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Microbioz India

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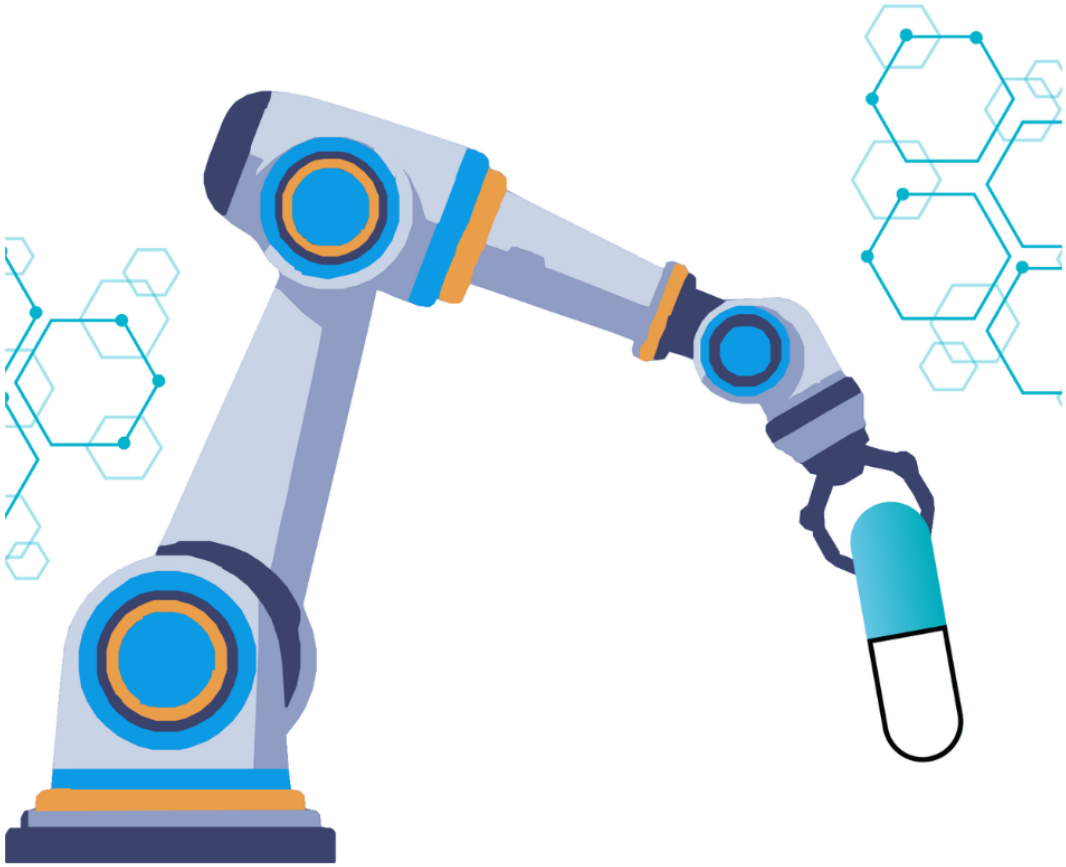
Science in Motion

The Technologies Shaping Tomorrow's **Pharmaceutical** Industry



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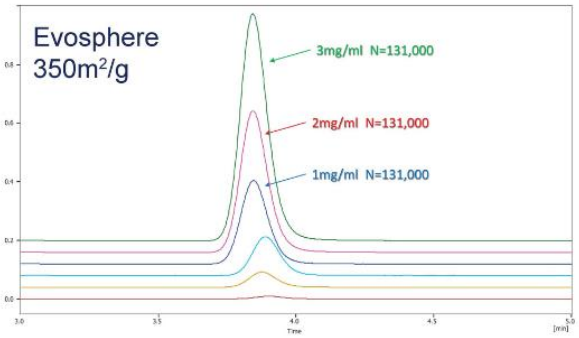

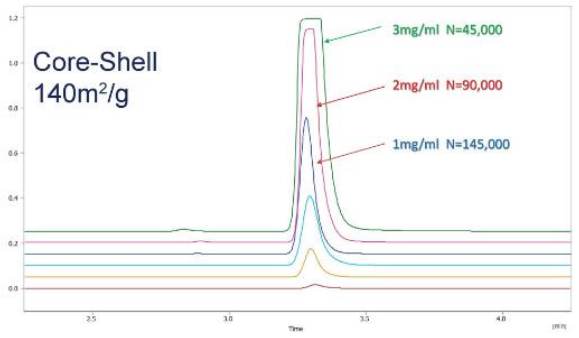

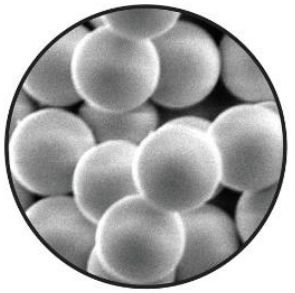

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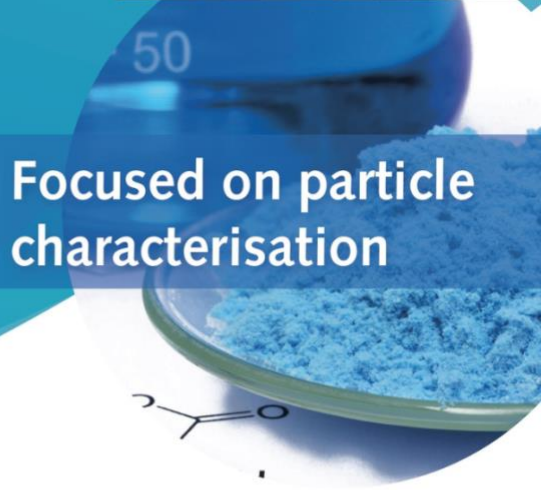

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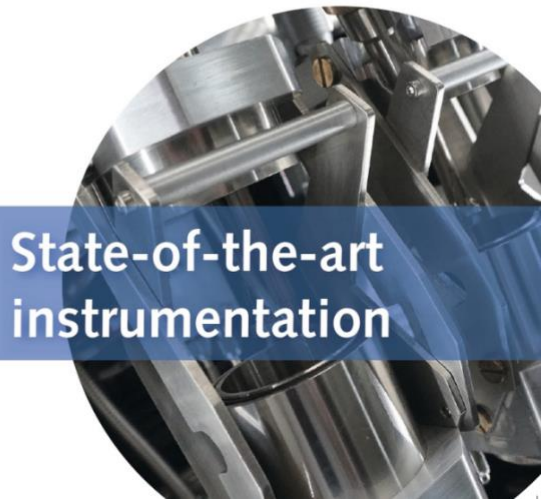

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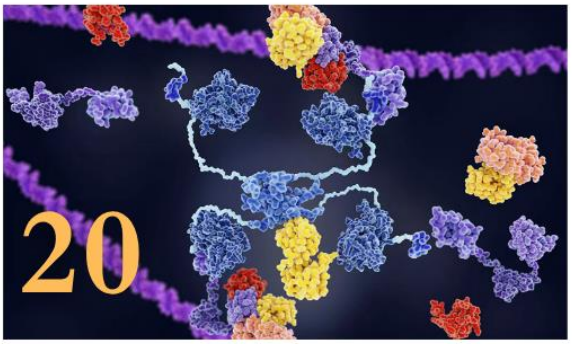

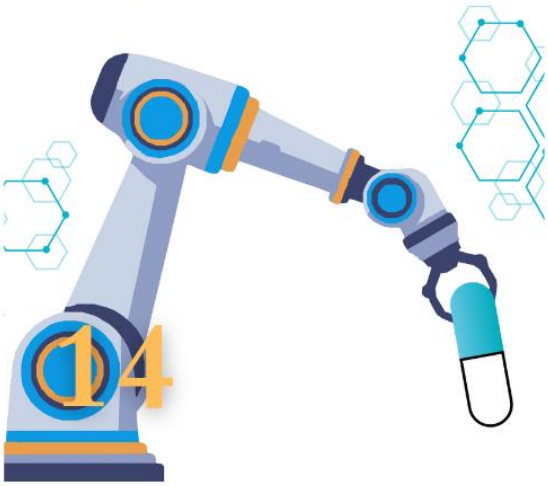

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Editor's Word

ear Readers,
Welcome to the latest issue of Microbioz India. As we delve into the pages of this edition, we are excited to bring you a collection of engaging stories, insightful features, and thought-provoking content that we believe will capture your imagination and enrich your knowledge.
In a world constantly in motion, Microbioz India remains steadfast in its commitment to delivering high-quality content that informs, inspires, and entertains. We take pride in curating content that reflects the diverse interests of our readers, and in this issue, you will find a wide range of topics to explore.
In our cover story, we shine a spotlight on **"Science in Motion: The Technologies Shaping Tomorrow's Pharmaceutical Industry"** delving deep into its intricacies and uncovering the stories and people that make it an intriguing subject. Additionally, you'll find articles How Single-Use Sterile Connectors Are Tested for Quality and Sterility" contributed by Ami Polymer, covered by Thermo Fisher Scientific, 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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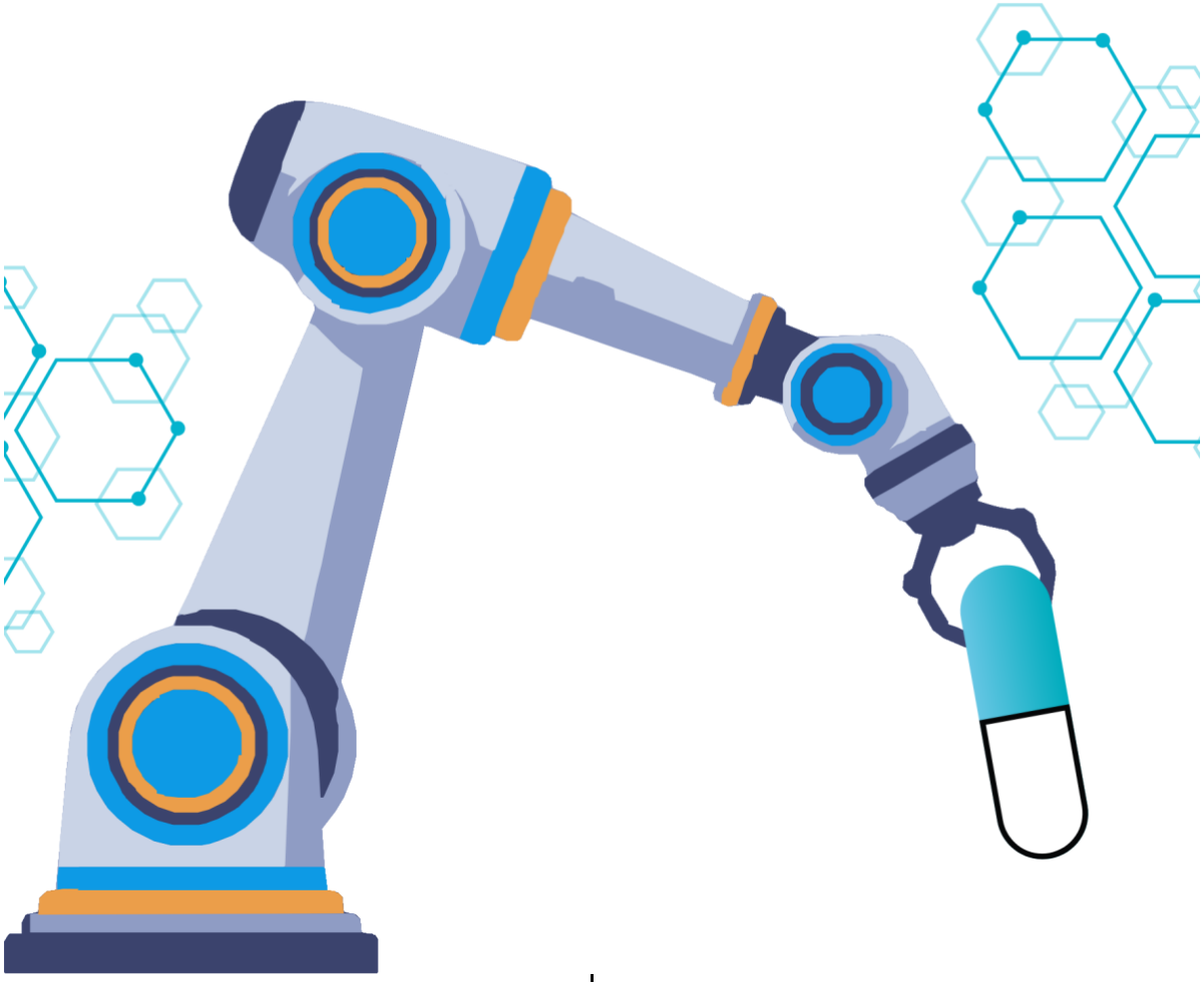


The pharmaceutical sector is experiencing revolutionary changes for the first time in decades. Drug discovery, development, manufacturing, and delivery to patients in all corners of the globe is being altered due to the rapid pace of technologies, enhanced delivery and requests in healthcare, and the development of precision medicine.

We are approaching 2026 and the world of science is no longer confined to laboratories. This world is dynamic and is being fueled by artificial intelligence, automation, digital connections and the science of decision.

Innovative technologies are being adopted by pharmaceutical companies for research, to create more resilient supply chains and to optimize patient outcomes.

Healthcare will be defined by its rapid, precise, sustainable, and personalized services.

Artificial Intelligence: Changing the Landscape of Drug Discovery Artificial Intelligence (AI) is impacting the way research is done in the pharmaceutical industry. Using AI, pharmaceutical companies can analyze huge databases of biology and make predictions and decisions about which compounds to consider for drug discovery.

The benefits are:

1. Identification of therapeutic targets occurs at an accelerated pace.
2. Research and development time is decreased.
3. Clinical trial design is improved.
4. Drug safety and efficacy is predicted with far more confidence.
5. Cost of developing drug compounds is substantially decreased.

For the first time pharmaceutical companies are able to research, discover, and create drugs to combat emerging diseases in a timely manner to fulfill unmet needs.

Precision Medicine: Customizing Treatments

The age of "one-size-fits-all" medicine is coming to an end. Today's medicine is built around a patient's genetic makeup.

Progress in genomic sequencing has opened new opportunities for healthcare providers to:

1. Personalize treatment options
2. Decrease negative drug interaction
3. Enhance prophylactic measures
4. Produce specific treatment options for cancer

The future of medicine relies heavily on personalized healthcare.

The transformation of the pharma manufacturing process into a fully connected system is termed Pharma 4.0. The integration of automation and robotics, cloud computing, and real-time analytics, results in smart manufacturing systems.

Smart manufacturing systems offer:

1. Continuous Manufacturing
2. Automated Quality Control
3. Predictive Maintenance
4. Lower Likelihood of Human Error
5. Improved Quality of Work

Pharmaceutical companies can maintain high levels of quality and improve efficiencies.

Digital Twins – the Virtualization of Pharmaceutical Systems

Digital Twin technology aids the creation of virtual copies of manufacturing systems, lab automation systems, and manufacturing facilities.

With this technology systems, manufacturers can:

1. Simulate Manufacturing Processes
2. Predict Failures
3. Optimize Processes
4. Reduce Downtime
5. Increase Efficiency

The ability to model systems digitally before physically implementing a solution allows for a great improvement in the speed and quality of decision making.

Laboratory Automation and Robotics

Laboratories are more automation friendly and robotic systems offer superior performance and consistency in work.

Some Lab Automation offers systems that perform:

1. High Throughput Screening
2. Sample Prep
3. Pipetting
4. Cell Culture
5. Testing

Laboratory automation systems help scientists and researchers spend more time on other areas and improve innovation. These systems also improve the time to perform lab services and improve reproducibility.

Enhanced Analytical Technology

The technology of some of the new analytical instruments offers sensitive and precise measurements never before possible.

The following are examples of new technology:

1. High-resolution mass spectrometers
2. Advanced chromatography systems

3. Real time process analytical technologies (PAT)
4. Digital microscopy
5. AI data interpretation

These all help improve quality assurance and facilitate expedited regulatory approvals.

Sustainable Pharmaceutical Manufacturing

It is becoming commonplace in the industry for sustainability to be viewed as a strategic priority and for pharmaceutical companies to pursue Environmental Sustainable Solutions (ESS).

Sustainable initiatives can be:

1. Eco-friendly energy use
2. Green chemistry
3. Lower use of solvents
4. Circular models of waste management
5. Reducing carbon footprints

The pharmaceutical industry's future growth will be found in new product lines and in environmental sustainability.

Connected Supply Chains and Digital Ecosystems

The pharmaceutical supply chain is becoming smart, transparent, and resilient.

Digital transformation in the supply chain is a result of:

1. IoT
2. Blockchain traceability
3. Predictive analytics
4. Monitoring inventory in real-time
5. Digital logistics systems

The safety and efficacy of delivering product to patients is a primary focus of these systems.

The Human Element in a Digital Future

Pharmaceutical innovation relies on the presence of people even as advanced technology is developed. Breakthroughs in pharmaceutical innovations will be the domain of scientists, engineers, clinicians, and health care partners.

The pharmaceutical industry for the future will depend on safety, and efficacy of healthcare, incorporating human intellect with advanced technology to scale solutions.

Conclusion

The pharmaceutical industry is on the precipice of a new era in science with the ability to rapidly innovate. Concepts like artificial intelligence, precision medicine, smart manufacturing, digital labs, and sustainability are no longer science fiction.

The next wave of healthcare innovations will arrive thanks to organizations utilizing these technologies.

Progressing science means an evolving pharmaceutical industry and a future where treatment, development, and patient access will be faster and more tailored.

The changes to medicine are already happening.

Innovation Without Limits: Advancing Pharma, Analytical Science & Laboratory Technologies

Innovation is central to the transformation of the pharmaceutical, analytical, and laboratory sectors. Organizations strive to harness the technologies of tomorrow in an effort to discover and develop operationally efficient methods to provide better solutions to patients.

Challenges in global healthcare are more prevalent and complex. Innovation, in this case, is not a luxury, but a requirement.

The limitations of scientific progress are disappearing with cutting edge technologies from artificial intelligence and laboratory automation to advanced analytical instruments and new methodologies in sustainable manufacturing. Today we see more of these converging patterns between the disciplines of pharmaceutical research, analytical science, and the technologies of the laboratory.

The Digitization of Pharmaceutical Research

The digital revolution is the paradigm now determining the direction of the pharmaceutical industry. Powerful new tools enable researchers to process and analyze massive amounts of biological and clinical data faster than ever before.

Digital technologies are shaping the future of the pharmaceutical industry through:

1. Faster drug discovery and development
2. Increased efficiency of clinical trials
3. Improved outcome prediction and patient safety monitoring
4. Faster regulatory approvals

While addressing all the issues above, the aim is to provide greater access to the new therapies.

The Emergence of Smart Laboratories

The modern laboratory is constructed of systems that seamlessly integrate speed, precision, and reliability.

At the core of the smart laboratory are:

1. AI
2. IoT
3. Robotics and automation
4. Cloud-based data with systems for real-time monitoring

These technologies empower scientists to design better, more productive laboratories while minimizing mistakes.

Analytical Science: Achieving Precision

Analytical sciences are pivotal in the detection of pharmaceutical product quality and safety.

New technology creates an opportunity to enhance analytical capabilities through:

1. Mass spectrometry with high-resolution power
2. Ultra-performance liquid chromatography
3. Spectroscopy platforms with automation
4. Digital imaging
5. Artificial Intelligence to assist in data interpretation

Each of these technologies features

Laboratory Automation: Improving Efficiency

A major transformative use of automation is in the construction of highly reliable research laboratories.

Examples of the reliable research laboratories include:

1. Automated sample preparation
2. Rapid liquid handling robotics
3. High-throughput screening
4. Digital documentation
5. Maintenance predicted through technology

Reproducibility is greatly enhanced through automation and research scientists are able to dedicate their full time to the advancement of scientific research.

Precision Medicine: Transforming Healthcare

Precision medicine is impacting the paradigm of diagnosis and treatment of disease. The integration of genomics and biomarkers along with the patient data empowers clinicians to design and deliver precise and targeted therapeutics.

The healthcare industry is undergoing a major transformation of the paradigm of patient care due to:

1. Targeted and individualized therapy
2. Improved therapeutic outcomes
3. Minimization of adverse effect profiles
4. Improved detection of disease in the early stages

Sustainable Science

A focus on the protection of the environment is being incorporated into developing new research. Sustainable practices support innovation and protection of the environment.

Some sustainability practices involve:

1. Green chemistry
2. Energy conservation
3. Reduction of waste
4. Business with eco-packaging
5. Sustainability of the carbon footprint

The future of science and technology must integrate sustainable practices in all other activities.

Data-Controlled Decision Making

In contemporary scientific analyses, data is among the most critical components. With sophisticated analytical frameworks, organizations can convert raw data to useful insights.

Utilization of data-controlled systems can aid organizations in:

1. Accelerating the speed of studies
2. Streamlining processes in production
3. Forecasting consumer requisites
4. Improving control measures
5. Boosting the capability of meeting standards

Evidence-based decisions made quickly are quickly becoming a core competitive differentiator.

Collaboration: Fuel of Upcoming Innovations

Stronger cooperation of industries, the academic sphere, health care and technology will be essential for the next wave of scientific innovations.

Cross-industry cooperation will be vital for the rapid advancement of:

1. Pharmaceuticals
2. Bioscience
3. Tests and Measurements
4. Healthcare Informatics
5. Advanced Laboratory concepts

Joint knowledge will be key to resolving worldwide health care issues.

Final Word

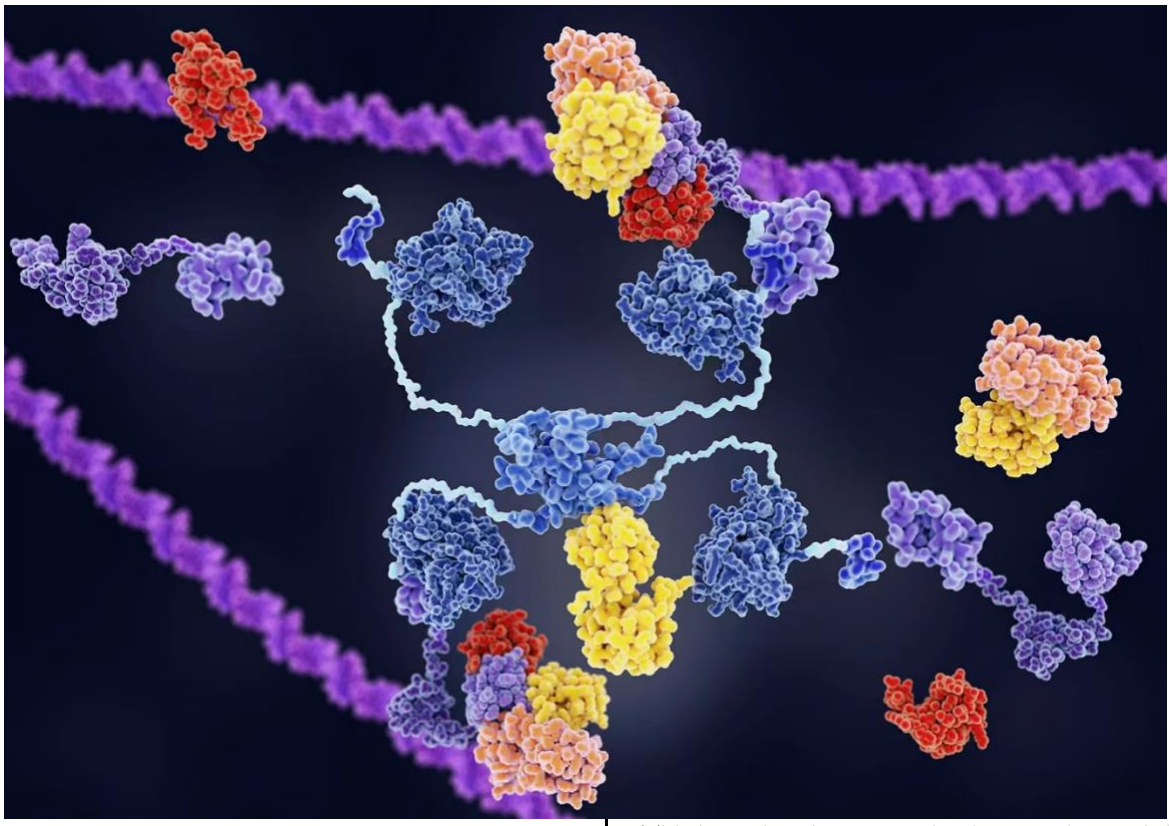
The limitless ideas for the future of pharmaceuticals, measurement sciences, and laboratory systems will define the next generation of leaders in scientific fields. Digital adjustment, the intelligent use of Automation, Advanced Analytics, and the proactive adoption of sustainable methodologies will characterize this era.

With the consistent integration of technological solutions, improvement of health care systems, and rapid discoveries, the innovation of tomorrow has already begun today.

The voyage has already begun for smarter, faster, and more efficient scientific research.

How AI-driven analysis can accelerate drug discovery

Written by
- Dr Phillpp Natho (Postdoctoral Researcher in Synthetic Organic Chemistry)
- Suparna Roy (Information Scientist)



Strained spiro heterocycles are increasingly recognized as valuable three-dimensional bioisosteres in drug discovery. These rigid, three-dimensional molecular frameworks offer the pharmaceutical industry a potential solution to "escape from flatland" by providing scaffolds that can better complement complex biological binding sites compared to traditional flat aromatic compounds.

Whereas the beneficial properties have been demonstrated extensively for spiro[3.3]heptanes, their lower homologues spiro[2.3]hexanes – a strained subset consisting of a three-membered ring fused to a four-membered ring through a shared spiro-carbon, remain largely unexplored due to synthetic challenges and limited biological data.

This is a missed opportunity, because beyond their rigid geometric structure, these strained spiro systems can induce enhanced target selectivity, improved solubility, increased metabolic stability, and reduced off-target effects.

In addition, they also offer novel intellectual property advantages in previously inaccessible chemical spaces. How can researchers better access these motifs to understand potential target-ligand interactions and predict which of these 3D candidates might be most promising for drug development? To answer this question, a team of scientists led by Professor Renzo Luisi at the University of Bari "A. Moro" in Italy developed a new synthetic approach to nine spiro[2.3]hexane analogues and used new AI-driven predictive analytics available in CAS BioFinder® to assess their potential as biologically active compounds.

The project received funding support from the European Commission Horizon Europe Framework, Project SusPharma (Grant Agreement 101057430). The full results of this study have recently been disclosed as a research article in Angewandte Chemie International Edition.

This method is a practical way to accelerate research in this space by enabling rapid, literature-grounded *in silico* evaluation of ligand–target interactions and pharmacological potential, thereby helping to uncover a new class of therapeutically relevant molecules from this underexplored chemical territory.

Advantages of spiro[2.3]hexanes and synthesis challenges

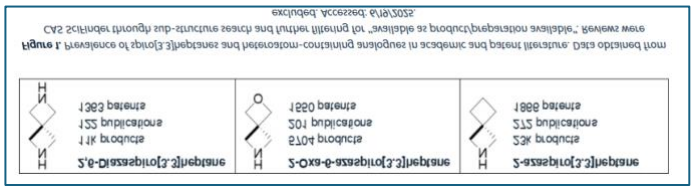
The "escape from flatland" and "conformational restriction" concepts demonstrate that increasing the fraction of sp^3-hybridized carbon centers in drug candidates is associated with higher success rates as compounds progress from discovery to clinical approval. Strained, sp^3-rich spirocyclic scaffolds satisfy these criteria, making them valuable structural motifs in drug discovery and attractive to medicinal chemists.

Until now, medicinal chemists have devoted considerable attention to heteroatom-containing spiro[3.3]heptanes — two spirofused four-membered rings — and are exploring them as bioisosteric replacements for conventional, non-strained heterocycles such as piperazine or morpholine. These studies have shown that incorporating such strained, sp^3-rich motifs can deliver compounds with improved physicochemical properties that progress into clinical trials.

An analysis of publication data in CAS SciFinder® reveals the utility of the spiro[3.3]heptanes due to the presence of substantial number of reported synthetic derivatives and the large volume of patent applications and academic publications centered on this scaffold (see Figure 1).

Although the lower homologue spiro[2.3]hexanes have attracted increasing academic attention over the past five years, demonstrated by a rising number of related publications shown in Figure 2, a systematic investigation of their bioisosteric potential remains elusive. This is despite their comparable physicochemical properties and reported biological activities, including inhibition of HDAC1/3 and HIPT1.

Comprehensive CAS SciFinder data presented in Table 1 illustrates the prevalence of nine distinct spiro[2.3]hexane structural motifs reported in the literature. Notably, most heterocyclic analogues of spiro[2.3]hexanes remain underdeveloped, with limited academic reports and few or no patent applications identified.



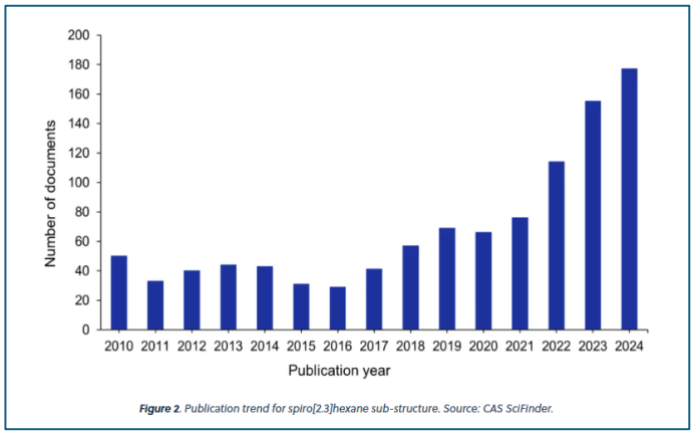


Figure 2. Publication trend for spiro[2.3]hexane sub-structure. Source: CAS SciFinder.

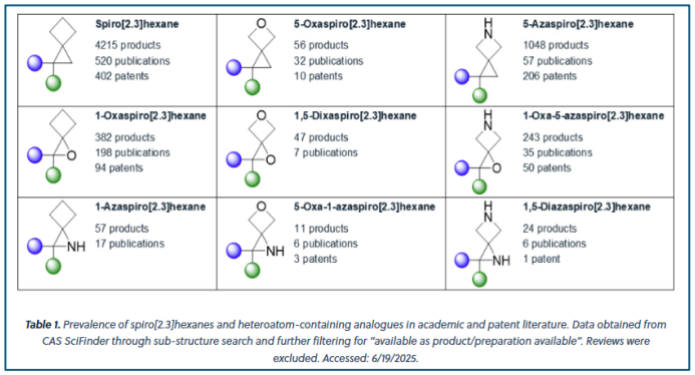


Table 1. Prevalence of spiro[2.3]hexanes and heteroatom-containing analogues in academic and patent literature. Data obtained from CAS SciFinder through sub-structure search and further filtering for "available as product/preparation available". Reviews were excluded. Accessed: 6/19/2025.

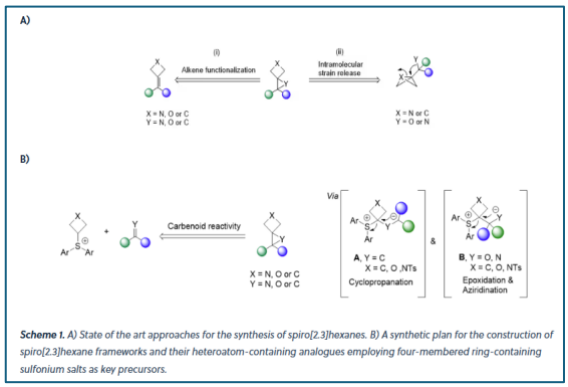
Synthetic challenges associated with the efficient incorporation of such motifs, together with scarce chemical reactivity and stability data, have likely curtailed their widespread implementation in drug discovery.

Traditional syntheses of spiro[2.3]hexanes typically install the three-membered ring onto a preassembled four-membered scaffold via epoxidation, aziridination, or cyclopropanation [see Scheme 1A (i)].

These methods, however, often require harsh conditions, tolerate few functional groups, and lack modularity, as structural variation of the substituents on the three-membered ring necessitates resynthesis of the precursor.

A more flexible strategy has recently emerged based on intramolecular strainrelease reactions of bicyclo[1.1.0]butanes, enabling modular access to the spiro[2.3]hexane framework [see Scheme 1A (ii)]. Nonetheless, this approach still depends on reactive intermediates and is incompatible with the preparation of cyclopropane and oxetane-derived spiro analogues.

To address the aforementioned shortcomings and allow rapid access to a library of heteroatom-containing spiro[2.3]hexanes, the team designed novel sulfonium salts bearing four-membered rings, which can be transferred under mild conditions to a range of π-electrophiles (alkenes, carbonyls and imines) via a Johnson-Corey-Chaykovsky-type reaction to assemble nine different spiro[2.3]hexane motifs in a modular fashion, as shown in Scheme 1B.



Scheme 1. A) State of the art approaches for the synthesis of spiro[2.3]hexanes. B) A synthetic plan for the construction of spiro[2.3]hexane frameworks and their heteroatom-containing analogues employing four-membered ring-containing sulfonium salts as key precursors.

Synthesis of spiro[2.3]hexanes

To realize the design plan shown in Scheme 1B, three novel sulfonium-based reagents bearing four-membered rings **1**-**3** (cyclobutane, oxetane, and azetidine) were developed. An aryl sulfide bearing the four-membered ring was found to be the key intermediate, which was oxidized to the sulfoxide, before being converted to the sulfonium salt by reaction with 1,3,5-trimethoxybenzene and triflic anhydride.

This route was scalable to multigram-quantities and the reagents were found to be stable, free-flowing solids, meaning they are easy to handle in the laboratory, adding an important practicality aspect to the approach.

Full details for the preparation can be found in the original article.

After optimization of the desired Johnson-Corey-Chaykovsky reaction, the practicality and modularity of this synthetic strategy was showcased by accessing over 60 substrates representing all nine spiro[2.3]hexane cores, fulfilling all predefined objectives.

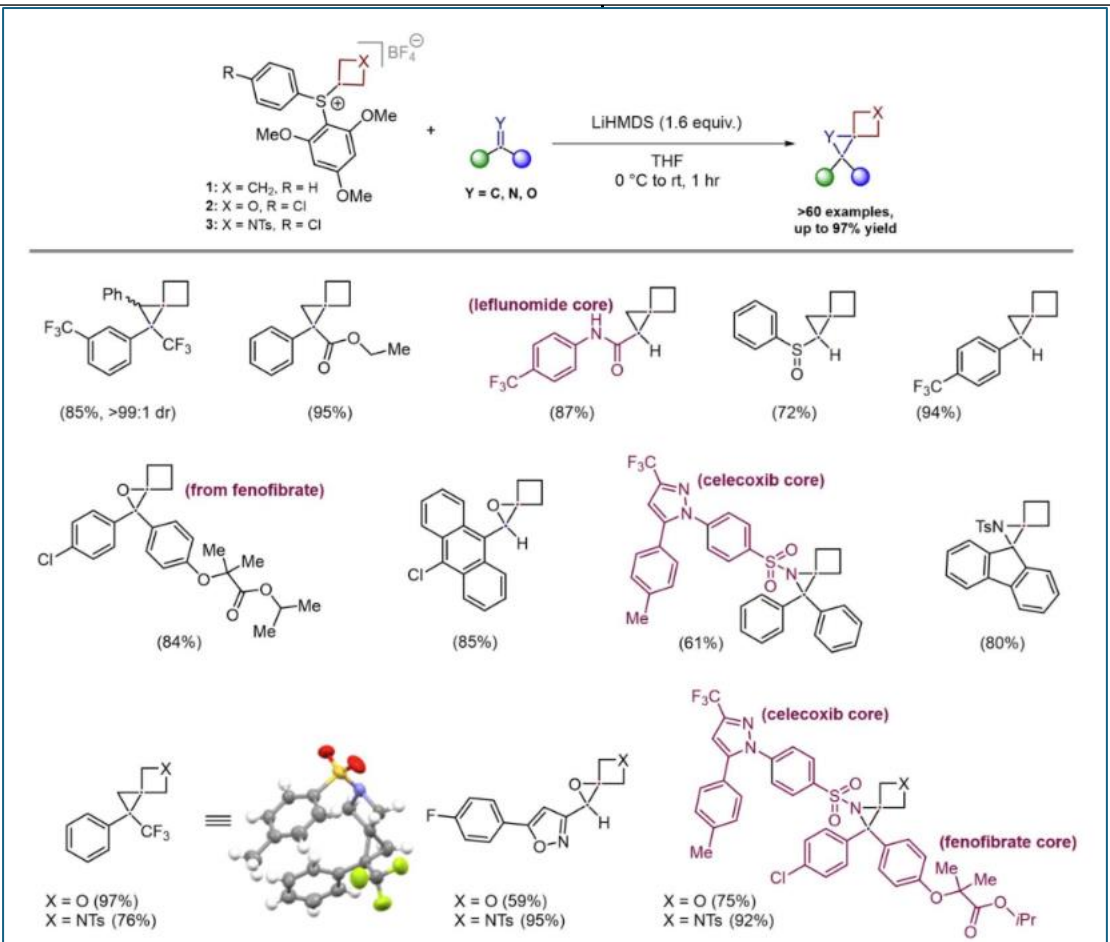
Some representative examples are shown in Scheme 2. For example, reaction with a range of electron-deficient alkenes, including styrenes, vinyl sulfoxides, acrylates, and acrylamides affords the desired spiro[2.3]hexanes and allows incorporation of pharmaceutically relevant cores, such as the leflunomide derivative.

The differing reactivity of the sulfonium salt toward electron rich and electron deficient alkenes indicates that the reaction proceeds via nucleophilic attack by the ylide rather than carbene insertion.

The corresponding epoxide derivatives are accessible by reaction with ketones and aldehydes, and this was amenable to the incorporation of active pharmaceutical ingredient fenofibrate. Last, the aziridine-bearing analogues can be obtained by reaction of the sulfonium salts **1**-**3** with imines.

The strategy also enabled the installation of spiro[2.3]hexane motifs into complex imines, facilitated by the facile functionalization of the imine nitrogen.

Accordingly, spiroaziridines incorporating the celecoxib core alone, as well as spiroaziridines bearing both celecoxib and fenofibrate cores, were successfully synthesized, demonstrating the capability of this method to deliver druglike molecules featuring spiro[2.3]hexane motifs (see Scheme 2). Notably, the reaction proceeded well regardless of the nature of the four-membered ring, allowing access to heteroatom-bearing spiro[2.3]hexane derivatives.

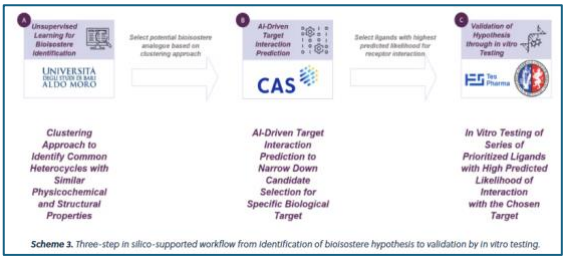


Scheme 2. *Synthesis of spiro[2.3]hexanes.*

Systematic evaluation of bioisosteric potential of spiro[2.3]hexane analogues

The availability of all nine spiro[2.3]hexane analogues enables a systematic investigation of their bioisosteric potential, analogous to that of spiro[3.3]heptanes. To date, a thorough systematic characterization of these structural motifs has not been conducted.

To perform this evaluation, we developed a bioisostere identification strategy with a three-step workflow as presented in Scheme 3.



Scheme 3. *Three-step in silico-supported workflow from identification of bioisostere hypothesis to validation by in vitro testing.*

Step 1.
Clustering-based approach to identify heterocycles with shared physicochemical properties:

First, an unsupervised learning approach was employed to compare all nine obtained (heteroatom-containing) spiro[2.3]hexane cores against a virtual database of over 70 commonly used drug discovery heterocycles to identify potential bioisosterism between spiro[2.3]hexanes and popular heterocycles in medicinal chemistry.

Thus, all structures were subjected to DFT optimization (ωB97XD3BJ/631++G(d,p)) to obtain energetically minimized three-dimensional conformations and their associated properties. One-dimensional (molecular weight, heteroatom count), two-dimensional (druglikeness, logP, topological polar surface area), and three-dimensional (dipole moment, plane of best fit, asphericity) molecular descriptors were selected and computed using RDKit to enable comparison of physicochemical properties and assessment of druglikeness.

To ensure robust statistical analysis, descriptors were manually inspected and excluded when $\log_{10}(\text{VIF}) \geq 5$. Dimensionality reduction via principal component analysis (PCA) and k-Medoids clustering enabled visualization of the high-dimensional dataset. PCA reduced the chemical space dimensionality and evaluated descriptor contributions, while k-Medoids clustering identified five distinct clusters (k = 5) based on Silhouette score analysis.

Eight of nine spiro[2.3]hexane analogues clustered together alongside pharmaceutically relevant heterocycles: isoxazole (found in leflunomide) and pyridine.

Although in different clusters, piperidine showed spatial proximity to spiro[2.3]hexane cores. In 3D PCA space, piperidine and 5-azaspiro[2.3]hexane displayed average intra-cluster distances of 3.20 ± 0.76 and 2.28 ± 1.11, respectively, with an inter-cluster distance of only 1.69, confirming physicochemical similarity. Similarly, spiro[2.3]hexane showed an average intracluster distance of 3.59 ± 1.18 and a piperidine distance of 3.18. Compared to piperidine, spiro[2.3]hexane, 5-azaspiro[2.3]hexane, and 5-oxaspiro[2.3]hexane exhibited similar molecular volumes (crucial for binding site compatibility) and superior 3D drug-likeness indicators (PBF). Notably, 5-azaspiro[2.3]hexane showed comparable dipole moment, but increased strain energy.

The clustering proximity and molecular descriptor similarities support 5-azaspiro[2.3]hexane as a promising strained piperidine bioisostere (see Table 2).

Molecular structure	PBF	Volume	Dipole	Strain
N	0.58	90.87	1.35	0.02
O	+0.18 (+31%)	-1.22 (-1%)	-1.18 (-87%)	+34.58
NH	+0.15 (+25%)	-8.75 (-9%)	+0.85 (+63%)	+38.48
	+0.13 (+22%)	-5.38 (-6%)	+0.13 (+10%)	+37.48

Table 2: Comparison of molecular properties. Delta values shown in blue are comparison to piperidine, not absolute values

Step 2. AI-driven prediction of target–ligand interactions to refine candidate selection for a specific biological target:

Having established *in-silico* the potential similarity with piperidine, this hypothesis was tested on a real-life example. Pethidine, a piperidine-containing μ-opioid receptor agonist, was selected as a test case due to its structural compatibility with the current methodology and clinical need for safer alternatives (given toxic norpethidine metabolite formation) (see Figure 3a).

To identify the most likely analogues to be active against the μ-opioid receptor and prioritize candidates for *in vitro* testing, we turned to AI-enhanced predictive analytics. CAS BioFinder was selected for this purpose. This platform enabled rapid, data driven *in-silico* prediction of pharmacological activity by modeling protein–ligand interactions using curated chemical–biological relationships extracted from scientific literature. An iterative predictive analytics workflow was applied to evaluate pethidine analogues containing the 5-azaspiro[2.3]hexane core against the human μ-opioid receptor (see Figure 3b).

Initial screening (pAct and confidence scores; Table 3) identified analogues **4** and **5** as promising, with predicted pAct values of 6.54 and 5.92, respectively. The spiro[2.3]hexane and 5-oxaspiro[2.3]hexane analogues (**6** and **7**), identified as less promising by clustering, showed no predicted activity. Guided by these results, further 5-azaspiro[2.3]hexane derivatives were explored by modulating the ester side chain. Substituting the ethyl ester with methyl (**8**) or isopropyl (**9**) groups caused only slight decreases in predicted pAct (6.50 and 6.48). Interestingly, introducing an azetidine ester (**10**) substantially increased the predicted activity (pAct 7.22), whereas the oxetane ester (**11**) showed no predicted activity against the evaluated targets.

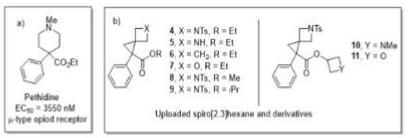


Figure 3. a) Pethidine, Synthetic opioid used in Labour and Delivery. b) Uploaded potential bioisosteres and derivatives to CAS Biofinder.

Spiro[2.3]hexane derivatives	Predicted pAct (confidence score) μ-type opiod receptor (Homo sapiens)
4	6.54 (0.51)
5	5.92 (0.64)
6	n.d.
7	n.d.
8	6.50 (0.47)
9	6.48 (0.52)
10	7.22 (0.43)
11	n.d.

Table 3. AI-driven target interaction prediction (pAct including confidence score)

Step 3. *In vitro* validation of prioritized ligands demonstrating high interaction probability with the selected target:

To experimentally evaluate the predictive analytics approach, the three ligands with the highest predicted activity (pAct) against the μ-opioid receptor (compounds **4**, **8**, and **10**) were selected for *in vitro* testing, together with spiro[2.3]hexane **6** as a negative control.

All these compounds were synthesized using the developed methodology and were assessed using a label-free binding assay (EnSpire platform, PerkinElmer) employing SHSY5Y neuroblastoma cells expressing μ-opioid receptors. Serial dilutions (0.03–150 μM) were analyzed via optical biosensors detecting refractive index changes, with DAMGO, a known μ-opioid receptor agonist, used as a positive control.

Dose–response analysis revealed micromolar binding activity (10–39 μM) for all tested compounds, confirming μ-opioid receptor engagement (see Figure 4). The observed binding of the predicted active compounds (**4**, **8**, and **10**) is consistent with the *in silico* predictions and validates the suitability of the 5-azaspiro[2.3]hexane core as a substituted piperidine bioisostere. Analogue **10**, for which the highest pAct was predicted on CAS BioFinder, showed the best binding activity (10 μM).

While unsupervised learning enabled identification of generally suitable bioisosteric scaffolds, AI-driven target prediction effectively prioritized candidates for experimental validation. Notably, compound **6**, which was predicted to be inactive despite structural proximity to piperidine in the clustering analysis, also displayed measurable binding activity, highlighting current limitations of predictive models when applied to scaffolds with limited representation in available training data.

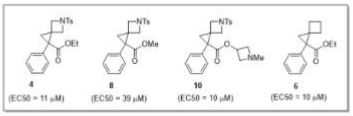


Figure 4. Micromolar binding activity of the tested ligands.

New approaches for bioisostere identification in drug discovery

A simple, general, and functional group tolerant strategy was developed for accessing previously underexplored spiro[2.3]hexane analogues using three novel sulfonium salt reagents. This synthetic platform was shown to be broadly applicable, with electron deficient alkenes, carbonyl compounds (ketones and aldehydes), and imines serving as effective reaction partners for the formation of spirocyclic cyclopropanes, epoxides, and aziridines, respectively. In total, over 60 examples were reported, highlighting the versatility and robustness of the methodology.

Beyond synthetic development, the bioisosteric potential of spiro[2.3]hexanes was systematically evaluated using an integrated *in silico* workflow combining unsupervised learning and AI-enhanced predictive analytics. Application of CAS BioFinder enabled data-driven prediction of protein–ligand interactions based on curated chemical–biological relationships extracted from scientific literature. By narrowing the candidate list from 66 compounds to four likely candidates in just a few minutes, CAS BioFinder saved at least $15,000 on external testing for this single project and accelerated the overall project timeline to eight months from initial project design to biological validation. Similar projects often take years without CAS BioFinder.

This analysis identified 5-azaspiro[2.3]hexane as a promising piperidine bioisostere based on its predicted structural and interaction features. Using pethidine, a piperidine-containing μ-opioid receptor agonist employed in obstetric analgesia, as a model system, this hypothesis was subsequently validated through *in vitro* binding studies.

Overall, this work demonstrates how modern AI-enabled predictive tools such as CAS BioFinder can complement synthetic chemistry by guiding target-focused compound selection and accelerating the timeline between discovery of novel chemical space and biological evaluation *in vitro*. With transparent and well-founded predictions from CAS BioFinder, synthetic chemists can more easily identify targets for completely novel molecules that would not have been designed by rational drug design in the first place. Starting *in vitro* testing with a shorter, pre-screened candidate list reduces the risks and costs for *in vitro* testing through pre-validation and focus.

It is anticipated that the sulfonium salt reagents described herein will find broader application in organic synthesis, and that this modular route to spiro[2.3]hexanes, combined with predictive analytics, will facilitate further exploration of these motifs as valuable cores in medicinal chemistry.

Watch the recording here *of a webinar where Dr. Natho walked through a practical, AI-powered workflow that makes the process of finding the right molecular scaffold faster and more efficient. They show how a flexible new synthesis method combined with AI-driven predictive analytics can quickly identify the most promising candidates before committing to expensive lab testing.*

Reliable, high-performance pump for HPLC and UHPLC

Biotech Fluidics announce the **ASI 540** – an **affordable, standalone solvent delivery pump** - design optimized for liquid chromatography applications.

All models of the ASI 540 pump range feature an intuitive touchscreen display that enables full control of the pump functions, flow rates, and gradient programs. ASI 540 pumps can also be remote controlled. The pump is available in several different models for UHPLC, HPLC, semi-preparative, preparative, and flash chromatography, together covering liquid flow rate ranges from 0.5 µL/min to 300 mL/min. With pump heads in stainless-steel or biocompatible PEEK, the ASI 540 pump can withstand pressures up to 15,000 psi (1050 bar) while also being compatible with many solvents and requirements.

ASI 540 standalone solvent delivery pump

While the ASI 540 pump is extremely easy to use, it also includes advanced functionality for experienced separation scientists.

The ASI 540 pump includes useful features such as a patented floating pump seal that stays perfectly aligned with the piston for reduced wear and longer seal lifetime. The pump head is also self-priming and comes with an integral purge function for rapid solvent changes. Flow precision using an ASI 540 pump exceeds 0.25% within the entire flow rate range and pulsations are below 1%.

Each ASI 540 pump is designed for easy maintenance while also being RoHS compatible and CE certified. All user serviceable components are accessed via the front panel, and the cartridge seal design makes seal replacement straightforward.

For further information about the ASI 540 pump please visit https://biotechfluidics.com/products/liquid-handling/asi-540-hplc-pump/ or contact Biotech Fluidics on + 46 300 56 91 80 / + 1-612-703-5718 / info@biotechfluidics.com.

BIOTECH FLUIDICS

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

Driving Innovation Through Fluidics: An Exclusive Conversation with **Fritiof Pontén PhD, CEO** of **Biotech Fluidics**

The life sciences sector's rapid metamorphosis is obvious, stemming from innovations in the automation of labs, fluidics, digitalization, and sustainability. One individual leading these changes is **Dr. Fritiof Pontén**, CEO of Biotech Fluidics. His career has taken him from synthetic organic chemistry to global leadership in innovation, granting Dr. Pontén a thorough understanding of the trends in the future of scientific research and lab technologies.

In this exclusive Microbioz India interview, **Dr. Fritiof Pontén** describes the fluidics and flow management technologies in which he is immersed, and the professional developments that have shaped this emerging field at Biotech Fluidics. This emerging field is directed toward the optimization of labs in the pharmaceutical and biotechnological industries, as well as those performing analytics and those in the healthcare sector.

Automation, artificial intelligence, and sustainability are all encompassed in Dr. Pontén's concepts for the scientific innovations of the next decade. The innovations and concepts that he presents further reveal the importance of scientific and customer-driven excellence in the life sciences.

This interview presents the innovations and concepts of one of the most advanced companies in the industry while also describing the importance of robust fluidic technologies, which will enable the scientific innovations of the future.

You began your scientific journey in synthetic organic chemistry at Lund University. What initially inspired you to pursue chemistry and life sciences?

Dr. Fritiof Pontén :I was intrigued but the opportunity to create new molecules with the potential to help people and more specifically people with health issues.

Behind this was of course a chemistry teacher that once opened my eyes to the fascinating world of organic molecules.

Fritiof Pontén PhD, CEO
Biotech Fluidics

The combination of theory in reaction mechanism and 3D structure combined with the practical aspects fitted me perfectly and nurtured several of my sides.

Your background spans medicinal chemistry, process development, biopharma innovation, and fluidics technologies. How have these diverse experiences shaped your approach as a CEO?

Dr. Fritiof Pontén :I use my understanding of what the users actually need and demand from the instrument manufacturers to create the best business offering possible. Being able to communicate with customers based on own experience gives respect and trust in return.

As CEO of Biotech Fluidics since 2020, what has been your primary vision for the company's growth and global positioning?

Dr. Fritiof Pontén :Working from a very stable platform as *the* global premium distributor of IDEX Health & Science the targets have been sustainable growth of existing business, strong growth of products not origin from IDEX making Biotech Fluidics even stronger and more independent and generation of an increased OEM customer basis.

How do you balance scientific excellence with commercial and business objectives in a rapidly evolving market?

Dr. Fritiof Pontén :There is no compromise in the setup of the technology and sales team at Biotech Fluidics. The team has intentionally been setup with highly experienced and educated personnel where 50% have a MSc and the rest a PhD within well spread scientific areas.

It is only with an in depth understanding of the challenges the best solutions can be provided. In addition there is a lot of carry-over from areas solving hurdles in new ways. This does not only help sales but is also of kea importance to pick up solutions generation new products or applications of excising products.

In the end it is straight forward to make an excellent technical sales representative out of someone with a scientific background but much more challenging for a sales person to pick up the scientific excellence.

Biotech Fluidics has built a strong reputation in fluidic solutions and laboratory technologies. What differentiates your company from others in this space?

Dr. Fritiof Pontén :From many customers we receive that we are small enough to respect and care for them at the same time we are strong enough to keep inventory enabling flexible, fast and creative solutions differentiate us from the large and slow self-sufficient big companies in the field.

The solutions we bring to the market have often been stress tested with users validation both the need and the robustness of the offering.

Could you share some of the latest innovations or technologies currently being developed by Biotech Fluidics?

Dr. Fritiof Pontén :The last year has been very intensive with several launches brought to the market

1. Within the DEGASi® family the DEGASi® FlatFilm offers new opportunities by greatly reducing the flow resistance at the same time as it handles all common solvents, including hexane, in a fully biocompatible flow path. All this with an increased flow capacity per hold up volume.
2. Mikron 91 in line pH flow meter optimised for chromatography systems offers a special opportunity to monitor chromatography of biologics such as proteins, conjugates and antibodies.
3. SPEedy is the new device for smooth and well controlled Solid Phase Extraction (SPE) eliminating external vacuum tanks and pressure manifolds. This is a simple to use device for both single and parallel use that we anticipate will for ever change the way SPE is done.

4. Mott Corporation has identified Biotech fluidics as their preferred partner for distribution of spargers used in both bio- and chemical-processing.

5. This just hooks on Biotech Fluidics tag line "No Troubles With Bubbles" to well.
6. Biotech Fluidics has also teamed up with ASI to provide state of the art HPLC and UHPLC pumps for fluidic applications from nL/min to preparative flow rates.
7. Finally but in no way the least Biotech Fluidics is driving a development project within the field of pulsation free pumping of biologicals without adding detrimental shear forces. This product is developed within the subsidiary VentriLabs with the intention to launch the first product during Q4-26.

Sustainability and efficiency are becoming major priorities in laboratories worldwide. How is Biotech Fluidics addressing these emerging demands?

Dr. Fritiof Pontén :With my background in process development I know by heart that the sustainability of a process or a product is mainly dependent of the quality and robustness it offers. The solutions Biotech Fluidics offers are based on components of the highest quality delivered with the value add of critical competence. It is in our philosophy and DNA that all delivered solutions should bear the hallmark of care and quality to deliver the best performance to the end user. The nature of our industry makes re-makes and unknowns extremely costly.

What role does R&D play in the company's long-term strategy and product development roadmap?

Dr. Fritiof Pontén :R&D at Biotech Fluidics first of all plays the role of understanding and validating customer needs for new applications. With in-house R&D we can provide data and solutions for upcoming needs. Another aspect of our R&D is to work with inventors and developers where we can add the user and business understanding adding the extra value to the product. At the same time Biotech Fluidics is the excellent partner for developers that need to reach the market, to get their concepts and solutions within the doors of the high ranked OEM's. There is a very tough selection process often supported by our own in-house R&D used in the selection process for such products.

How important are collaborations, partnerships, and customer feedback in shaping your innovation pipeline?

Dr. Fritiof Pontén :As stated above we work a lot with partners and candidate partners to find innovation that brings value to the market. We meet the key customers many of our partners have on their top target list.

With this contact we bring market intelligence and scientific understanding to the table and this is then used to give the products the competitive edge making them interesting enough for the OEM's.

How do you see fluidics and flow management technologies evolving over the next five to ten years?

Dr. Fritiof Pontén :We know that the scientific and healthcare sector will continue to require high quality data and this demand will rather grow than decline with the integration of AI. For every new scientific brake throw based on fluidics there will be a demand for fluid management. Miniaturisation will continue and that will also increase the demands on the fluidic solutions. This is just as with self-driving cars that will also require suitable roads to drive on.

Innovation often requires taking calculated risks. How do you encourage experimentation and entrepreneurship within your organization?

Sometimes you win – sometimes you learn must be the leading star and it is then combined with in depth understanding on what the market need.

In your view, what are the biggest challenges facing life science innovators today?

Dr. Fritiof Pontén :Some challenges are very healthy such as cost pressure or pressure to deliver value for the money. But there is also other challenges and one of them is the huge conglomerates purchasing and often burying innovation in bureaucracy etc. Such super eaters rarely contributes to development of ground breaking developments.

Looking ahead, what are your strategic priorities for Biotech Fluidics over the next few years?

Dr. Fritiof Pontén :Biotech Fluidics is active with offices in Sweden, Germany, USA and Japan but as the request of our products and services grew expansions will be seriously considered. With the trade agreement between EU and India a very interesting market is opening up.

Biotech Fluidics will also use the strong position to further develop the product portfolio with new product offerings.

We currently see a good growth into the MedTech sector with our degassers being included in for example the Abbott Alinity clinical analysers. The opportunities within this field are very demanding but also huge.

Which emerging technologies or scientific fields excite you the most for the future of life sciences?

Dr. Fritiof Pontén :This is very difficult for me to judge on. But what I know for sure is that any technology or scientific field will use and measure more and more substile effects and that will in turn continue to raise the demands on the systems used to produce data. For fluidic systems this will mean that the demands on the components will only increase and in no way may such a fundamental thing as a gas bubble disturb.

How do you envision the future relationship between laboratory science, automation, and sustainability?

Dr. Fritiof Pontén :Automation will continue and in combination with AI the outcome offers fantastic opportunities. Just as the use of computers did not create the paperless office, rather the contrary, automation and AI will further extend the need for robustness and reliability. Only such systems will also fill the aspect of sustainability.

How **Single-Use Sterile Connectors** Are Tested for Quality and Sterility

Authored By: Dr. Priyabrata Pattnaik
Chief Executive Officer, Ami Polymer Pvt. Ltd.

Sterile-to-sterile (S2S) single-use connectors have become foundational technologies in modern biopharmaceutical manufacturing. As biologics, cell therapies, mRNA platforms, and highly potent drug products continue to drive flexible manufacturing strategies, the industry has increasingly shifted away from fixed stainless-steel transfer systems toward disposable closed fluid management technologies. In this transition, sterile connectors are no longer viewed merely as tubing accessories — they are considered critical process-enabling devices that directly influence contamination control strategy, batch integrity, operational agility, and regulatory compliance.
S2S connectors harness the concept of built-in sterility assurance.

Because of the unique design of the S2S connector, two fluid paths can remain independently sterile and physically connected without exposing the fluid contact components to the external environment. S2S connectors and systems that employ the same design principle allow for the transfer of sterile fluids in a variety of systems with little to no human contact.

Absent a robust, comprehensive quality assurance program, the safety of S2S sterile connector systems cannot be assumed. Because of the unique design of S2S connectors, if even one sterile connector system of many in a given manufacturing process fails, that entire manufacturing process will be rendered non-sterile.

Therefore, the development of a new sterile connector design and system incorporates rigorous and comprehensive safety assessments.

These assessments consider many specialized domains, including, but not limited to, the design and verification process, sterility and microbiological assurance, polymer science and engineering, and the integrity of the closure and packaging systems.

The challenge is particularly important because sterility cannot be fully "tested into" a product. Sterility assurance depends primarily on validated manufacturing and sterilization processes rather than end-product testing alone.

This principle is deeply embedded across pharmaceutical and medical device regulations and reinforced by modern container closure integrity philosophies such as USP <1207>.
This article explores in depth how sterile-to-sterile single-use connectors are quality controlled, validated, and sterility integrity tested during manufacturing.

It also examines the engineering rationale behind these tests, the regulatory expectations shaping them, and the future direction of contamination control technologies in advanced bioprocessing.

Understanding the criticality of sterile-to-sterile connectors

The core function of an S2S connector is deceptively simple: connect two sterile fluid pathways while maintaining aseptic conditions. Yet achieving this consistently across thousands or millions of manufacturing cycles requires an extraordinary level of engineering control.

Modern connectors may include membrane-based aseptic separation systems, genderless mechanical interlocks, steam-compatible sealing interfaces, needle-free sterile mating mechanisms, radiation-stable polymer geometries, and integrated flow control architectures, etc.

Each design introduces unique failure risks, i.e., microbial ingress, seal deformation, mechanical misalignment, polymer degradation after irradiation, channel leakage, particulate generation, packaging seal failure, and operator misuse.

Therefore, manufacturers must demonstrate not only sterility, but also functional sterility maintenance under worst-case operational conditions.

This distinction is important. A component can be sterile when shipped yet still fail aseptically during use. Regulatory agencies increasingly expect manufacturers to validate the entire use scenario, not merely terminal sterility.

The regulatory philosophy behind sterility assurance

One of the most misunderstood aspects of sterile connector manufacturing is the assumption that routine sterility testing alone guarantees safety. In reality, sterility testing is statistically limited and inherently destructive.

Modern regulatory philosophy instead relies on validated sterilization processes, controlled manufacturing environments, demonstrated microbial barrier performance, container closure integrity validation, process reproducibility, and risk-based quality systems.

Standards such as ISO 11137 define the framework for radiation sterilization validation and routine process control. Similarly, USP <1207> emphasizes that package integrity and microbial barrier assurance should rely on deterministic and scientifically justified methods rather than probabilistic testing alone. This philosophy has profoundly changed how single-use technologies are qualified.

Raw Material and Polymer Quality Control
Assurance of sterility encompasses pre-sterilization processes and procedures.
The selection of the polymers in the construction of sterile connectors must consider a number of different characteristics, including their biocompatibility, mechanical strength, radiation stability, as well as their extractables and leachables, weldability, seal integrity, and particulate shedding.

Incoming raw materials are likely to be subjected to identity tests (e.g., FTIR, melt flow index, visual inspection, traceability, and certificate of analysis). Manufacturers are also likely to conduct stress cracking, and oxidative degradation tests alongside long-term storage stability and gamma discoloration tests.

A key engineering challenge in selection of polymers for construction of flexible, sterile connectors is maintaining flexibility and the ability to withstand mechanical stress, and brittleness caused by gamma irradiation, among other things. These are of particular concern in the construction of sterile connectors, as any sort of cracking (even microscopic) has the potential to invalidate the integrity of the system.

Cleanroom Assembly and Manufacturing Controls
Although many sterile connectors are terminally sterilized, they are typically assembled in controlled cleanroom environments to minimize initial bioburden and particulate contamination. Such manufacturing environments are ISO Class 7 cleanrooms, ISO Class 8 support areas, with localized laminar airflow stations.

Environmental monitoring programs typically include viable air sampling, non-viable particle counting, surface monitoring, personnel gown monitoring, differential pressure control, and temperature and humidity monitoring.

Operators assembling sterile connectors often undergo gown qualification, aseptic handling certification, behavioral monitoring, and periodic retraining.

Bioburden minimization is critical because sterilization validation depends partly on the initial microbial load.

Bioburden Testing Prior to Sterilization

Characteristics of product-associated microbial populations must be documented by the manufacturer prior to bioburden and sterilization validation.

Typical bioburden assay techniques include sampling for the presence of organisms on product surfaces, filtration recovery and concentration techniques, CFU enumeration, and organism identification.

The goal of bioburden assays is not solely the sheer quantification of organisms, but to understand their resistance(s), the variation from lot to lot, and the variation of bioburden for a given lot over time.

Bioburden data is critical for determining the necessary sterilization dose in accordance with ISO 11137.

Validation of Radiation Sterilization

Currently, the majority of sterile, single-use connectors are gamma or e-beam irradiated. These technologies are preferred because of their ability to penetrate sealed packaging, their ability to avoid moisture and their ability to provide terminal sterilization and high throughput.

Validation of sterilization is required beyond simply stating that products are exposed to radiation. This includes mapping the radiation dose, determining the minimum and maximum radiation dose, determining the product density, the packaging configuration, assessment of the biological indicators, and the sterility assurance level (SAL).

The target SAL for a sterilization process is 10^{-6}, which means there is a less than one in one million chance that a viable microorganism would be present after sterilization.

For connector assemblies, dose mapping is of particular concern because of the potential for design features (e.g., folds in tubing, complex product shapes) to shield the radiation or lead to poor density and/or coverage. Manufacturers are required to perform numerous validation studies, utilizing dosimeters, to accurately assess the impact of these design features.

Functional QC Testing of Connector Assemblies

After manufacturing and before release, connectors undergo rigorous functional testing.

Mechanical Integrity Testing: These tests evaluate connection force, locking consistency, mating accuracy, seal engagement and disconnect resistance. Automated systems frequently simulate repeated mating cycles to identify wear-related failures.

Pressure and Leak Testing: Fluid path integrity is evaluated using pressure decay methods, vacuum decay methods, bubble emission testing, or helium leak testing.

Modern regulatory trends increasingly favor deterministic methods such as vacuum decay over traditional dye ingress techniques. USP <1207> strongly encourages deterministic approaches because they offer greater sensitivity and reproducibility.

Leak testing is particularly important because sterility failure may occur through sub-visible channels, microscopic leaks may not produce visible fluid loss, and pressure fluctuations during transport can amplify ingress risk.

Microbial Ingress and Barrier Integrity Testing: The most scientifically important validation activity is microbial ingress testing. These studies challenge the connector's ability to resist contamination under simulated worst-case conditions. Common challenge organisms is *Brevundimonas diminuta*, sometime *Bacillus* species, or environmental isolates. *Brevundimonas diminuta* is frequently selected because it is extremely small, highly mobile, and difficult to exclude through micro-defects.

Microbial ingress testing involve immersion challenges, aerosolized microbial exposure, dynamic connection simulation, and pressure differential exposure. After challenge exposure internal fluid pathways are incubated, growth media are evaluated for contamination, and connectors are inspected for integrity breaches.
This testing demonstrates not only sterility maintenance, but actual microbial barrier performance during use conditions.

Media Fill and Aseptic Process Simulation: Many manufacturers perform aseptic process simulations using microbiological growth media. In such case, the connector is used exactly as intended, operators perform fluid transfers, nutrient media replaces the actual product, and the assembled system is incubated. Absence of microbial growth demonstrates aseptic connection capability, operator usability robustness and system-level contamination control.

These studies often include multiple operators, deliberate process stress, extended hold times, and worst-case environmental conditions. Media fills are particularly valuable because they evaluate the complete process rather than isolated component characteristics.

Packaging Integrity and Sterile Barrier Validation: The sterile connector itself may perform perfectly while the packaging fails. Therefore, packaging integrity validation is a critical component of sterility assurance. Sterile barrier systems must undergo seal strength testing, vacuum decay testing, dye ingress testing, burst testing, transportation simulation and aging studies.
USP <1207> has significantly influenced industry expectations by emphasizing lifecycle-based package integrity assurance. An important evolution in recent years has been the transition from probabilistic methods toward deterministic leak detection technologies such as helium mass spectrometry, high-voltage leak detection, laser-based headspace analysis and vacuum decay systems. These approaches provide quantitative sensitivity, repeatability, lower operator variability, and improved statistical confidence

Particulate and Extractables Control: Sterility alone is insufficient for modern biologics manufacturing. Single-use connectors must also demonstrate low particulate generation, controlled extractables & leachables, and chemical compatibility.

Particulate testing includes light obscuration, microscopic particle analysis and dynamic flow particulate shedding studies.

Extractables studies evaluate compounds released under exaggerated conditions, while leachables studies assess compounds released under actual process conditions. These evaluations are especially important for cell therapy manufacturing, protein therapeutics, high-value biologics, and sensitive formulations.

Routine Batch Release Testing
Routine release programs generally combine sampling-based sterility testing, functional testing, visual inspection, packaging integrity verification, documentation review, and sterilization certificate review.

However, contrary to popular belief, routine sterility testing alone is not relied upon as the primary sterility assurance mechanism. USP <1207> and modern quality philosophies recognize that end-product sterility testing has severe statistical limitations.
A batch can pass sterility testing and still contain contaminated units. This is especially possible with low levels of contamination or when they are non-uniformly distributed. Because of this, manufacturers focus on process capability, environmental control, sterilization validation, and deterministic integrity verification.

This kind of documentation is important to meet other requirements.

More requirements for the manufacturers of sterile connectors are based on the need for advanced traceability, documentation of risk assessments, and change control tools. In addition, there are validation master plans and supplier qualification requirements.

Most quality systems and sterile connective systems are designed according to the requirements of the FDA, the European Medicines Agency, or the quality management principles outlined in ISO 13485.

Manufacturers are also required to maintain records of irradiation and track environmental factors along with the performance of corrective and preventive actions. Customer complaints and field performance are also required to be documented and investigated.

Regulators focus on assurance of sterility, the validation process, and the evaluation of risks during audits. They are also interested in changes to the process with irradiation, and the control of suppliers.

These are some of the more common failure modes and gaps in the assessment.
Despite sophisticated controls, failures still occur. Common industry blind spots include:

1. Radiation-induced polymer brittleness
2. Seal creep during long-term storage
3. Packaging microchannel formation
4. Operator misuse outside validated conditions
5. Undetected particulate shedding
6. Misinterpretation of sterility test limitations

One recurring misconception is confusing sterility with stability. Community discussions among sterile processing and pharmaceutical professionals repeatedly emphasize that a product may remain chemically stable while losing sterility integrity.

Similarly, many failures originate not from the connector design itself, but from packaging damage during shipping, excessive tubing stress, unvalidated process modifications, and incompatible sterilization dose adjustments.

Future Outlook: Intelligent Sterility Assurance and Next-Generation Connector Technologies

The future of sterile connector testing is moving toward increasingly data-driven and deterministic assurance models. Recent scientific developments are driving innovation in real-time leak detection, embedded sensor-enabled connectors, AI-supported visual defect recognition, digital batch traceability, predictive sterilization analytics, and advanced polymer stabilization technologies.

There is growing interest in machine vision inspection systems capable of detecting microscopic molding defects, inline vacuum decay testing integrated directly into automated production lines, smart packaging capable of monitoring sterile barrier degradation, low-dose sterilization technologies that reduce polymer damage, and hydrogen peroxide plasma sterilization compatibility for advanced disposable systems.
Emerging cell and gene therapy processes are also increasing demands for smaller aseptic connection volumes, faster connection cycles, robotic compatibility, and closed automated manufacturing integration.

In parallel, regulators are increasingly encouraging deterministic integrity testing over traditional probabilistic methods. USP <1207> has accelerated this transition by emphasizing scientifically measurable package integrity assurance.

The next decade will likely see sterile connectors evolve from passive fluid transfer devices into digitally monitored contamination-control platforms integrated within fully closed bioprocess ecosystems.

Conclusion

Sterile-to-sterile single-use connectors represent one of the most critical enabling technologies in modern biopharmaceutical manufacturing. Their reliability depends not on a single sterility test, but on an integrated quality architecture combining material science, sterilization validation, microbiological challenge studies, packaging integrity assurance, functional testing, and rigorous process control.
The industry is steadily moving away from reliance on destructive end-product sterility testing toward holistic sterility assurance systems grounded in deterministic science and lifecycle risk management.

This evolution mirrors broader trends across biopharmaceutical manufacturing where contamination prevention is increasingly engineered directly into process design.

As biologics manufacturing becomes more decentralized, automated, and personalized, the importance of robust sterile connector validation will only intensify. Manufacturers that understand the interplay between process engineering, microbiology, regulatory expectations, and polymer science will be best positioned to deliver the next generation of truly reliable closed processing technologies.

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Ami Polymer

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Chemical-Based Drug Discovery: Enabling Smarter Development with Advanced Analytics

The journey from identifying a potential drug candidate to delivering a safe, effective therapy is long and complex. It involves multiple stages of screening, optimization, and validation—each demanding accuracy, speed, and informed decision-making. At the center of this process are medicinal chemists, whose work transforms early-stage molecules into viable drug candidates.

A Shift in Drug Discovery Approaches

Modern drug discovery has moved far beyond studying one compound at a time. Today, researchers screen large numbers of molecules in parallel, sourced from natural, synthetic, or biological origins. This shift has made rapid and reliable characterization essential.

Early-stage decisions, driven by high-quality analytical data, play a crucial role in avoiding costly failures later in development.

The Role of Medicinal Chemists

Medicinal chemists typically work with small-scale experiments to identify promising lead molecules. To do this effectively, they rely on a combination of advanced tools—ranging from sample preparation systems and flexible synthesis platforms to precise analytical techniques. These technologies help accelerate workflows while ensuring consistent and reproducible results.

Optimizing Chemical Development

As compounds move into development, the focus shifts to optimizing synthesis processes. Chemists must balance performance, safety, and cost, particularly when scaling up reactions. Technologies such as automated laboratory reactors, combined with Design of Experiments (DoE) and Process Analytical Technology (PAT), offer valuable insights into reaction behavior and help streamline process optimization.

Power of Real-Time and Complementary Analytics

Real-time analytical tools are also transforming chemical development. Techniques like FTIR and Raman spectroscopy, along with in-line particle size analysis, allow scientists to monitor reaction kinetics, pH, dissolved gases, and particle formation as processes unfold.

When paired with complementary offline methods—such as UV-Vis spectroscopy, thermal analysis, and melting point determination—this integrated approach provides a deeper understanding of both compounds and processes.

Power of Real-Time and Complementary Analytics

Equally important is ensuring compliance in a highly regulated industry. Integrated instrument and software solutions enable data traceability, support regulatory requirements such as FDA 21 CFR Part 11, and simplify the transition from laboratory research to production.

Conclusion

In an environment where time, quality, and compliance are critical, advanced analytical technologies empower medicinal chemists to make faster, more confident decisions. Ultimately, they help the pharmaceutical industry bring innovative therapies to market more efficiently benefiting both researchers and patients alike.

About METTLER TOLEDO

METTLER TOLEDO is a leading global manufacturer of precision instruments. The Company is the world's largest manufacturer and marketer of weighing instruments for use in laboratory, industrial and food retailing applications. The Company also holds top-three market positions for several related analytical instruments and is a leading provider of automated chemistry systems used in drug and chemical compound discovery and development. In addition, the Company is the world's largest manufacturer and marketer of metal detection systems used in production and packaging. Additional information about

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EZ-CFU™ Single Step: Simplifying Growth Promotion Testing

In the pharmaceutical and biotechnology industries, and those that perform quality control assessments, **Growth Promotion Testing (GPT)** is integral in evaluating the performance and reliability of culture media used for microbial analysis. The traditional methods for preparing microorganism suspensions involve considerable time and labor, in addition, these methods have poor reproducibility.

EZ-CFU™ Single Step presents laboratories with an innovative, ready-to-use method to perform Growth Promotion Testing quickly and with improved accuracy and reproducibility. Designed to remove the tedious preparation steps, this product provides laboratories the ability to perform microbial quality control tests more readily and with greater confidence.

What is EZ-CFU™ Single Step?

EZ-CFU™ Single Step is a simple, single-use, microbiological reference preparation that contains a quantified freeze-dried preparation of an ATCC® reference culture. Each preparation, upon the addition of water, results in a preparation containing a precise and defined concentration of microorganisms.

Its extended usability and ease of use make this product an ideal solution for pharmaceutical and biotechnology laboratories and quality control laboratories.

Key Applications

EZ-CFU™ Single Step can be used for a variety of microbiological tests, such as:

1. Growth Promotion Testing (GPT)
2. Media Challenge Testing
3. Suitability of the Counting Method
4. Suitability Tests for Specified Microorganisms
5. Microbial Limits Testing
6. Microbial Enumeration Testing
7. Microbial Neutralization Methods
8. Tests requiring low CFU numbers

Product Features and Benefits

Delivering Microbes Accurately and Reliably

1. Delivers 10–100 CFU in 0.1 mL
2. Results will be clear and reproducible

Flexibility in the Laboratory

1. Stability up to 8 hours after preparation
2. Laboratories can plan and perform tests on their own schedule

High Testing Capability

Each kit contains:

1. 20 pellets, approximately 220 tests
2. 2 vials of quantified microorganism pellets
3. 20 vials of hydrating fluid (1.2 mL each)

Reference Strains with Assured Quality

1. Microorganisms will be no more than 3 passages from the original ATCC® reference culture
2. Helps maintain the quality of the microbes

Technical Specifications

Operational advantages of EZ-CFU™ Single Step:

1. ATCC® derivative strains
2. 3rd passage from reference culture
3. One vial containing 1.2 mL hydrating fluid with one lyophilized pellet
4. Stable at 25°C for 5 Days during Transport
5. 2°C to 8°C is the recommended storage temperature
6. Certificate of Analysis (COA) accompanies lot with ATCC® reference and mean CFU values with assay

EZ-CFU™ Single Step vs Conventional Alternatives

Some advantages EZ-CFU™ Single Step has over other systems:

1. ATCC® derivative strains
2. 3rd passage from reference culture maintained
3. Simple preparation using 1 vial of 1.2 mL hydrating fluid and 1 lyophilized pellet
4. Remains stable at 25°C for 5 days during transportation
5. Requires storage at 2°C to 8°C
6. Accompanied by a Certificate of Analysis (COA) with ATCC® reference and mean CFU assay values

Limitations of Conventional Alternatives

1. Frequently use NCTC® derivative strains
2. Microorganisms are usually at the 4th passage from the reference culture
3. Require the generation of a 1.1 mL suspension from one pellet
4. Demand the highly temperature-sensitive transportation of below 0°C
5. Need storage at -20°C
6. Provide a COA with NCTC® reference and mean CFU assay values

Supporting Laboratory Efficiency and Compliance

Regulatory expectations are shifting and laboratories are looking for ways to improve the standardization, reproducibility and efficiency of their operations.

EZ-CFU™ Single Step meets these expectations by reducing the preparation time and simplifying the application of consistent microbial concentrations for routine quality control tasks.

With the implementation of ready-to-use standardized microbial preparations, laboratories are able to strengthen their operations while upholding the utmost quality of their microbiological assessments.

About June4GMP

June Enterprises Pvt. Ltd. is a well-known name in the field of cleanroom and contamination control systems. Established in 2010, our primary goal is to provide products and technologies certified globally to India. We cater to the requirements of pharmaceuticals, biotechnology, health care, food processing, and microelectronics. We have partnered with several renowned manufacturers based in the USA and Europe in order to bring to you the best products which are compliant with international standards. Most importantly, we have been able to achieve this through our dedicated and talented team, which believes in the company and its long-term goals.

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Alembic Pharma gets tentative nod from USFDA for generic cancer drug

Alembic Pharmaceuticals Ltd on Friday said it has received tentative approval from the US health regulator for its generic version of cancer treatment drug Binimetinib tablets.

The tentative approval by the US Food & Drug Administration (USFDA) is for the Abbreviated New Drug Application (ANDA) of Binimetinib tablets of strength 45 mg, Alembic Pharmaceuticals said in a regulatory filing.

Based on USFDA's paragraph IV certifications list, Alembic is the sole first applicant to have filed its ANDA for Binimetinib Tablets, 45mg and upon final approval of this ANDA by the USFDA, the company may be eligible for 180 days of generic marketing exclusivity in the US, the company said.

Alembic had previously received tentative approval for Binimetinib Tablets, 15mg, it added.

Binimetinib in combination with encorafenib is used for the treatment of patients with unresectable or metastatic melanoma with resistance to specific targeted therapies in cancer.

It is also indicated, in combination with encorafenib, for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) with resistance to specific targeted therapies.

Citing IQVIA data, Alembic said Binimetinib tablets have an estimated market size of $259 million for 12 months ending March 2026.

Aurobindo Pharma stock gains over 1.5% after FTC clears Lannett acquisition

Shares of Aurobindo Pharma rose over 1.5% in early trade on Friday after the company said its wholly owned subsidiary, Aurobindo Pharma USA Inc., received approval from the US Federal Trade Commission (FTC) for the acquisition of Lannett Company LLC.

The stock climbed as much as 1.53% to Rs 1,465.80 on the NSE after the company informed exchanges that the required regulatory clearance for the transaction had been secured.

Aurobindo Pharma said it expects the acquisition to be completed before the end of June. The deal involves the purchase of 100% membership interest in Lannett Company LLC from LANNETT SELLER HOLDCO, INC.

The company had first announced the proposed acquisition in July 2025 and said it would keep exchanges informed of any further developments related to the transaction.

"Aurobindo's acquisition of Lannett would combine two of a limited number of competitors in the markets for four different generic pharmaceutical products that provide critical relief for patients, ranging from drugs used to prevent organ transplant rejection to tablets that treat dry mouth after radiation therapy," the FTC was quoted as saying by Reuters.

The positive development comes days after the stock came under pressure following regulatory concerns at one of its manufacturing facilities in the US market.

On June 15, shares of Aurobindo Pharma fell sharply after the US Food and Drug Administration (USFDA) classified Eugia Pharma Specialities' Unit III facility in Telangana as "Official Action Indicated" (OAI) following an inspection conducted between January 27 and February 6, 2026.

The facility, operated by Eugia Pharma Specialities, a wholly owned subsidiary of Aurobindo Pharma, received 11 observations during the inspection. The company was informed of the OAI classification on June 12.

An OAI status indicates that the USFDA has identified significant compliance concerns and may take regulatory or administrative action.

While the facility can continue manufacturing and supplying approved products, it will not be eligible to receive approvals for new drug applications until the observations are satisfactorily resolved.

Alembic gets USFDA nod for Binimetinib with 180-day exclusivity

Alembic Pharmaceuticals has received tentative approval from the US Food and Drug Administration (USFDA) for Binimetinib Tablets, 45 mg. This approval positions the company as the sole first applicant for the product, potentially granting it 180 days of generic marketing exclusivity in the US market upon final approval. The drug addresses a significant market need, with an estimated market size of $259 million for the twelve months ending March 2026, according to IQVIA.

Approval Details and Therapeutic Indication

The tentative approval was granted for the company's Abbreviated New Drug Application (ANDA) for Binimetinib Tablets, 45 mg. This product is therapeutically equivalent to the reference listed drug Mektovi Tablets, 15 mg, marketed by Array. Binimetinib is a kinase inhibitor indicated for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with encorafenib. It is also indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) with a BRAF V600E mutation.

Market Position and Exclusivity

Based on the FDA's Paragraph IV Certifications List, Alembic is the first applicant to have filed its ANDA containing a Paragraph IV certification for this dosage.

Consequently, upon final approval, the company may be eligible for 180 days of marketing exclusivity. Alembic had previously received tentative approval for Binimetinib Tablets, 15 mg.

Alembic Pharmaceuticals Limited announces USFDA Final Approval for Tretinoin Cream USP, 0.05%.

Alembic Pharmaceuticals Limited (Alembic) today announced that it has received final approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Tretinoin Cream USP, 0.05%.

The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Retin-A Cream, 0.05%, of Bausch Health US, LLC. Tretinoin cream is indicated for topical application in the treatment of acne vulgaris. Refer label for a detailed indication.

Tretinoin Cream USP, 0.05%, has an estimated market size of US$ 76 million for twelve months ending March 2026 according to IQVIA.

Alembic has a cumulative total of 242 ANDA approvals (222 final approvals and 20 tentative approvals) from USFDA.

About Alembic Pharmaceuticals Limited

Alembic Pharmaceuticals Limited, a vertically integrated research and development pharmaceutical company, has been at the forefront of healthcare since 1907. Headquartered in India, Alembic is a publicly listed company that manufactures and markets generic pharmaceutical products all over the world.

Alembic's state-of-the-art research and manufacturing facilities are approved by regulatory authorities of many developed countries including the USFDA. Alembic is one of the leaders in branded generics in India. Alembic's brands, marketed through a field force of over 5500 are well recognized by doctors and patients.

Information about the Company can be found at www.alembicpharmaceuticals.com;

Cipla Launches First-of-its-kind Sputum Inflammometry Lab

Housed at Mumbai's Breathefree Lung Wellness Center to advance airway inflammation testing capabilities in India

Cipla Limited (BSE: 500087; NSE: CIPLA; and hereafter referred to as "Cipla") today announced the launch of a first-of-its-kind Sputum Inflammometry Lab at the Breathefree Lung Wellness Center (BLWC) in Mumbai, marking the advancement of precision respiratory diagnostics and integrated respiratory care in the country.

The lab was inaugurated by Dr. Parameswaran Nair, globally recognised as one of the pioneers and leading experts in the field of Sputum Inflammometry. The inauguration took place in the presence of 15 eminent pulmonologists and respiratory experts from leading institutes across India.

Sputum inflammometry is an advanced diagnostic approach that assesses airway inflammation in patients with chronic respiratory conditions such as severe asthma, chronic obstructive pulmonary disease (COPD), and bronchiectasis.

By analyzing inflammatory cells and biomarkers in sputum samples, it enables more accurate diagnosis, personalised treatment, and better disease monitoring. Integrated within the Breathefree Lung Wellness Center, the lab will also support clinician training, respiratory research, and scientific collaboration on sputum inflammometry in India.

Speaking on the occasion, Dr Jaideep Gogtay, Global Chief Medical Officer, Cipla Limited said, "Chronic respiratory diseases are increasingly complex and heterogeneous in nature, making accurate assessment of airway inflammation critical for optimal disease management. Sputum Inflammometry has transformed the understanding and management of airway diseases globally by enabling clinicians to identify specific inflammatory phenotypes and tailor therapy accordingly. This advanced capability can now play an important role in improving respiratory care and advancing clinical research in India."

The Breathefree Lung Wellness Center (BLWC) is Cipla's integrated, one-stop destination for advanced lung health diagnostics and care, combining cutting-edge technology, globally recognised protocols, and specialised clinical expertise to enable early and accurate detection of respiratory diseases. With the launch of the Sputum Inflammometry Lab, BLWC Mumbai further strengthens its capabilities, reinforcing Cipla's commitment to comprehensive respiratory care through its flagship centres in Mumbai and Delhi.

About Cipla

Established in 1935, Cipla is a global pharmaceutical company focused on agile and sustainable growth, complex generics, and deepening portfolio in ourhome markets of India, South Africa, North America, and key regulated and emerging markets. Our strengths in the respiratory, anti-retroviral, urology, cardiology, anti-infective and CNS segments are well-known. Our 46 manufacturing sites around the world produce 50+ dosage forms and 1,500+ productsusing cutting-edge technology platforms to cater to our 80+ markets.

Cipla is ranked 3rd largest in pharma in India (IQVIA MAT Dec'25), 2nd Largest in the pharmaprescription market in South Africa (IQVIA MAT Nov'25), and 3rd largest by prescription in the US Gx (Repulses + MDI) products (IQVIA MAT Dec'25).

For over ninedecades, making a difference to patients has inspired every aspect of Cipla's work. Our paradigm-changing offer of a triple anti-retroviral therapy in HIV/AIDS atless than a dollar a day in Africa in 2001 is widely acknowledged as having contributed to bringing inclusiveness, accessibility, and affordability to the centre of the HIV movement.

A responsible corporate citizen, Cipla's humanitarian approach to healthcare in pursuit of its purpose of 'Caring for Life' and deep-rooted community links wherever it is present make it a partner of choice to global health bodies, peers, and all stakeholders. For more, please visit www.cipla.com, or clickon Twitter, Facebook, LinkedIn. To learn more about the diagnostics and wellness services offered at Breathefree Lung Wellness Center (BLWC), visitwww.ciplablwc.com

Sun Pharma Expands Specialty Drug Footprint Across APAC Markets

India's largest pharmaceutical company, **Sun Pharma**, has announced an aggressive expansion strategy across key Asia-Pacific markets, strengthening its specialty medicine portfolio in dermatology, ophthalmology, and oncology. The company aims to increase its presence in Southeast Asia, Australia, and Japan through strategic partnerships and localized commercialization.

The expansion comes amid rising demand for advanced therapies and specialty drugs throughout the region.

Sun Pharma plans to leverage its established manufacturing capabilities in India while enhancing regional distribution networks.

Industry analysts believe this move could significantly boost the company's international revenue contribution over the next three years, reducing dependence on traditional generic markets.

The company is also investing heavily in digital healthcare platforms to support physicians and improve patient engagement throughout APAC countries.

Several regulatory submissions are underway in Singapore, Malaysia, Thailand, and Australia for newly developed therapies.

This expansion further reinforces India's growing role as a global pharmaceutical innovation and manufacturing hub.

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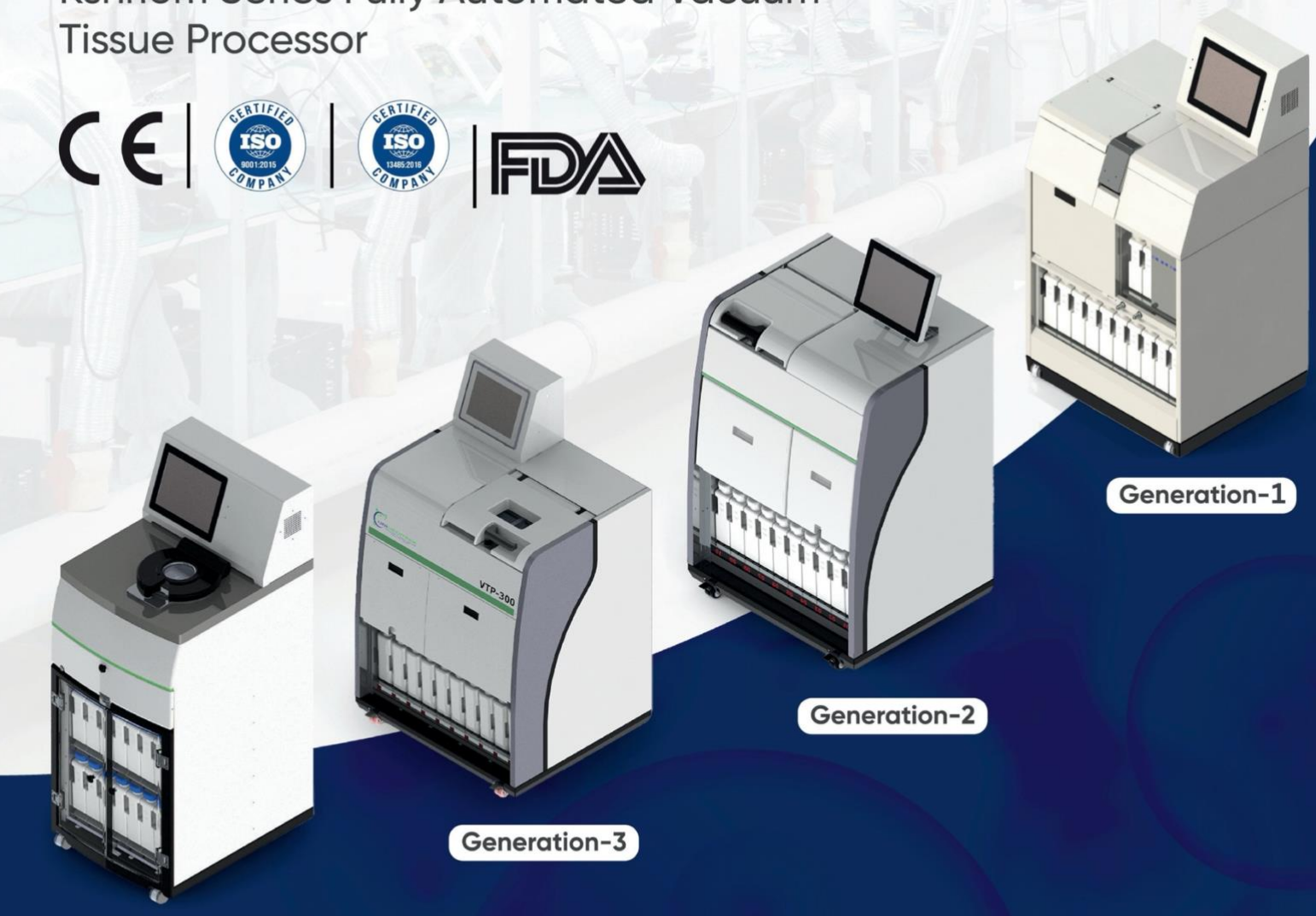

UPCOMING

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Biocon Advances Biosimilar Growth Across Asia-Pacific

Indian biopharmaceutical giant **Biocon** is expanding its biosimilar portfolio across multiple APAC markets to improve patient access to affordable biologic therapies.

The company is focusing on oncology, diabetes, and immunology treatments that have traditionally been expensive for many healthcare systems.

Regulatory approvals are progressing in several countries, including Australia and South Korea.

Biocon's strategy includes strengthening partnerships with local healthcare providers and distributors.

Experts believe biosimilars will become one of the fastest-growing segments in APAC healthcare over the next decade.

The company's investments position India as a major contributor to global biologics accessibility.

Takeda Asia Launches Regional Innovation Hubs in Singapore

Japanese pharmaceutical leader **Takeda Pharmaceutical Company** has expanded its Asia-Pacific innovation strategy by establishing regional hubs in Singapore.

The initiative aims to accelerate precision medicine, data analytics, and rare disease research throughout APAC.

Takeda will collaborate with universities, startups, and healthcare institutions to build a stronger innovation ecosystem.

The company expects these partnerships to accelerate clinical research and improve patient outcomes.

Singapore continues to emerge as a strategic life sciences destination due to its strong regulatory environment and research infrastructure.

The investment reflects increasing pharmaceutical competition within Asia's rapidly evolving healthcare market.

Samsung Biologics Expands Manufacturing Capacity for APAC Demand

South Korean biopharmaceutical manufacturing leader **Samsung Biologics** has announced plans to expand its manufacturing capabilities to support rising demand from Asia-Pacific pharmaceutical companies.

The expansion focuses on contract development and manufacturing services for biologics and advanced therapies.

Increasing investments in biotechnology across India, China, Japan, and Southeast Asia are driving demand for large-scale manufacturing partners.

Samsung Biologics aims to strengthen supply chain reliability and reduce production bottlenecks for regional customers.

The company is also investing in smart factories and automation technologies to enhance operational efficiency.

Industry experts believe APAC will become one of the world's fastest-growing biopharmaceutical manufacturing regions over the next decade.

Choosing the Right Laboratory Shaker for Precision

Sample preparation is critical for both reliability in analysis and reproducibility in testing results, and thoroughly mixing samples is essential for success in virtually all laboratory assays, including the growth and enumeration of microorganisms, performance of enzyme-linked immunosorbent assays (ELISAs) and DNA sample preparations and the testing of the quality of pharmaceuticals, among others.

Today's laboratory shakers are sophisticated instruments that provide controlled, reproducible movements for an increasingly large number of scientific applications. WIGGENS, an internationally recognized manufacturer of laboratory products, provides a broad selection of intelligent shaker systems specifically designed for the various requirements of research laboratories, pharmaceutical companies, biotechnological enterprises and universities.

The Importance of Efficient Shaking

The shaking of samples in a laboratory does require more than the act of simply moving the samples. An efficient shaker will provide:

1. Complete mixing of samples
2. Improved aeration for microbial cultures
3. More consistent results for experiments
4. Decreased sedimentation
5. More efficient reactions
6. Stable conditions for incubations

The applicable shaking technology will vary along the sample, the sample vessel, the task at hand, and the degree of mixing that is required.

The Versatility of Orbital Shakers

Orbital shakers are one of the most popular laboratory instruments. The circular mixing motion of an orbital shaker provides smooth and uniform mixing of samples while minimizing shear stress on biological samples.

Typical applications include:

1. Cell culture
2. Bacterial growth
3. Fermentation
4. Hybridization
5. Enzymatic reactions
6. Solubility
7. Laboratory mixing

WIGGENS Orbital Shaker has customizable speeds (10–300 rpm), highly accurate, fast, programmable time, and multiple orbit sizes. It can provide laboratories with different shaker sizes for different laboratory protocols. The corrosion resistant construction and customizable accessories allow laboratories to use the same shaker for flasks, culture bottles, separatory funnels, microplates, and sample containers of all sizes.

Rocking Shakers – Gentle Motion for Delicate Samples

Some biological samples require less vigorous agitation, but still require mixing to be done continuously. Rocking shakers create a controlled, see saw motion and minimize the formation of foam while still moving the sample well.

These instruments are optimal for:

1. Western blotting
2. Gel staining and destaining
3. DNA extraction
4. Blood sample mixing
5. Hybridization
6. Cell washing

WIGGENS Rocking Shakers boast adjustable tilt angles, BLDC motors for quiet operation, programmable timers, and overload protection to ensure reliable operation for long experiments.

Microplate Shakers – High Throughput Made Easy

As laboratories process greater and greater sample volumes, microplate shakers become essential to workflows in life sciences.

They are applied in:

1. ELISA
2. PCR prep
3. Immunoassays
4. Cell culture
5. Drug discovery
6. Molecular biology
7. Diagnostics

The WIGGENS Microplate Shaker uses a BLDC motor (150–1200 rpm) with programmable speeds and versatile design to offer laboratories the ability to perform high throughput screening with 96 and 384 well microplates, and a variety of laboratory tubes.

The Convergence of Design and Science

Modern laboratories need shaker systems that prioritize operational safety, ease of use, and reliable repeatability in addition to speed control.

WIGGENS incorporates the following into all their shakers:

1. Easy-to-use, digital TFT interfaces
2. Controlled, precise speed settings
3. Programmable timers
4. BLDC motors that never require maintenance
5. Quiet operation
6. An even greater number of interchangeable, highly reliable accessories
7. Shakers built to endure the day-to-day demands of a laboratory

These factors allow researchers to streamline their work without introducing greater variability.

Key Considerations When Selecting a Laboratory Shaker Systems

The following must be considered prior to purchasing a laboratory shaker:

1. Container/sample size
2. Shaking motion (orbital vs. rocking vs. waving vs. reciprocating)
3. Speed requirements
4. Shaker platform size
5. Shaker load capacity
6. Available timers and programming

7. Shaker compatibility with incubators/cold storage
8. Shaker system accessory options

The proper choice of shaker system not only optimizes shaker system redundancy, but also positively impacts the longevity of laboratory equipment.

INNOVATIVE LABORATORY TECHNOLOGY

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As a fully authorized agent for high-end laboratory and process equipment, Scientific Research Instruments Company Private Limited (SRICO) brings first class technologies to Indian laboratories.

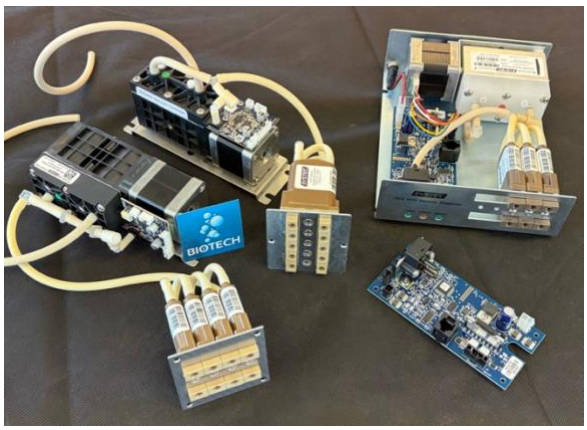
SRICO's presence in every region of India, combined with highly application oriented, in-country, technical support, allows them to provide optimal solutions for every segment of pharmaceutical and biotechnological research and diagnostics, as well as food testing, chemical analysis, environmental research, and even academic laboratories. SRICO and WIGGENS sustain research that demands reliable precision with a wide range of shakers designed for orbital, rocking, and even high-performance microplate shakers.

To know more:

Replacing Discontinued OEM degasser modules

Biotech Fluidics offer the most comprehensive range of degassing system products, enabling the company to provide **open-framed degasser modules** ready to be integrated into your **fluidic instrumentation.**

Recently it was announced that several **Original Equipment Manufacturer (OEM) open frame degasser modules on the market will be obsoleted soon.** To enable companies using these modules to supply products while avoiding the prohibitive costs of total system redesign – Biotech Fluidics is introducing **direct replacements** for all these modules based on upgraded vacuum technology.



An instrument specific OEM degasser module developed by Biotech Fluidics

For Further Information:

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All OEM degasser modules from Biotech Fluidics use high quality components from IDEX Health & Science to deliver the widest range of chemical compatibility and a lifetime that will honor the highest quality standard requirements. Each OEM system includes one or more degassing chambers and a vacuum control system.

Many of Biotech Fluidics more popular OEM degasser modules, are available from stock or can be assembled within a few days for fast delivery.

Biotech Fluidics offer OEM degasser solutions for specific flow rates, channel configurations, control features, and output options, thereby ensuring the stable operation of almost any fluidic instrument. Built for reliability these tailored degasser systems include advanced vacuum control and fault detection for consistent performance and long operating life.

BIOTECH FLUIDICS

OEM degasser module tailored to your fluidic system requirements are delivered from the sites in Sweden, USA, and Japan. Please contact Biotech Fluidics on + 46 300 56 91 80 / + 1-612-703-5718 / info@biotechfluidics.com for further information or visit https://biotechfluidics.com/products/degassing-debubbling/degasi-inline-degassers/oem-degassers/

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 from sites in Sweden, USA, and Japan. For further information - www.biotechfluidics.com

Inside the Laboratory: The **Essential Role of a Calorimeter**

In contemporary scientific research, knowledge on the production, transfer, and storage of energy has become central to many fields. For example, the development of pharmaceuticals and new materials, food science, even environmental science relies on scientists having the ability to control and measure energy in different forms. One of the most important tools for scientists to control energy is the calorimeter.

Outside of science, the calorimeter is an underappreciated tool, even an instrument of the utmost importance. It helps researchers understand heat changes in physical, chemical, and even biological processes.

What Is a Calorimeter?

A **calorimeter** is the tool of choice when measuring the heat released or absorbed in a chemical reaction or physical and even a biological change. Measuring the heat energy a reaction absorbs or releases helps researchers understand the energy, efficiency, and even the stability of the reaction.

There are several types of calorimeters, i.e. bomb calorimeters, reaction calorimeters, and even differential scanning calorimeters (DSC). Each has a different purpose and is used for different applications of research.

Why Is a Calorimeter Important?

Measures Energy

Changing energy is at the core of nearly every process. Calorimeters help measure the change of heat energy with the most accuracy which is crucial for every experiment and industrial process.

Drug Research

Calorimeters help researchers determine the stability of drugs, the safety and stability of the food and even the therapeutic properties of the food.

Material Science

Calorimeters are used to study materials in different states especially in a solid state and in a higher state of organization. Understanding thermal properties of materials helps researchers create materials that are helpful for implementation in everyday life.

Advancement of Food and Nutrition Analysis

Food scientists use these calorimeters to identify energy values of foods. This helps in providing food manufacturers with accurate food labels. It also helps manufacturers improve their food formulations.

Aid to Environmental and Energy Research

Calorimetry can aid research in many different areas such as renewable energy, the efficiency of fuels, management of wastes, and other topics related to environmental sustainability. This is due to measurement of energy transformations.

Improvement of Chemical Safety

Many reactions in chemistry can release a lot of energy in the form of heat and can be unsafe if the heat energy is released uncontrollably. Calorimeters assist in determining the safety of a reaction. It also helps design safer conditions of a reaction.

Common Types of Calorimeters

Bomb Calorimeter

This is used to measure the energy value of fuels and foods. It also measures the energy of other materials that can burn.

Differential Scanning Calorimeter (DSC)

This calorimeter measures the flow of heat during the process of melting or crystallization or the transitions of liquids to glass.

Isothermal Calorimeter

This calorimeter measures the heat that is produced while a temperature is held constant. This is helpful in many biological and pharmaceutical studies.

Reaction Calorimeter

This calorimeter measures heat of chemical reactions. This helps improve the efficiency of the process of manufacturing while ensuring chemical safety.

Calorimeter-Using Industries

The following industries use calorimeter technology:

Pharma and biopharma

1. Chemistry
2. Food & drink
3. BioTech
4. Schools & research institutes
5. Environmental Sciences
6. Energy & fuel research
7. Material Sciences and Engineering

Calorimeter Benefits

1. High measurement accuracy for thermal testing
2. Supports quality and safety
3. Improves reproducibility in research
4. Manufacturing and research processes are more efficient
5. Reproduction and research-related risks are lower
6. Supports faster research

Calorimeter Measurement Reliability

For accurate calorimetric measurement lab scientists should

1. Calibrate regularly
2. Use standard operating protocols
3. Use samples prepared in advance
4. Have stable surrounding environments
5. Clean before and after every use
6. Have careful record keeping and data signing

Calorimetry Developments

As labs are more automated and data centric, calorimetry is keeping in step with new data tech. Calorimeters will have more sensitive measurements, the ability to assess and report data in real-time, and more user-friendly software to assist data interpretation.

Thermal energy research will be clearer with new data-driven medicine or research-centered fuel sustainability and/or energy research.

Even with thermal research invisibility, calorimeters tech is important.

Calorimeter Conclusion

Although the **calorimeter** is not a showy research tool, it measures heat changes with the highest level of precision and highest usefulness for research tool. It drives innovations and product improvements for industry and safety and research.

Thermo Fisher Launches Thermal Cycler for Workflow Flexibility and Lab Automation

The system features advanced thermal technology and modular block configurations to support complex molecular biology protocols.

Thermo Fisher Scientific has launched the Applied Biosystems PowerFlex Thermal Cycler, a next-generation polymerase chain reaction (PCR) instrument designed to improve flexibility and productivity for molecular biology laboratories.

PCR remains a foundational technique in life science research, and laboratories are increasingly sharing instruments across teams while managing more complex workflows. The PowerFlex Thermal Cycler was developed to address these needs through new block technology and precise thermal performance.

ThermoFisher SCIENTIFIC

"Today's labs are being asked to run more complex PCR workflows, often across shared instruments and under increasing time pressure. That's where traditional systems start to fall short," says Pawan Singh, vice president and general manager, molecular biology, Thermo Fisher Scientific, in a release. "With the PowerFlex Thermal Cycler, we've reimagined flexibility and performance together so researchers don't have to choose between speed, accuracy, and ease of use. We've also added support for fully skirted plates to enable lab automation."

Modular Configurations for Throughput

The system is available in two models to accommodate different laboratory requirements.

A standard 96-well configuration offers broad plate compatibility for existing environments.

For laboratories running multiple assays, a 3×32-well configuration features independently controlled VeriFlex blocks. This allows three different protocols to run simultaneously on a single instrument, helping to maximize bench space.
The technology is engineered to shorten run times while maintaining the reproducibility required for both routine and complex molecular biology workflows.
"We especially value the flexibility of running three independent experiments simultaneously, as well as the ability to set precise ramp rates in °C per second to optimize our protocols," says Maria Lung, a research scientist at Xpress Genomics AB, in a release. "The intuitive interface and the option to easily share log files provide additional confidence and support."

Interface and Automation Support

Operation is managed through a 10.1-inch touchscreen with a user-friendly interface. The system includes built-in simulation capabilities and AI-assisted Smart Help features to guide users through setup and troubleshooting, which the company says helps reduce training time and minimize workflow disruptions.

The PowerFlex Thermal Cycler is intended for use in life science research, biotechnology, pharmaceutical research, food testing, and human identification workflows. The platform is designed to support future expansion as laboratory needs evolve.
The instrument is currently designated for research use only and is not for use in diagnostic procedures. Additional information regarding technical specifications and PCR workflow solutions is available through the company's digital platforms.
Photo caption: Applied Biosystems PowerFlex Thermal Cycler
Photo credit: Thermo Fisher Scientific

Bruker Expands Microbiology and Infection Diagnostics Portfolio

New updates include expanded capabilities for microbial identification and advancements in sepsis diagnostics and sequencing workflows.

Bruker is showcasing an expanded portfolio of microbiology and infection diagnostics at the ASM Microbe 2026 meeting in Washington, DC. The updates include new innovations in microbial identification, sepsis diagnostics, molecular testing, and next-generation sequencing workflows.

The company is highlighting the expanded clinical capabilities of the MALDI Biotyper CA System, which is supported by Food and Drug Administration (FDA) Claims 7 and 8.

These enhancements include the MBT Compass HT CA software, the MBT FAST Shuttle US IVD, and an expanded FDA-cleared reference library that covers 549 clinically validated microbial species across bacteria, anaerobes, and yeasts.
Bruker is also focusing on bloodstream infection and sepsis diagnostics with a new vision for rapid antimicrobial susceptibility testing.

This workflow, which is currently under development, combines the MALDI Biotyper CA System with the Bruker Arc automated sample preparation solution for positive blood cultures to support earlier clinical decision-making for critically ill patients.

"We believe the future of microbiology lies in integrated innovations that can deliver faster, clinically actionable answers for some of the most critical patient conditions, including sepsis," says Carla Schneider, Bruker's director of commercial operations for microbiology and infection diagnostics, Americas, in a release. "At ASM Microbe 2026, we are showcasing how our expanding portfolio and innovation pipeline are helping laboratories move toward faster decision-making, including the next wave of solutions for rapid positive blood culture analysis."

New solutions for the MALDI Biotyper RUO/GP systems are also being introduced to the US market. These include the MBT Easy T Kit (GP), the MBT Compass HT RUO/GP v.500 with a library of 5,325 species, and the MBT HT Library Creator (RUO). The library expansion adds more than 600 species, including improved coverage of filamentous fungi. Additionally, new classifiers for the IR Biotyper are intended to enhance outbreak investigation and surveillance.

The portfolio expansion includes the US introduction of the MBioSEQ Ridom Typer software (RUO), which supports reflex next-generation sequencing testing.

This software works alongside the MALDI Biotyper and IR Biotyper to create a workflow that moves from identification to genomic characterization and epidemiological insight.
According to the company, the US microbiology business saw 140 new system placements in 2025, with growth momentum continuing into 2026 for both systems and consumables.
Photo caption: MALDI Biotyper CA System
Photo credit: Bruker

Sapio Sciences Integrates Claude Cowork to Streamline Laboratory Data Management

The integration of the AI assistant with the Sapio Platform provides a single interface for searching, retrieving, and analyzing research and development data.

Sapio Sciences, an AI lab informatics company, announced that Claude Cowork, an agentic AI assistant from Anthropic, is now integrated with the Sapio Platform. The integration, facilitated through the Sapio Elain AI assistant, provides scientists and project leaders with a conversational interface to search, retrieve, and analyze data across a research and development (R&D) organization.

Working autonomously, Claude Cowork searches across various data sources to collate findings and return verified, structured outputs, including reports and dashboards. When connected to the Sapio Platform, the assistant can take actions within electronic laboratory notebook and laboratory information management system processes. All actions performed by the assistant are executed with traceability and attributed to the requesting user.

"Sapio Elain is the AI co-scientist inside the Sapio Platform, making every interaction smarter for the scientist at the bench," says Kevin Cramer, CEO and founder, Sapio Sciences, in a release. "Claude acts as an extension of Elain's capabilities, opening up new reporting and analytical possibilities and enabling action on data across the entire organization. Together they give our customers AI that works at every level of the organization, all from a single prompt."

Addressing Research Bottlenecks

For scientists, the integration is designed to address bottlenecks in the research process. Questions that involve multiple processes or experiments typically require manual data exports and multiple searches. Claude Cowork is intended to answer these questions through a single prompt by retrieving and analyzing data across the full Sapio environment.

For project leaders and managers, the tool provides visibility across programs without requiring a direct login to the platform. Users can request real-time project status, identify which experiments are finished, and locate operational bottlenecks.

Applications in Lab Operations

The integration supports several use cases within the lab environment, including:

- Cross-experiment analysis: Identifying experiments related to specific molecules, comparing synthesis conditions, and surfacing optimal parameters for future work.
- Project data analysis: Pulling activity data for specific targets and running trend analysis across compound series.
- Program tracking: Providing real-time views of program status, completed experiments, and outstanding tasks.
- Compliance: Reporting on unsigned experiments that are past due, generating reagent inventory reports with reorder alerts, and producing key performance indicator dashboards.

"Scientists and project leaders spend too much time hunting for information that already exists across their organizations," says Rob Brown, vice president and head of the scientific office, Sapio Sciences, in a release. "Whether that data lives across experiments, across teams, or buried in email, Claude Cowork gives them a single conversation to find it, analyze it, and act on it. That is a meaningful shift in how R&D teams operate day to day."

The company also noted that Sapio Elain can be connected to other supported AI assistants, such as Microsoft Copilot and ChatGPT, allowing organizations to use their preferred tools.

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SPT Labtech and EMBL GeneCore Partner to Advance Automated Genomics

The collaboration focuses on implementing a liquid handling platform to streamline end-to-end laboratory processes and protocol development.

SPT Labtech and the European Molecular Biology Laboratory Genomics Core Facility (EMBL GeneCore) have announced a collaboration to develop fully walkaway automated genomics workflows. As part of the agreement, SPT Labtech has installed its firefly+ liquid handling platform at the EMBL GeneCore facility in Heidelberg, Germany.

Through the installation, EMBL GeneCore will expand its capacity to develop new protocols and optimize existing workflows for applications such as metagenomics and low-input samples.

The firefly+ platform is an all-in-one instrument that integrates pipetting, dispensing, incubating, and shaking technologies into a single system.

"The installation of SPT Labtech's firefly+ platform as part of our collaboration underscores our commitment to remain at the forefront of scientific innovation," says Vladimir Benes, head of genomics core facility at EMBL, in a release.

"Fully walkaway automation will address key bottlenecks in genomics workflows, helping us develop high-quality, scalable [next-generation sequencing] protocols."

The automated protocols utilize New England Biolabs (NEB) next-generation sequencing, known as NEBNext, to produce high-yield libraries from various input ranges. These kits are designed to enable the development of high-sensitivity next-generation sequencing protocols while minimizing plastic waste.

"Our latest collaboration with EMBL GeneCore marks a significant step towards advancing fully walkaway automation, providing end-to-end genomics workflows for a much wider range of applications, including environmental and rare species research," says Morten Frost, chief commercial officer at SPT Labtech, in a release.

The integration of the liquid handling platform with NEB library preparation kits is intended to create a foundation for end-to-end workflows, allowing laboratories to scale automation more easily.

"Integration of our library prep kits with SPT Labtech's firefly+ platform at EMBL GeneCore creates a compelling opportunity for faster, scalable DNA and RNA-Seq workflows, and we look forward to working together to develop novel solutions to overcome persistent challenges in genomics research," says Bjoern Textor, PhD, sales and senior applications manager at New England Biolabs GmbH, in a release.

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Selection **Guide**

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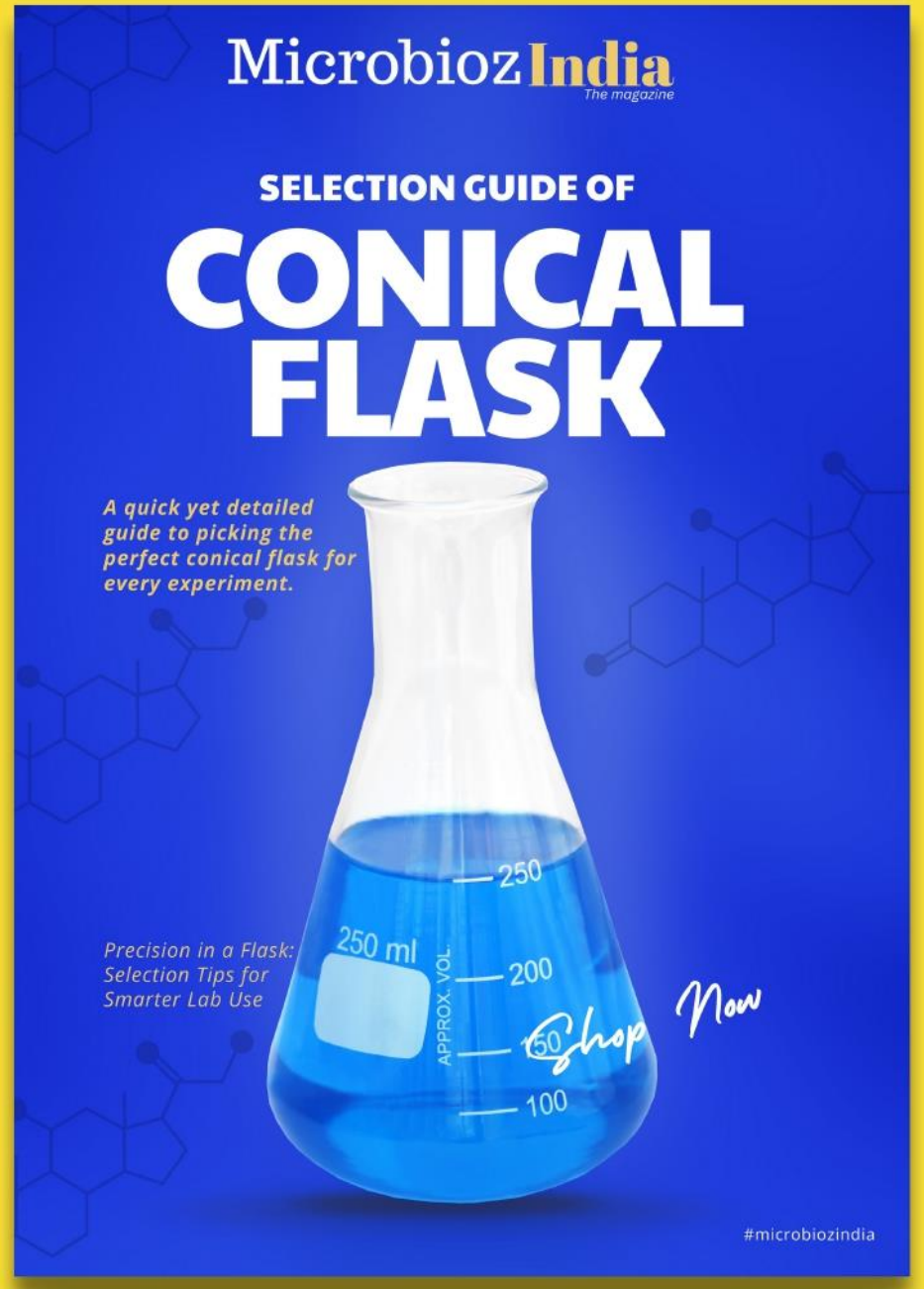

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Agilent Launches Next-Generation Analytical Platforms at ASMS 2026

Agilent Technologies has introduced multiple analytical innovations at ASMS 2026, including its new **9500 Triple Quadrupole ICP-MS**, upgraded **8890B and 8860B Gas Chromatography systems**, and enhanced intelligent chromatography workflows.

The new 9500 ICP-MS platform is designed to simplify elemental analysis while improving interference removal and accelerating data acquisition speeds.

Agilent Technologies

Agilent has also introduced automation features such as GC Assist to reduce manual intervention and improve laboratory productivity.

The company is heavily focusing on AI-enabled workflows that can improve data quality and accelerate decision-making in pharmaceutical and biopharma laboratories.

These systems are expected to be rapidly adopted by CROs, pharmaceutical QC laboratories, and environmental testing facilities across India and APAC.

Industry experts say this launch signals a strong shift toward connected, intelligent laboratories where instruments, software, and analytics operate as a unified ecosystem.

Waters Launches New Mass Spectrometry Platforms for Multiomics Research

Waters Corporation has unveiled two new mass spectrometry platforms during ASMS 2026 to support structural biology, multiomics, and gene therapy applications.

Waters™

The new systems are designed to improve biomolecule characterization while simplifying complex analytical workflows.

Waters is also expanding its software ecosystem to enable seamless integration between instruments and laboratory informatics platforms.

The company showcased solutions targeting pharmaceutical R&D, biologics manufacturing, and advanced therapeutic development.

The launch aligns with growing investments in precision medicine and cell & gene therapies throughout APAC.

Waters recently strengthened its India presence through expanded technology development capabilities in Bengaluru.

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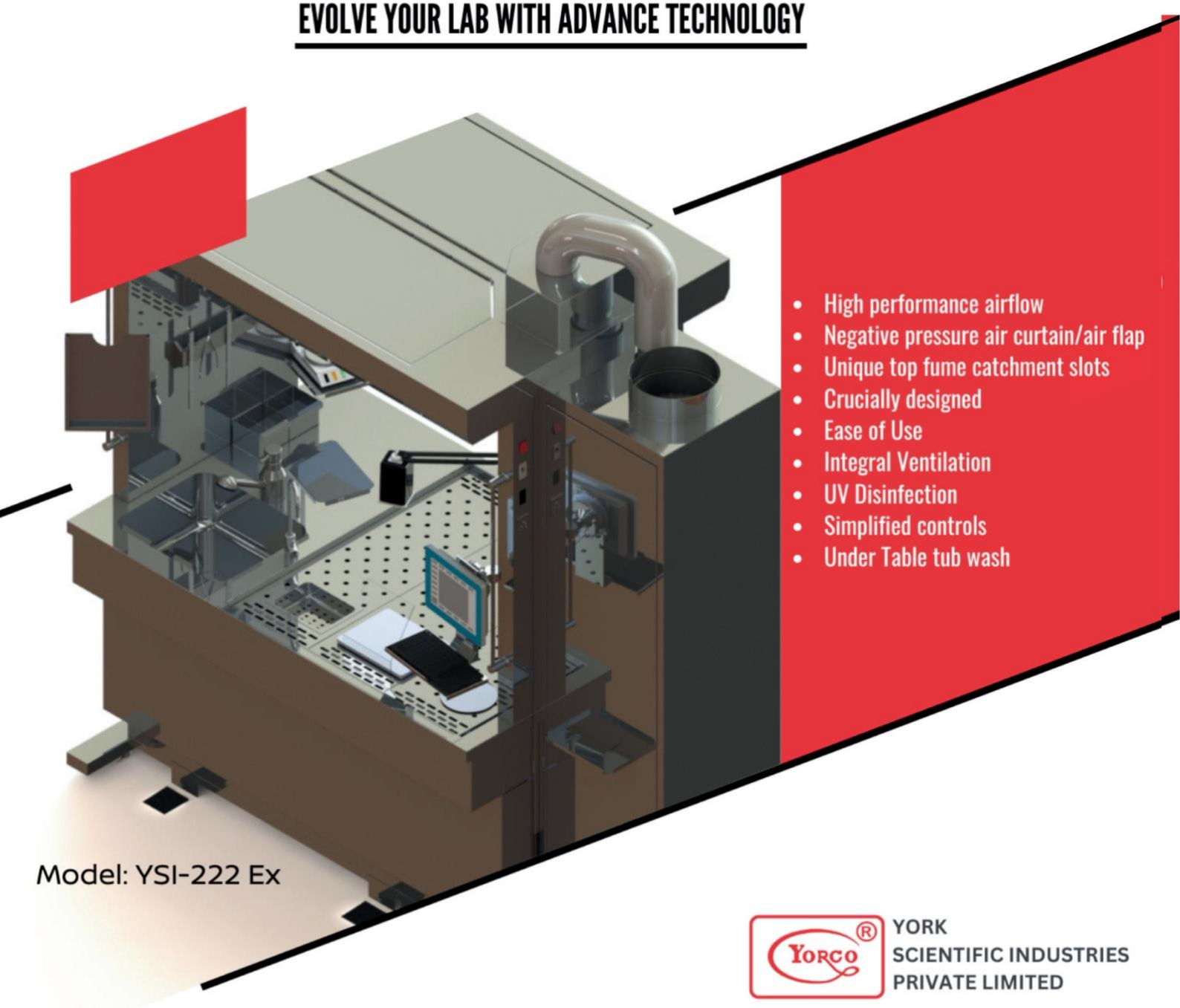

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