efficiency of accelerator technology and digital control systems for X-ray sterilization are expected to make X-ray sterilization the preferred choice for biopharmaceutical manufacturers. For manufacturers looking for stable supply chains and sustainable solutions for equipment sterilization, X-ray technology is a considerable development in radiation processing over the last 20 years.

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EasyMax 102i: Making Pharmaceutical R&D More Reliable

Pharmaceutical research depends on reliable experiments. A small variation in temperature, stirring, dosing, or sampling can affect the final result—and may influence important decisions about process development and scale-up.

The **METTLER TOLEDO EasyMax 102i** is designed to help scientists manage these variables more consistently. As an intuitive synthesis workstation, it brings together five essential experiment operations: **temperature, stirring, dosing, sampling, and observation**.

By standardizing these activities, the EasyMax 102i helps researchers create complete and reproducible experimental records.

Precise control for everyday experiments

Temperature control is critical in pharmaceutical development. It can influence reaction speed, product quality, selectivity, crystallization, and impurity formation. The **METTLER TOLEDO EasyMax 102i** supports temperatures from approximately **–40 °C to 180 °C**, making it suitable for a wide range of chemical reactions and process studies.

The system also provides smart stirring control from approximately **10 to 1,000 rpm**. Consistent mixing is important when working with changing viscosities, suspensions, or reactions that generate solids. By maintaining controlled stirring conditions, the EasyMax 102i helps reduce variation between experiments.

Dosing and sampling can also be managed using plug-and-play peripherals. This supports more consistent reagent additions and sampling schedules, reducing dependence on manual intervention.

Real-time visibility with an integrated camera

Numbers alone do not always tell the full story of a reaction. A mixture may change color, become cloudy, form solids, separate into phases, or begin to foam. These events can provide important clues about reaction behavior.

The **METTLER TOLEDO EasyMax 102i** includes an integrated real-time camera that continuously records the experiment. Scientists can review visual changes alongside process data to understand what happened and when it happened.

This can be particularly helpful when investigating unexpected results. Instead of relying only on written notes or memory, researchers can review the reaction's visual history and identify possible links between physical changes and process conditions.

Complete data for confident decisions

The EasyMax 102i automatically records process parameters, with data logging available at intervals as short as **1 second**. During a 60-minute experiment, this can generate up to **3,600 data points for one parameter**.

This level of data capture helps researchers compare experiments, identify process deviations, and understand the relationship between operating conditions and results. It also reduces the risk of missing important information during analysis.

For pharmaceutical development teams, complete records can support better decisions during reaction screening, process optimization, impurity investigations, crystallization studies, and scale-up preparation.

Flexible sensors and future-ready connectivity

Laboratories often need to adapt their equipment to different applications. The **METTLER TOLEDO EasyMax 102i** supports smart temperature sensors, smart stirrers, and integrated pH monitoring. Additional sensors can also be connected to capture other process information.

This flexibility allows laboratories to expand the system as their needs develop. The workstation also supports native **OPC UA connectivity**, helping it integrate with automation platforms and wider digital laboratory workflows.

With plug-and-play peripherals, researchers can gradually introduce automated dosing, sampling, and other functions without replacing the entire system.

Supporting smarter pharmaceutical development

The **METTLER TOLEDO EasyMax 102i** helps transform routine laboratory experiments into structured, reproducible workflows. By combining precise control, automatic data capture, real-time visual monitoring, smart sensors, and automation-ready connectivity, it gives scientists a clearer understanding of every experiment.

For pharmaceutical teams, this means less reliance on manual records, faster troubleshooting, and greater confidence when moving from laboratory studies toward process scale-up.

The **METTLER TOLEDO EasyMax 102i** is more than a reaction workstation. It is a practical platform for generating dependable data and supporting faster, more informed decisions throughout pharmaceutical development.

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. For more information, please visit mt.com.

More information on **EasyMax 102i can be found here: EasyMax 102i Advanced**

Zydus announces final approval from the USFDA for Ascorbic Acid Injection with 180-Days CGT exclusivity

Zydus Lifesciences Limited (Zydus) announces the receipt of final approval from the United States Food and Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) for Ascorbic Acid Injection USP, 25,000 mg/50 mL (500 mg/mL), 5,000 mg/10 mL (500 mg/mL). The product is primarily used for the short-term treatment of scurvy in adult and paediatric patients age 5 months and older for whom oral administration is not possible, insufficient or contraindicated.

zydus
Dedicated To Life

Zydus' Ascorbic Acid Injection is the generic equivalent of the reference listed drug (RLD), Ascor® Injection, 25,000 mg/50 mL (500 mg/mL). The USFDA has designated the ANDA for the product as a Competitive Generic Therapy (CGT).

Eligibility for the 180-day exclusivity available to certain competitive generic therapies is determined by the USFDA and, where applicable, the period runs from the date of first day of commercial marketing of the product.

The product will be manufactured at the group's USFDA-approved injectable manufacturing plant at Jarod, near Vadodara in Gujarat, and will be marketed in the US market by Zydus Pharmaceuticals (USA) Inc. The brand product had annual sales of approximately USD 11.6 mn in the United States. (IQVIA MAT June-2026).

The Group now has 448 approvals and has so far filed 513* ANDA with the USFDA. (*As on 30-June-2026)

Mankind Pharma Enters into Exclusive In-Licensing Agreement for Insulin Degludec and Insulin Degludec + Aspart Combination for India

Partnership further strengthens Mankind Pharma's growing presence in the diabetes segment and expands its injectable diabetes portfolio

Mankind
Serving Life

Mankind Pharma Limited, one of India's leading pharmaceutical companies, has entered into an exclusive in-licensing and marketing agreement with Chongqing Chenan Biopharmaceutical Co., Ltd., China, for the commercialisation of two insulin analogues, Insulin Degludec and Insulin Degludec + Aspart Combination, in India.

The partnership marks another significant step in Mankind Pharma's strategy to strengthen its presence in diabetes care and broaden its portfolio of advanced injectable therapies. The addition of these products will further enhance, Mankind Pharma's position in the injectable diabetes segment, contributing to a more comprehensive portfolio and reinforcing its commitment to addressing the evolving needs of patients.

The latest partnership further reinforces the company's commitment to expanding its diabetes portfolio and bringing a broader range of treatment options to patients in India.

Commenting on the partnership, **Atish Majumdar, Senior President – Sales and Marketing, Mankind Pharma Ltd.**, said, *"China is rapidly emerging as a hub for innovative biopharmaceutical assets. Building on our partnerships for Insulin Aspart and Insulin Degludec, we remain focused on expanding our in-licensing pipeline from China. This partnership reinforces our commitment to expanding access to advanced therapies for patients in India while further strengthening our presence in the injectable diabetes segment."*

The partnership with Chongqing Chenan Biopharmaceutical is also aligned with Mankind Pharma's broader strategy of leveraging global innovation through strategic partnerships and in-licensing opportunities. China's rapidly developing biopharmaceutical ecosystem presents opportunities for Indian pharmaceutical companies to access differentiated and innovative assets that can complement their existing portfolios.

For more information, visit www.mankindpharma.com

Sentynl Therapeutics and Mereo BioPharma Announce Option and License Agreement for alvelestat in Alpha-1 Antitrypsin Deficiency-Associated Lung Disease (AATD-LD)

1. *Sentynl expands its rare disease portfolio with potential first-in-class oral treatment for AATD-LD, a rare genetic respiratory disease*
2. *On option exercise, Sentynl will have the right to commercialize the product in the United States; Mereo to lead global development and retains rest of the world rights*
3. *Mereo will receive an upfront option fee and, on option exercise, is eligible to receive up to $40 million in upfront and R&D payments until NDA filing, and double-digit tiered royalties on U.S. sales*
4. *Companies will collaborate to refine the Phase 3 design during short option period*

Sentynl Therapeutics, Inc. ("Sentynl"), a U.S.-based biopharmaceutical company and wholly-owned subsidiary of Zydus Lifesciences Limited ("Zydus") and Mereo BioPharma Group plc (Nasdaq: MREO) ("Mereo" or the "Company"), a clinical-stage biopharmaceutical company focused on rare diseases, today announced that they have entered into an option and license agreement for the U.S. commercial and global manufacturing rights to alvelestat for AATD-LD. Alvelestat is a neutrophil elastase inhibitor being readied for Phase 3 and, if approved, would be the first oral treatment for this rare, progressive genetic lung disease affecting an estimated 50,000-80,000 individuals in the United States.1,2,3,4,5,6

The option and license agreement grants Sentynl the exclusive right to acquire a license to commercialize alvelestat for AATD-LD in the United States, with Mereo retaining commercial rights in the rest of the world. The agreement also grants Sentynl global rights to manufacture alvelestat for AATD-LD and on option exercise, it provides funding for the alvelestat Phase 3 development program, which could be initiated in early 2027.

"This partnership marks a pivotal moment for Sentynl's rare disease strategy. Mereo's alvelestat is a highly promising, differentiated candidate that meaningfully expands our portfolio and has the potential to address an area of significant unmet need," said Dr. Sharvil P. Patel, Managing Director, Zydus Lifesciences Limited. "AATD-LD has a profound impact on patients' lives. If approved, alvelestat has the potential to be a meaningful new option that could help their quality of life."

"We take great pride in having built a sustainable approach for developing therapies for ultra-rare conditions, and this partnership allows us to expand that strategic focus to a larger population within the rare disease community, enabling us to help more people," said Matt Heck, Chief Executive Officer of Sentynl Therapeutics. "For patients with AATD-LD, the current standard of care is demanding, often relying on generalized therapies or frequent intravenous treatments. We see a clear opportunity to improve upon that with alvelestat. Mereo has built a strong foundation for this asset, making them an ideal partner as we collaborate during the option period to prepare for the next phase of development."

"We are very pleased to have the opportunity to partner with Sentynl to advance alvelestat for patients with AATD-LD. We have been preparing alvelestat for a global Phase 3 study, backed by positive efficacy data from two Phase 2 studies. We believe Sentynl's commitment to rare diseases and established commercial infrastructure make them the ideal partner for alvelestat and look forward to collaborating with them during the option period, when we plan to refine the global Phase 3 study design," said Denise Scots-Knight, Chief Executive Officer of Mereo BioPharma.

Mereo will receive a non-refundable option fee from Sentynl and, on exercise of the option, the Company would also receive up to $40 million in upfront and R&D payments until NDA filing. Under these terms, Mereo would also be eligible to receive double-digit tiered royalties on U.S. net sales of alvelestat. Mereo will lead the global Phase 3 study and regulatory interactions until the study is completed. However, during the option period, the companies will collaborate to advance manufacturing and streamline the Phase 3 study design.

Lincoln Pharmaceuticals Ltd Reports Consolidated Net Profit of Rs. 36.23 crore in Q1 FY27, growth of 30.90% Y-o-Y

1. EBITDA in Q1FY27 up 32.29 % Y-o-Y to Rs. 51.70 crore;
2. Total Income in Q1FY27 up 19.02% Y-o-Y to Rs. 201.55 crore

Lincoln Pharmaceuticals Ltd (BSE: 531633 | NSE: LINCOLN), one of India's leading healthcare companies, has reported its operational and financial performance for Q1 FY27 ended June 30, 2026. The company reported consolidated net profit of Rs. 36.23 crore in Q1 FY27 as compared to a net profit of Rs. 27.68 crore reported in Q1 FY26, registering a growth of 30.90 % Y-o-Y. Total income for the quarter ended June 2026 stood at Rs. 201.55 crore, higher by 19.02 % Y-o-Y compared to total income of Rs. 169.34 crore in Q1 FY26. EBITDA for Q1 FY27 stood at Rs. 51.70 crore as compared to EBITDA of Rs. 39.08 crore in Q1 FY26, registering a growth of 32.29 % Y-o-Y. EPS for Q1 FY27 stood at Rs. 18.09 per share.

During FY26, the Company reported net profit of Rs. 87.89 crore (6.74% Y-oY growth), Total income of Rs. 704.48 crore (9.10% Y-o-Y growth), EBITDA of Rs. 131.14 crore (5.78% Y-o-Y growth). Company recommended a dividend of 18 %, Rs. 1.80 per share on the face value of Rs. 10 per share for the FY 2025-26, subject to shareholder approval at the upcoming Annual General Meeting.

The Company is targeting revenue of Rs. 1,000 crore over the next three years, as part of its broader strategy to achieve an annual growth rate of 15-18%. The company expects its growth to be supported by strong performance across key therapeutic segments including cardiac, diabetic, dermatology and ENT.

The company is also committed to expanding its global footprint while meeting diverse healthcare needs. CRISIL Ratings has reaffirmed its 'CRISIL A/Stable/CRISIL A1' ratings on Lincoln Pharmaceuticals' bank facilities, reflecting the promoters' strong industry experience, established market position, and healthy financial profile, despite working-capital intensity and regulatory and competitive challenges. Foreign Institutional Investors (FIIs) have steadily increased their stake in the company to 4.60% as on 30 June 2026.

Speaking on the financial performance and future outlook, **Mr. Munjal Patel, Director, Lincoln Pharmaceuticals Ltd**, said, "We have started FY27 with a clear focus on building on our existing growth momentum while strengthening the core areas of our business.

We are also evaluating opportunities to expand our reach across domestic territories and international markets, supported by our manufacturing capabilities and product pipeline.

With our continued focus on operational efficiency, portfolio expansion and disciplined execution, we remain committed to achieving our medium-term objective of crossing Rs. 1,000 crore in revenue and delivering sustainable growth for our stakeholders while maintaining a debt-free balance sheet."

Company remains focused on strengthening its presence in regulated and semi-regulated markets. It currently exports to 60+ countries across East and West Africa, Central and North America, Latin America, and Southeast Asia. Company aims to expand this footprint to 90 countries over next 2–3 years. With recent entry into the Canadian market and approvals from TGA - Australia and EU GMP, the company is poised for further global expansion.

Company has a state-of-the-art manufacturing facility unit at Khatraj in Ahmedabad, Gujarat, complying with stringent international quality and compliance norms and certified by EUGMP, TGA, WHO-GMP; ISO-9001:2015, ISO-14001:2015 and ISO-45001:2018. Company has developed 600 plus formulations in 15 therapeutic areas and has a strong product/brand portfolio in anti-infective, respiratory system, gynaecology, cardio & CNS, anti-bacterial, anti-diabetic, anti-malaria among others. Company has filed 25 plus patent applications and is awarded with seven patents.

Lincoln Pharmaceuticals Limited: https://www.lincolnpharma.com/

Providing Affordable and Innovative medicines for healthier lives. Lincoln Pharmaceuticals Limited is one of the leading healthcare companies in Gujarat, India. Established in the year 1979, the company develops and manufactures affordable and innovative medicines for healthier lives. The company has developed 600 plus formulations in 15 therapeutic areas and has a strong product/brand portfolio in anti-infective, respiratory system, gynaecology, cardio & CNS, anti-bacterial, anti-diabetic, anti-malaria among others. Company has over 1,700 registered products and another 700 in pipeline. The company has its strong presence in Domestic market with good strength of own field force and also exports to more than 60 Countries.

Company has developed many new drug delivery dosage forms over years and has a track record of launching many first-of-its-kind innovative products. Company works with vision for nurturing innovations and bringing them to Indian patients at affordable cost to create **"Healthcare for All".**

Lincoln Pharma has two state-of-the-art manufacturing facility units at Khatraj in Ahmedabad and Mehsana, Gujarat. Company's manufacturing facilities comply with stringent international quality and compliance norms and certified by EUGMP, TGA, WHO-GMP; ISO-9001:2015, ISO-14001:2015 and ISO-45001:2018, other ROW and emerging market regulatory approvals. Company is engaged in manufacturing of pharma formulations like Tablets, Capsules, Injectables, Syrups, Ointments, etc.

Company's key strength is embedded in its cutting-edge research and development capabilities. The company has a strong R&D team including 30 plus scientists. It has filled 25 plus patent applications and is awarded seven patents. R&D facility of the company is recognised by the Department of Scientific and Technology, Government of India and furnished with state-of-the-art devices and equipment for internal physical, chemical and microbiological analysis of all products.

Company has a strong presence in the domestic market nationally with a dedicated field force of over 600. Company has a wide national distribution network through 21+ Super Stockist in 26 states across India.

Going green, company has also set up a new Solar Plant at Mehsana factory and Khatraj factory in addition to at Radhanpur, Gujarat and two windmills.

This way we are nearly a 100% green renewable energy consuming company resulting significant saving in the electricity cost and helped the company to become a self-sustainable and environment-friendly organization.

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RPG Life Sciences Announces Strategic API Initiative to Accelerate Next Phase of Growth

RPG Life Sciences Limited ("RPG Life Sciences" or "RPG LS") today announced the execution of a Business Transfer Agreement for the transfer of the Company's Active Pharmaceutical Ingredients (API) business to RPG Active Pharma Limited ("RPG Active Pharma" or "RPGAP"), a wholly owned subsidiary of RPG Life Sciences, as a going concern on a slump sale basis.

RPG LIFE SCIENCES LIMITED
Inspired by Challenge

The proposed transfer is part of RPG Life Sciences' strategy to create a focused API business with dedicated capital, sharper management attention and greater strategic flexibility, while the Company also continues to build its formulations business. This business has been created at a time when the global pharmaceutical supply chains are undergoing structural realignment and India is increasingly emerging as a preferred destination for reliable, high-quality API manufacturing. The Company has entered into an investment agreement to forge a strategic partnership with lnvAscent, a healthcare-focused private equity investor, through an investment in RPG Active Pharma.
The partnership brings together RPG Life Sciences' pharmaceutical experience, manufacturing capabilities and execution track record with lnvAscent's 20-years' experience of investing in and scaling pharma businesses. Accordingly, funds managed by lnvAscent will make an initial investment of an amount upto Rs. 243 er. in RPG Active Pharma.

The agreement envisages investments by the Company and lnvAscent upto Rs. 700 er. in RPGAP in tranches. The investment is expected to provide RPG Active Pharma with the capital and strategic support required to strengthen manufacturing infrastructure, expand the product portfolio, enhance process development capabilities and pursue organic and inorganic growth opportunities.

In addition, the RPG Active Pharma has also executed a Share Purchase Agreement for acquisition of 100% equity share capital of Actis Generics Private Limited - an API manufacturing company based in Visakhapatnam. The proposed acquisition is expected to expand RPG Active Pharma's manufacturing base, broaden its operating platform and support its strategic growth objectives.

The investment by India Life Sciences Fund - a life sciences focused fund - and the proposed acquisition of Actis Generics are intended to establish RPG Active Pharma as a focused API manufacturer for the next phase of RPG Life Sciences·

API growth. RPG AP will focus on augmenting its manufacturing capabilities, expanding its API portfolio and serving customers across domestic and international markets with a strong emphasis on quality, reliability and long-term partnerships.

The transactions are subject to customary regulatory approvals and pre-closing conditions.

Commenting on the development, Ashok Nair, Managing Director, RPG Life Sciences, said:
"Building a meaningful and scalable presence in APfs has *been* a *strategic priority for RPG Life Sciences. RPG Active Pharma gives* us a *focused business* to *pursue this opportunity with greater speed, discipline and* scale. We *are pleased* to *partner with fnvAscent,* whose *pharma investing experience and long-term partnership approach complements our vision for the business. The proposed acquisition of Actis Generics further strengthens this business and supports our ambition to build a high-quality AP! business with expanded manufacturing capabilities, a broader product portfolio and the ability to create sustainable value for all stakeholders."*

Commenting on the partnership, Dr. Jeevak Gupta, Managing Director, lnvascent, said:
"We are excited to partner with RPG Ufe Sciences in building RPG Active Pharma into a differentiated AP/ business. RPG Life Sciences has established pharmaceutical capabilities, a strong operating foundation and a clear ambition to *scale* its *AP/ business. We believe RPG AP is well positioned to benefit from the long-term growth opportunity in high-quality AP/ manufacturing, and we look forward to supporting the business through capital, strategic guidance and our healthcare* sector *experience."*

Khaitan & Co. acted as the legal counsel and structuring advisor to RPG group for the investment transaction. o3 Capital acted as an exclusive financial advisor, Quillan Partners acted as legal counsel and Deloitte undertook financial due diligence on the acquisition of Actis by RPG Active Pharma.

Gland Pharma and Neuland Laboratories Join Forces for Sterile API Manufacturing

Gland Pharma & Neuland Laboratories Partner to Build Dedicated Sterile API Manufacturing Capability

Gland Pharma and Neuland Laboratories have entered into a strategic collaboration aimed at manufacturing sterile active pharmaceutical ingredients for global pharmaceutical customers. Under the partnership, Gland Pharma plans to establish a dedicated sterile API manufacturing suite at its JNPC facility in Visakhapatnam, Andhra Pradesh.

The collaboration brings together Gland Pharma's expertise in sterile pharmaceutical manufacturing with Neuland Laboratories' capabilities in API development and manufacturing. The initiative is expected to strengthen India's position as a reliable global source for complex pharmaceutical ingredients.

Sterile APIs represent a highly specialised segment of pharmaceutical manufacturing because they require stringent controls across production, contamination prevention, environmental monitoring, quality assurance and aseptic handling.

The planned manufacturing suite is particularly significant as global pharmaceutical companies continue to diversify their supply chains and seek qualified manufacturing partners capable of meeting demanding regulatory and quality requirements. For India, investments in high-value and technically complex manufacturing could help the country's pharmaceutical industry move further beyond conventional generic production toward specialised pharmaceutical technologies and services.

The partnership also reflects the growing role of Indian CDMO and manufacturing companies in global pharmaceutical supply chains. As demand for reliable sterile manufacturing capacity grows, collaborations between established Indian players could create new opportunities for export-oriented pharmaceutical production.

Pulse Pharmaceuticals Receives DCGI Nod for Nano Vitamin D3 Platform

Pulse Pharmaceuticals Secures DCGI Approval for Nano-Carrier Vitamin D3 Oral Dispersion

Hyderabad-based Pulse Pharmaceuticals has received approval from the Drugs Controller General of India for its nano-carrier entrapped vitamin D3 oral dispersion delivery platform, marking a significant development in pharmaceutical drug-delivery technology in India.

The platform uses a nano-based delivery approach designed to improve the absorption and bioavailability of vitamin D3. By applying advanced drug-delivery technology to a widely used nutritional compound, the development demonstrates how nanotechnology is increasingly moving from laboratory research toward commercial pharmaceutical applications.

Improving bioavailability is a key objective in drug-delivery research. Advanced carrier systems can potentially influence how active ingredients are dispersed, absorbed and utilised in the body, potentially creating more efficient formulations.

The regulatory approval represents an important milestone for Pulse Pharmaceuticals because it provides a pathway for translating its nano-drug-delivery research into a product intended for patient use. The development also highlights India's expanding capabilities in formulation science and advanced delivery technologies.

Indian pharmaceutical companies have traditionally been strong in generic formulation development, but emerging technologies such as nanocarriers are opening opportunities in more specialised pharmaceutical innovation.

As the pharmaceutical industry increasingly focuses on improving therapeutic performance rather than simply reproducing conventional formulations, technologies that enhance absorption, stability and delivery could become increasingly important.

Takeda Commits Up to $30 Million to Indonesia's Plasma Ecosystem

Takeda Announces Up to US$30 Million Investment in Indonesia Plasma Donation Network

Japan-based pharmaceutical company Takeda has announced an investment of up to US$30 million to support the development of plasma donation infrastructure in Indonesia. The initiative is being undertaken in collaboration with Indonesia's Ministry of Health and is intended to establish a pilot plasma-collection ecosystem.

Under the initiative, Takeda and the Indonesian government will evaluate the feasibility of expanding plasma collection and developing a more structured national plasma-donation network. Indonesia's Ministry of Health has also granted Takeda a plasma fractionation licence supporting the initiative.

The collected plasma will initially be processed through Takeda's international manufacturing network, while the programme evaluates the potential for a larger domestic ecosystem. The initiative is expected to prioritise Indonesia's domestic pharmaceutical needs in accordance with applicable regulations. Plasma-derived medicinal products are important for treating a range of serious and chronic conditions, including immune deficiencies and certain bleeding disorders.

Building a reliable domestic plasma supply can therefore have implications for healthcare resilience and long-term medicine availability.

The project represents a broader shift in Southeast Asia toward strengthening local pharmaceutical and biologics capabilities. Governments across the region are increasingly looking at domestic manufacturing, supply security and strategic partnerships with multinational pharmaceutical companies.

For Indonesia, the Takeda partnership could become an important step toward developing a more integrated plasma ecosystem, combining local collection infrastructure with international expertise in plasma-derived therapies.

Novartis Expands Biopharmaceutical Manufacturing Footprint in Singapore

Novartis Expands Singapore Manufacturing Operations to Strengthen Biopharmaceutical Supply

Novartis is expanding its biopharmaceutical manufacturing capabilities in Singapore, reinforcing the city-state's role as a strategic manufacturing hub for innovative medicines and advanced pharmaceutical production in Asia. The expansion builds on Novartis' long-standing presence in Singapore and its investments in the country's pharmaceutical sector.

Novartis has maintained a partnership with Singapore for decades, with cumulative investments reported at more than US$1 billion. The latest expansion further demonstrates the company's commitment to using Singapore as part of its global manufacturing and supply network. Singapore has increasingly positioned itself as a high-value pharmaceutical and biopharmaceutical manufacturing centre, attracting major global companies because of its regulatory environment, advanced infrastructure, skilled workforce and connectivity with Asian markets. The expansion is particularly relevant as pharmaceutical manufacturing moves toward more complex biologics and advanced production technologies. These manufacturing systems require sophisticated facilities, stringent quality controls and highly skilled technical teams.

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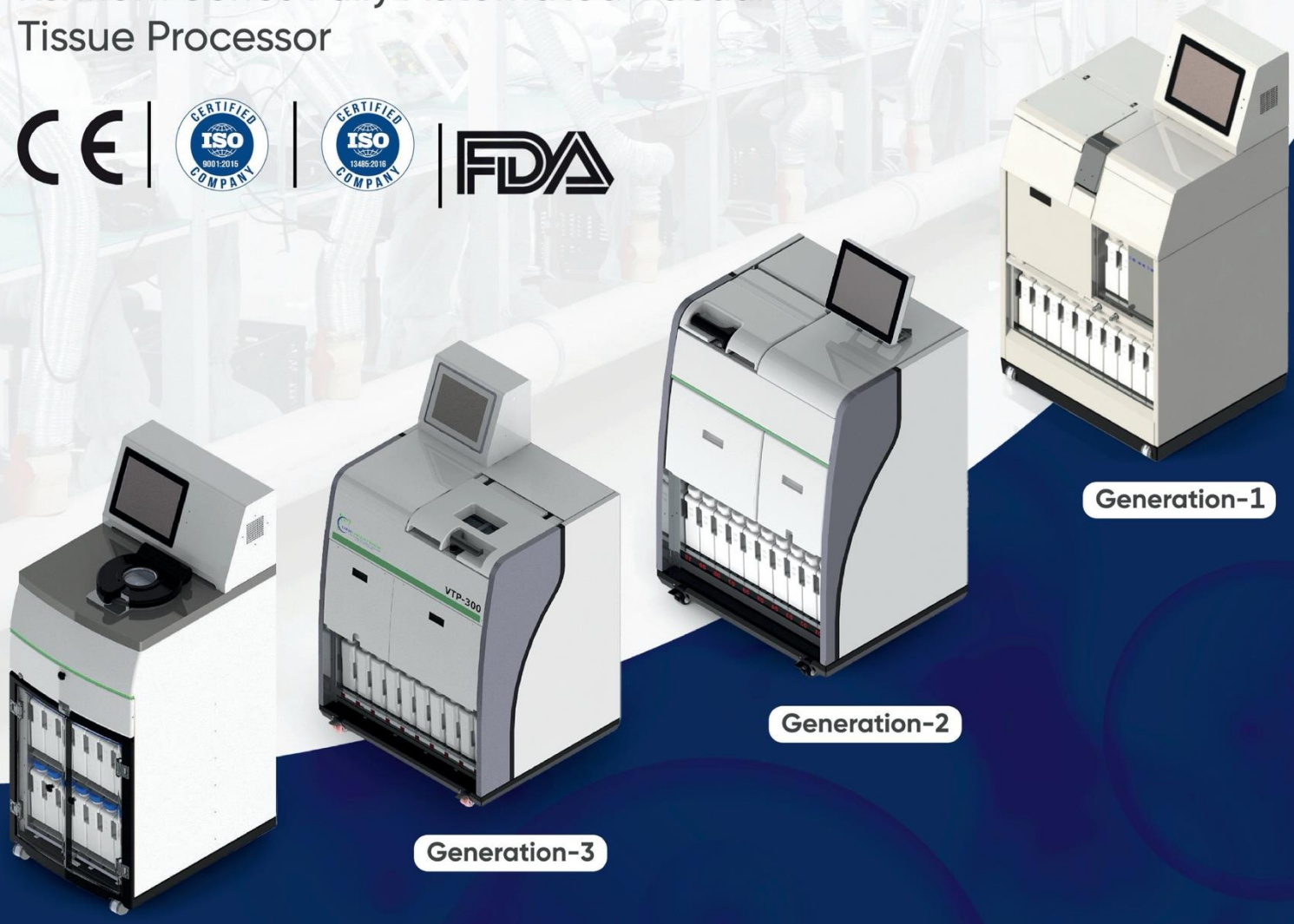

UPCOMING

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AstraZeneca Announces $1.5 Billion Singapore ADC Manufacturing Facility

AstraZeneca to Invest US$1.5 Billion in Singapore for Next-Generation ADC Manufacturing

AstraZeneca has announced plans for a major US$1.5 billion investment in Singapore to establish an advanced manufacturing facility for antibody-drug conjugates (ADCs), creating a significant new platform for next-generation oncology manufacturing in Asia. The project is expected to create more than 800 skilled jobs.

ADCs represent one of the most rapidly advancing areas of modern cancer therapy. These medicines combine the targeting capabilities of antibodies with potent therapeutic payloads, allowing drug molecules to be delivered more selectively to cancer cells.

The planned Singapore facility highlights the increasing importance of Asia in the global biopharmaceutical manufacturing landscape. Rather than limiting advanced production to traditional pharmaceutical centres, companies are increasingly building sophisticated facilities closer to major Asian markets and regional supply chains.

The scale of AstraZeneca's investment also demonstrates the growing economic importance of high-value biopharmaceutical manufacturing. Advanced facilities require specialised engineering, quality systems, analytical capabilities, process development expertise and highly trained scientific personnel. For Singapore, the project strengthens its position as a leading Asian centre for complex pharmaceutical and biologics manufacturing. It also aligns with the country's broader strategy of attracting investment in advanced manufacturing and life sciences.

Sun Pharma's Organon Deal Reshapes India's Global Pharma Ambitions

Sun Pharma Advances $11.75 Billion Organon Acquisition, Creating a New Global Growth Platform

Sun Pharmaceutical Industries is advancing its planned acquisition of Organon in a landmark transaction valued at approximately **US$11.75 billion including debt**. The deal is positioned as the largest overseas acquisition by an Indian pharmaceutical company and represents a major strategic move to expand Sun Pharma's global commercial footprint beyond its established generics and specialty-medicine businesses.

The proposed transaction would significantly expand Sun Pharma's presence across international markets and provide access to Organon's portfolio, commercial infrastructure and established brands. The acquisition comes as Indian pharmaceutical companies increasingly look beyond traditional generic medicines for higher-value growth opportunities. Sun Pharma has already been strengthening its specialty portfolio, particularly in areas such as dermatology, oncology and chronic diseases. During the company's latest reported quarter, specialty sales increased 12.8%, while India remained a major growth driver, highlighting the company's broader transition toward differentiated and specialty products.

The Organon transaction also demonstrates the growing scale and confidence of Indian pharmaceutical companies in pursuing global M&A. Indian drugmakers are increasingly using acquisitions to gain access to established brands, new therapeutic areas, regulatory capabilities and international distribution networks rather than relying exclusively on organic expansion.

The deal could also strengthen India's position in the global pharmaceutical value chain. As international pharmaceutical markets become increasingly competitive and generic pricing remains under pressure, scale and access to differentiated products are becoming increasingly important strategic advantages.

For Sun Pharma, the Organon acquisition could therefore represent more than geographic expansion—it could become a transformational step toward building a broader global pharmaceutical platform combining specialty medicines, branded products and established international commercial capabilities.

ChrysCapital Takes Control of Novartis India

ChrysCapital Completes Majority Acquisition of Novartis India, Signalling New Phase for Indian Pharma

Indian private-equity firm ChrysCapital has completed the acquisition of a **70.68% stake in Novartis India**, marking one of the notable recent ownership transitions in India's pharmaceutical sector. The transaction represents ChrysCapital's first majority-controlled investment in an Indian pharmaceutical company and is expected to usher in a new phase of strategic development for the business.

The transaction brings an established pharmaceutical portfolio under majority Indian investment ownership at a time when domestic investors are showing increasing interest in healthcare and life sciences businesses. The change in ownership is expected to provide the company with greater strategic flexibility while maintaining its presence in the Indian pharmaceutical market.

ChrysCapital has also appointed **Dr. Vikas Gupta**, a former senior executive of Alkem Laboratories, as chief executive officer. The leadership transition indicates an emphasis on combining investment expertise with experienced pharmaceutical management as the business enters its next phase.

The transaction is significant against the backdrop of increasing private-equity participation in India's pharmaceutical sector. Investors are increasingly targeting established businesses with strong brands, distribution networks, specialised portfolios and opportunities for operational improvement.

For the Indian pharma ecosystem, the transaction highlights the attractiveness of established pharmaceutical assets to domestic investment firms. It also reflects the broader evolution of India's healthcare investment landscape, where pharmaceutical businesses are increasingly being evaluated as long-term platforms for growth and consolidation.

The Novartis India transaction could therefore become a notable reference point for future pharma investments, particularly as private capital seeks opportunities across branded medicines, specialty healthcare, manufacturing and life-sciences businesses in India.

Akums Expands Beyond Core Pharma Manufacturing

Akums Acquires Oriflame India Manufacturing Business in ₹56 Crore Diversification Move

Indian contract pharmaceutical manufacturer **Akums Drugs & Pharmaceuticals** has expanded its business portfolio through the acquisition of Oriflame India's manufacturing business in a transaction valued at approximately **₹56 crore**. The deal includes two production facilities and represents a strategic move by Akums to enter the colour-cosmetics manufacturing segment.

The acquisition broadens Akums' manufacturing capabilities beyond its traditional pharmaceutical activities and provides an opportunity to participate in the expanding personal-care and cosmetics manufacturing market.

The company can potentially leverage its existing manufacturing infrastructure, quality systems and supply-chain capabilities across the new business segment.

Contract manufacturing has become an increasingly important component of India's pharmaceutical ecosystem, with global and domestic companies seeking specialised partners to reduce manufacturing costs, accelerate product launches and improve operational flexibility. Akums' move also reflects a wider trend among Indian pharmaceutical manufacturers to diversify into adjacent healthcare and consumer categories.

Cosmetics, nutraceuticals, wellness products and other consumer-health segments can provide additional growth opportunities while allowing manufacturers to utilise existing technical and production capabilities.

The acquisition could also strengthen Akums' position as a diversified manufacturing partner. As pharmaceutical companies increasingly outsource production and focus internal resources on R&D, marketing and commercialisation, capable manufacturing platforms are becoming strategically valuable.

The transaction demonstrates how Indian pharma businesses are increasingly pursuing growth through **capacity acquisition, diversification and vertical expansion**, rather than relying exclusively on conventional pharmaceutical manufacturing.

India's Pharma M&A Market Enters a High-Value Growth Phase

Indian Pharma M&A Accelerates as Companies Pursue Scale, Capabilities and Global Markets

India's pharmaceutical sector is entering a period of heightened M&A activity, driven by large strategic transactions, private-equity investments and cross-border expansion. Industry deal activity has been supported by companies seeking new therapeutic portfolios, manufacturing capabilities, geographic access and opportunities to strengthen their competitive positions.

The proposed Sun Pharma–Organon transaction has emerged as a major catalyst for India's pharmaceutical deal landscape. Valued at approximately US$11.75 billion including debt, the transaction illustrates the scale at which Indian pharmaceutical companies are now willing to pursue international opportunities.

According to Grant Thornton Bharat's Q2 2026 Dealtracker, India recorded **565 M&A and private-equity transactions worth US$36.3 billion** during the second quarter of 2026. Although overall transaction volumes declined sequentially, deal values increased sharply, reflecting the influence of several large transactions.

Pharmaceutical companies are increasingly using M&A as a strategic tool to address challenges in mature markets while gaining access to specialty products, advanced technologies and international commercial infrastructure.

The approach is particularly relevant as generic businesses face pricing pressure and companies seek higher-margin growth areas. At the same time, private-equity investors are becoming more active in India's healthcare ecosystem, targeting established pharmaceutical, manufacturing and specialty-healthcare platforms. This provides companies with additional capital for expansion, acquisitions and business transformation.

The emerging deal environment suggests that India's pharmaceutical industry is moving toward a more consolidated and globally integrated model, where scale, differentiated portfolios and access to international markets will increasingly determine long-term competitiveness.

Southeast Asia Strengthens Its Position as a Pharmaceutical Business Hub

CPHI South East Asia 2026 Generates More Than 4,000 Business-Matching Opportunities

Thailand is strengthening its position as a pharmaceutical and life-sciences business hub in Southeast Asia, highlighted by the strong participation at **CPHI South East Asia 2026** in Bangkok. The event attracted more than **11,000 pharmaceutical professionals from over 70 countries** and generated more than **4,000 business-matching requests** across the pharmaceutical supply chain.

The event brought together 369 exhibitors from 25 countries, spanning pharmaceutical ingredients, APIs, excipients, processing technologies, manufacturing equipment and other critical areas of the pharmaceutical supply chain. The scale of participation highlights the growing importance of ASEAN as a market for pharmaceutical partnerships and commercial expansion.

Thailand is increasingly positioning itself as a strategic gateway into Southeast Asian pharmaceutical markets. Its geographic location, manufacturing infrastructure and established healthcare ecosystem provide opportunities for international companies seeking access to the wider ASEAN region.

The business activity surrounding the event also reflects the growing importance of partnerships in Southeast Asian pharma. Companies are increasingly looking for local distributors, contract manufacturers, technology providers, ingredient suppliers and strategic commercial partners to enter and expand within regional markets.

For Indian pharmaceutical companies, the ASEAN market offers opportunities across generics, APIs, contract manufacturing, pharmaceutical machinery, laboratory technologies and healthcare products.

Stronger India–ASEAN commercial relationships could therefore create new channels for exports and strategic collaboration.

The continued growth of pharmaceutical business platforms such as CPHI South East Asia indicates that ASEAN is evolving from a primarily emerging pharmaceutical market into an increasingly important regional manufacturing, sourcing, investment and commercialisation ecosystem.

Singapore Remains a Strategic Destination for Advanced Pharma Investment

Singapore Continues to Attract High-Value Pharmaceutical Manufacturing Investments

Singapore continues to strengthen its position as a strategic pharmaceutical manufacturing hub in Asia, supported by major investments from global pharmaceutical companies and an ecosystem built around advanced manufacturing, research, supply-chain connectivity and skilled talent. The country's pharmaceutical sector remains closely integrated with global production networks.

The country's attractiveness is particularly evident in advanced pharmaceutical and biopharmaceutical manufacturing, where companies require sophisticated facilities, highly controlled production environments and access to specialised scientific and engineering talent.

Recent developments also show that pharmaceutical companies are reassessing global manufacturing footprints in response to changing demand, trade policies and supply-chain considerations.

BioNTech, for example, has announced plans to wind down its Singapore vaccine and therapeutic manufacturing facility by February 2027 following a strategic review, demonstrating that pharmaceutical investment decisions are increasingly influenced by global market conditions.

At the same time, Singapore remains an important base for major pharmaceutical companies. Pfizer opened a US$1 billion manufacturing facility in Singapore in 2024, demonstrating the country's continued ability to attract large-scale investment in **advanced** pharmaceutical production.

The changing investent landscape highlights an important characteristic of Southeast Asian pharma: competitiveness increasingly depends not only on low-cost manufacturing but also on technology, regulatory capabilities, infrastructure, talent and proximity to major Asian markets.

For pharmaceutical companies across India and ASEAN, Singapore therefore remains a valuable benchmark for developing high-value manufacturing ecosystems and integrating regional operations with global pharmaceutical supply chains.

Enhancing Laboratory Accuracy with the JULABO PURA Water Bath

The JULABO PURA series is a modern line of laboratory water baths designed for precision, safety, and ease of use. These units are made to support a range of temperature-controlled tasks—routine or demanding—while offering durability and intuitive operation. Their temperature range (usually from ~ +25°C up to ~ +99.9 °C) makes them suitable for many lab processes.

Features

- **Temperature Stability**: ± 0.15 °C, helps with reproducibility and sensitive samples.
- **Timer Function**: Integrated timer, so heating periods can be set and monitored.
- **Dry-running protection**: Prevents damage if water level drops too low.
- **Splash-protected mains switch**: Safety around moisture.
- **Drain screw (except PURA 4)**: Makes draining the bath easier and cleaner.
- **Ergonomic design**: Recessed side grips for moving; non-slip rubber feet for stability; smooth interior to avoid interfering parts.
- **Bright LED display**: Easy to read, and models provide notifications/reads clearly (°C/°F) etc.
- **Accessories**: Removable platform; bath covers; special edges to guide condensed water back into bath; optional drain pans etc.

Focus Products:

- **PURA 4**: The smallest model. Simpler, no drain screw. Good for small-volume tasks.
- **PURA 10**: Mid-size bath; ~1.4–9.5 L fill volume, depth ~14 cm.
- **PURA 14**: Larger capacity (~14 L), greater heating power.
- **PURA 22**: ~25.5 L fill volume, strong heating (≈2 kW), large usable bath opening.
- **PURA 30**: The largest in this lineup (up to ~36 L), for higher capacity tasks.

Benefits

- **Precision & Reliability**: Tight temperature control and stability promote repeatable experiments.
- **Durability**: Use of corrosion-resistant materials, robust construction makes them suitable for constant use.
- **Ease of use / Maintenance**: Features like drain screw, protection against dry run, easy clean surfaces, etc., reduce labour and potential downtime.
- **Safety**: Splash protection, stable footing, safe electrical design.
- **Versatility**: Wide volume options, ability to handle many types of standard lab tasks (incubation, heating, sample preparation).

Applications

- Incubation of samples at controlled temperature
- Chemical reactions that require steady heat
- Biological sample treatments (e.g. heating, thawing, etc.)
- Material testing (e.g. thermal exposure)
- Quality control in food, beverages, dental labs, etc.
- Routine heating or sample preparation tasks

Temperature Control with JULABO PURA Water Baths and Shaking Water Baths

In today's laboratory workflows, effective and reliable temperature control has become a standard. For both simple quality control and complex research, temperature control must be consistent. This consistency ultimately assists with reproducibility and data quality. For multiple laboratory applications, JULABO PURA water baths and shaking water baths give the temperature control, consistent performance, and long-lasting dependability that meets the standard.

Stability and Accuracy

Certain temperature control technologies are possessed by the JULABO PURA water baths. These technologies provide a high degree of temperature control stability, uniform heating, and thermal stability.

With digital control and the quick heating capabilities of the water baths, consistent temperature control can be flow for long periods of time. Such dependability is required for sensitive applications like enzyme reaction, incubation, materials testing, and calibration adjustments.

Heat is more easily transferred though high-quality stainless steel, and it will react less the chemicals and course materials of the laboratory. If PURA water baths are used with the high-quality stainless steel, consistent performance can be achieved seamlessly.

Versatility Across Laboratory Applications

The PURA water bath range supports a broad spectrum of laboratory tasks, including:

1. Sample thawing and warming
2. Incubation of biological and chemical samples
3. Temperature-dependent quality control tests
4. Calibration of sensors and measuring devices

SRICO
INNOVATIVE LABORATORY TECHNOLOGY

Purpose-built **JULABO shaking water** baths provide uniform movement for applications that demand agitation. These water baths are suitable for cell culture, solubility studies, hybridization, and biochemical reactions due to their ability to provide uniform temperature distribution and thorough mixing. Safety and user comfort are defenining design aspects of JULABO appliances. The design of JULABO appliances features user to set and monitor device interaction parameters.

JULABO has a reputation all over the world for its quality and precise PURA water baths and shaking water baths.

To know more:

Micro Spargers improve **Bioreactor yields**

Biotech Fluidics offers a range of **micro spargers** engineered to significantly reduce bubble size and increase gas transfer and volumetric mass transfer coefficient (kLa), resulting in reduced gas consumption and improved upstream reactor yields.

Sintered porous micro sparger tips

Microbubbles produced by sparger

A micro sparger is a device that introduces a gas such as air, oxygen, or carbon dioxide into a liquid by creating very small bubbles. These devices, typically made from sintered porous materials like stainless steel, create tiny bubbles, which increases the surface area for gas-liquid contact, leading to more efficient mass transfer and enabling processes like aeration and fermentation.

Biotech Fluidics has teamed up with MOTT Corporation to offer **micro spargers** for **bioreactor applications** that efficiently dissolve gases, promote cell growth, and provide agitation.

These micro spargers have proven to increase benchtop laboratory bioreactor and fermenter mass transfer rates by 100% to 400% over standard drilled pipes or single-opening dip tubes.

BIOTECH FLUIDICS

Biotech Fluidics offers a wide variety of porous metal sparger tips for laboratory and pilot scale bioreactors and fermenters.

With media grades ranging from 2 µm to 15 µm, Biotech Fluidics can offer a micro sparger optimized to generate bubble sizes which are optimal for your specific media, organism, and mass transfer requirements. Whatever your bioreactor application, there is a micro sparger tip optimized for your needs.

To learn more about micro spargers for bioreactors please visit https://biotechfluidics.com/products/mixers-and-reactors/micro-gas-spargers/ or contact Biotech Fluidics on + 46 300 56 91 80 / + 1-612-703-5718 / info@biotechfluidics.com.

Biotech Fluidics is a leading supplier of fluidic system solutions, liquid transfer components, degassing systems, and innovative laboratory technology to instrument developers, manufacturers, and distributors all around the world. The company's mission is to empower its customers by designing and assembling unique products, being a dependable partner, offering first-class service, in-depth knowledge, and offering advanced technical support for all the items it provides. For further information - www.biotechfluidics.com

Thermo Fisher Scientific Launches Orbitrap Tribrid Apex

Thermo Fisher Scientific Introduces Orbitrap Tribrid Apex for Next-Generation Proteomics

Thermo Fisher Scientific introduced the **Orbitrap Tribrid Apex mass spectrometer** at ASMS 2026 in June, adding a new high-performance platform to its Orbitrap portfolio. The launch combines Orbitrap Tribrid technology with advanced direct-mass capabilities and is aimed at laboratories requiring deeper molecular characterisation and high-resolution analytical performance.

The new platform is designed to address increasingly complex proteomics and biopharmaceutical research workflows. Its combination of high-resolution mass analysis and advanced fragmentation capabilities is intended to help researchers obtain more comprehensive information from challenging biological samples.

The launch comes at a time when pharmaceutical and biotechnology laboratories are generating increasingly complex datasets from proteins, peptides, metabolites and other biomolecules. Researchers require analytical systems capable of delivering high sensitivity and resolution while maintaining throughput.

For biopharmaceutical laboratories, advanced mass spectrometry can support applications including protein characterisation, peptide mapping, impurity analysis, biomarker research and multiomics. Such capabilities are becoming increasingly important as drug-development pipelines move toward more complex biological molecules.

The Orbitrap Tribrid Apex also reflects a broader industry movement toward integrated analytical workflows. Instrument manufacturers are increasingly combining high-performance hardware with advanced software and data-processing capabilities to simplify complex research workflows.

With its June 2026 introduction, the Orbitrap Tribrid Apex represents one of the notable new mass-spectrometry platforms launched during the year's major analytical-instrumentation season, particularly for laboratories focused on proteomics and advanced pharmaceutical research.

Thermo Fisher Scientific Unveils Orbitrap Excedion

Thermo Fisher Launches Orbitrap Excedion to Accelerate High-Throughput Multiomics

Thermo Fisher Scientific also unveiled the **Orbitrap Excedion** during ASMS 2026, introducing another next-generation mass-spectrometry platform aimed at accelerating high-throughput multiomics and molecular research. The instrument was among the major mass-spectrometry launches highlighted during the June 2026 event.

The platform is designed for laboratories that need to combine high analytical performance with faster acquisition and greater throughput. This is increasingly important as researchers move from targeted experiments toward broader molecular profiling involving thousands of analytes.

Multiomics workflows generate large volumes of information across proteomics, metabolomics and other molecular disciplines. The ability to acquire and process this information efficiently can influence both the speed and scale of research programmes.

In pharmaceutical research, high-throughput mass spectrometry can contribute to drug discovery, biomarker identification, systems biology and biopharmaceutical characterisation. Faster analytical workflows can also help laboratories process larger sample numbers without proportionally increasing instrument time.

The launch demonstrates how mass spectrometry is evolving beyond a focus on sensitivity and resolution alone. Speed, throughput, automation and data handling are becoming equally important considerations for laboratories investing in new analytical platforms.

The Orbitrap Excedion therefore adds to the growing portfolio of high-performance mass spectrometers designed for modern, data-intensive life-science research and highlights the continuing transformation of mass spectrometry into a high-throughput analytical technology.

Bruker Introduces timsMRMS

Bruker Launches timsMRMS, Combining Trapped Ion Mobility with Magnetic Resonance Mass Spectrometry

Bruker introduced the **timsMRMS** at ASMS 2026 in June, bringing together trapped ion mobility spectrometry with magnetic resonance mass spectrometry. The new platform represents an unusual combination of technologies designed to expand analytical capabilities for complex molecular and proteomic research.

Trapped ion mobility spectrometry adds an additional dimension of separation to mass spectrometric analysis. By providing information related to molecular shape and mobility in addition to mass, ion mobility can help researchers distinguish compounds that may be difficult to separate using conventional mass measurements alone.

The integration with magnetic resonance mass spectrometry further expands the platform's analytical potential.

Such combinations are particularly relevant to research involving complex molecular mixtures, where conventional mass-to-charge measurements may not provide sufficient information for confident characterisation.

The technology is relevant to pharmaceutical and biotechnology laboratories working in areas such as proteomics, metabolomics, biomolecular research and structural characterisation. Advanced multidimensional measurements can provide researchers with richer molecular information from a single analytical workflow.

Bruker's June launch also reflects a broader trend toward combining complementary analytical technologies within increasingly sophisticated instrument platforms. Laboratories are looking for systems that can provide more molecular information while reducing the need for multiple independent analytical steps.

The timsMRMS consequently stands out among the June 2026 analytical-instrument launches as an example of how next-generation mass spectrometry is moving toward multidimensional characterisation and deeper molecular analysis.

Waters Introduces Xevo MRT P10

Waters Launches Xevo MRT P10 Benchtop Mass Spectrometer for Advanced Multiomics

Waters Corporation introduced the **Xevo MRT P10** at ASMS 2026, adding a new benchtop mass-spectrometry platform designed for advanced multiomics research. The system was highlighted among Waters' major product introductions during the June analytical-science event.

The Xevo MRT P10 is based on quadrupole time-of-flight technology and is designed to provide high-performance MS/MS analysis in a benchtop format. Waters has positioned the system for laboratories seeking greater analytical capability without moving to larger, more complex instrument configurations.

According to information presented around the launch, the platform delivers substantially improved MS/MS sensitivity compared with its predecessor and can identify significantly more lipid species than competing benchtop instruments. These capabilities are particularly relevant to laboratories conducting complex molecular profiling.

Waters™

For pharmaceutical and biotechnology researchers, the platform can support applications in metabolomics, lipidomics, proteomics and other multiomics workflows. Such analyses are increasingly being used to investigate disease mechanisms, drug responses and biological pathways.

The benchtop format is also commercially significant because it makes advanced analytical performance accessible to a broader range of laboratories. Compact, high-performance instrumentation can help research groups expand their analytical capabilities without the infrastructure requirements associated with larger platforms.

The Xevo MRT P10 is therefore an important June 2026 launch for the analytical-instrumentation market, illustrating the industry's movement toward powerful but increasingly accessible benchtop mass-spectrometry solutions.

HORIBA Launches Partica Particle Size & Shape Analyzer

HORIBA Introduces Partica Analyzer for Rapid Particle Size and Shape Characterisation

HORIBA has launched **Partica**, a new particle size and shape analyser designed to combine laser diffraction and dynamic image analysis within a single analytical platform. The system is designed for research and quality-control laboratories working with advanced materials and particulate samples.

HORIBA

One of the key features of the new platform is its ability to measure particle-size distribution and particle shape in the same workflow. HORIBA states that the system can provide results in approximately one minute, with measurement time potentially reduced by as much as 50% compared with conventional models, depending on the application and operating conditions.

Particle characterisation is important across pharmaceutical manufacturing, materials science, chemicals, food, cosmetics and other industries. Particle size and morphology can influence properties such as dissolution, flowability, stability, processing behaviour and product performance.

For pharmaceutical laboratories, the ability to obtain both size-distribution and shape information can be particularly valuable during formulation development and quality control. Combining multiple measurements into one workflow may also reduce analytical complexity and improve laboratory productivity.

The launch reflects a growing demand for analytical instruments that deliver faster results without sacrificing the quality of characterisation. Laboratories are increasingly looking for systems that can support higher sample throughput while simplifying routine analytical operations.

HORIBA's Partica therefore represents a notable recent addition to particle-characterisation technology and is particularly relevant to pharmaceutical, materials and industrial laboratories where rapid and comprehensive particle analysis is essential.

Teledyne DALSA Launches 67 MP Scientific Imaging Camera

Teledyne DALSA Introduces Falcon4-CLHS M8200-Scientific for High-Resolution Laboratory Imaging

Teledyne DALSA has launched the **Falcon4-CLHS M8200-Scientific**, a new 67-megapixel scientific camera designed for life-science imaging, scientific research and precision-measurement applications. The camera expands the company's Falcon4-CLHS family with a high-resolution option aimed at demanding imaging workflows.

The new camera combines ultra-high resolution with imaging performance intended for applications where researchers need to capture detailed structures and measurements. High-resolution scientific imaging is increasingly important in microscopy, materials research, inspection and advanced laboratory instrumentation.

For life-science laboratories, high-quality imaging can support applications ranging from microscopy and cellular research to instrument-based imaging and quantitative analysis. Higher-resolution imaging can provide researchers with additional information when investigating small or complex features.

The camera is also designed for precision measurement applications, extending its relevance beyond conventional laboratory imaging. Industrial and scientific laboratories increasingly rely on digital imaging systems for automated inspection, measurement and documentation.

The launch reflects the broader convergence of imaging hardware and analytical laboratory workflows. Modern scientific cameras are increasingly becoming quantitative measurement tools rather than simply devices for visual observation.

With its 67 MP configuration, the Falcon4-CLHS M8200-Scientific represents a significant recent development in scientific imaging hardware and provides laboratories with a high-resolution option for demanding research and measurement applications.

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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Titan Enterprises Advances Engineering Validation of PFAS-Free Materials for Turbine Flowmeters

Titan Enterprises is undertaking an extensive material evaluation programme to identify high-performance, non-PFAS materials for its turbine flowmeter range. This is part of a continuing commitment to innovation and regulatory readiness to ensure suitable fluorine-free polymers can be used to maintain the performance characteristics demanded by industrial flow measurement applications.

Titan Enterprises Ltd

Increasing international scrutiny of per- and polyfluoroalkyl substances (PFAS), coupled with anticipated legislation within global markets, is driving manufacturers to reassess material selection across critical components. The OECD's broad definition of PFAS encompasses a wide range of fluorinated materials traditionally used in engineering applications, prompting companies to review product designs and material selections. Final legislation is anticipated by the end of 2026 to be accepted by European Member States, with the likelihood of changes coming into effect in 2027. Recognising the importance of staying ahead of evolving legislation, Titan Enterprises is conducting comprehensive testing of non-PFAS materials to determine their suitability for precision moulded flowmeter components.

PFAS-FreeMaterialTesting

The research focuses on finding alternatives that deliver the durability, dimensional stability, chemical resistance and long-term reliability customers expect, without compromising measurement accuracy or operational performance.

"Our objective is to provide customers with confidence that their flow measurement solutions will remain compliant, reliable and fit for purpose as regulations evolve," said Neil Hannay, Senior R&D Engineer for Titan Enterprises. “Currently no single alternative material exists that has the properties required across all our industry applications where the mini turbines are being used, therefore our ideal is to have 3-4 options for our customers to choose.”

With the likelihood of multiple polymer types to be offered to suit specific customer process and application requirements, the priority is also for any chosen material to be FDA and/or NSF-Approved in order to be viable for use within the food, beverage and pharmaceutical industries.

Two such materials - Hostaform® and polypropylene - are currently performing well under testing, with key properties of good chemical resistance to solvents, fuel and strong alkalis, as well as high resistance to thermal and oxidative degradation, being significantly important to Titan’s turbine flowmeters.

The research forms part of Titan's long-term engineering strategy to minimise the impact of emerging PFAS regulations without compromising the accuracy, repeatability and robustness for which its turbine flowmeters are recognised.

Neil emphasises: "By investing in material research today, we are helping to future-proof our product range while maintaining the high standards of performance our customers rely on."

Alongside its material development programme, Titan Enterprises has published a PFAS Statement outlining the company's position on current and proposed PFAS legislation and the potential implications for its product portfolio. The document provides customers with guidance on Titan's ongoing material qualification activities and its commitment to supporting compliance throughout the regulatory transition.

Through continued investment in material science, product validation and engineering development, Titan Enterprises remains focused on delivering high-performance flow measurement solutions that meet the technical, environmental and regulatory challenges of the future.

More information can be found at **www.flowmeters.co.uk**

About Titan Enterprises

With over four decades of expertise in liquid flow measuring solutions, Titan Enterprises designs and manufactures high-performance flowmeters for OEMs, industrial and laboratory applications. Known for innovation, reliability, and a collaborative engineering approach, Titan supports customers worldwide in precision flow measurement challenges.

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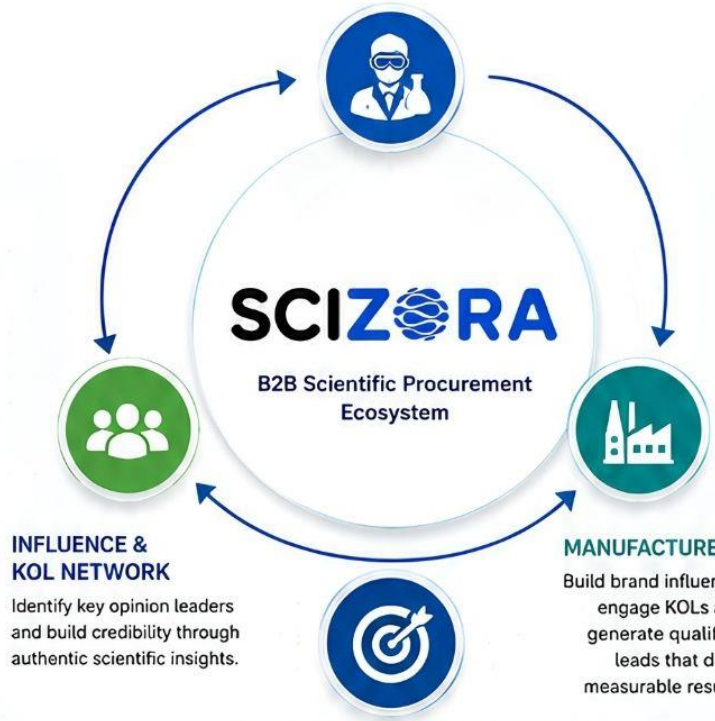

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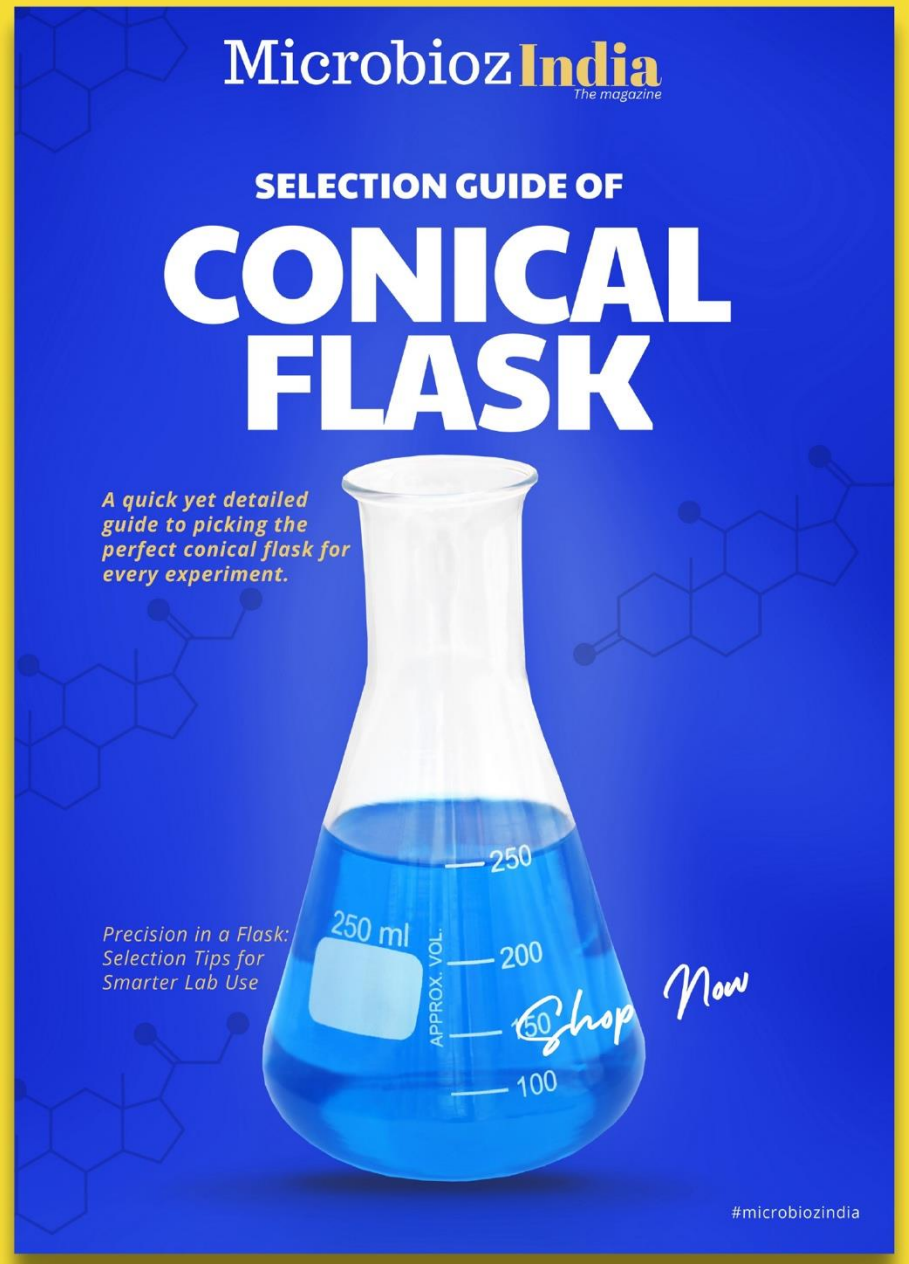

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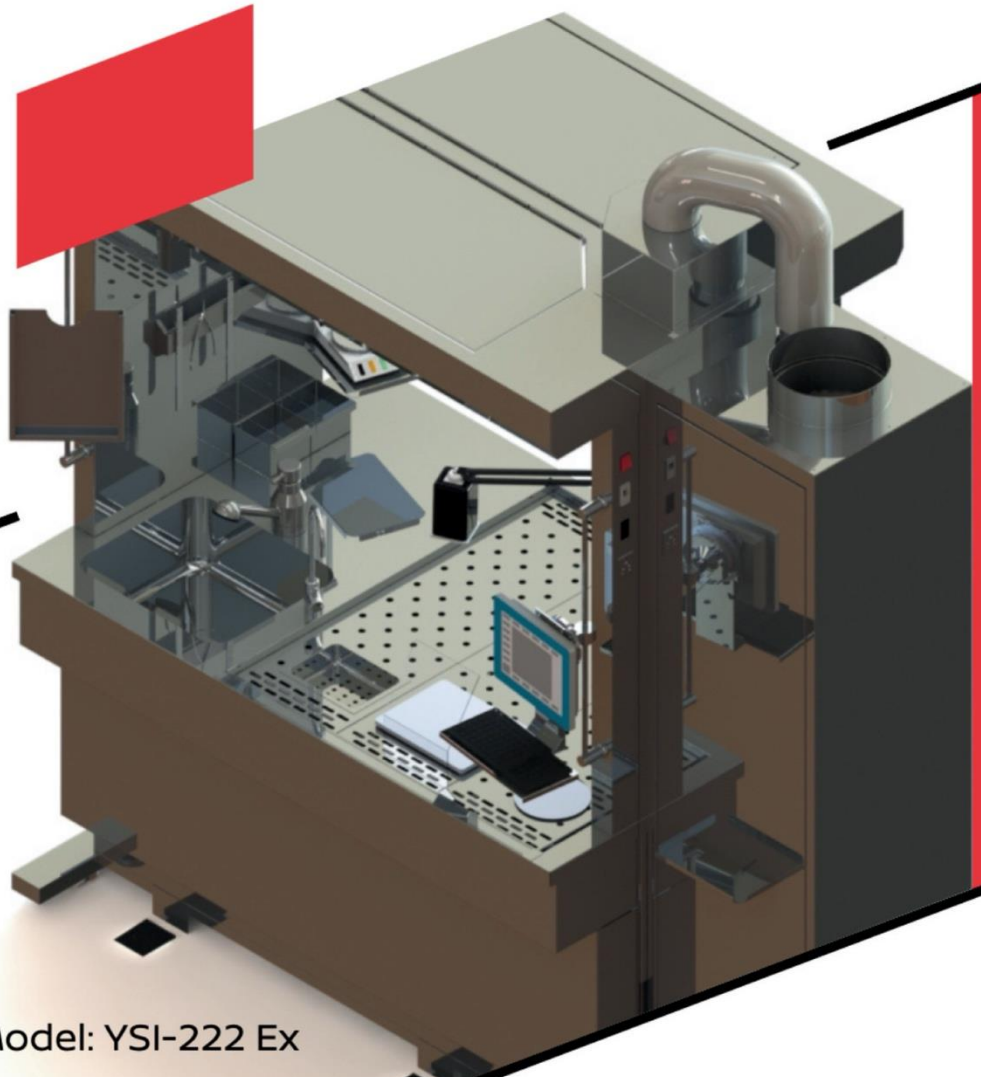

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