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Microbioz India

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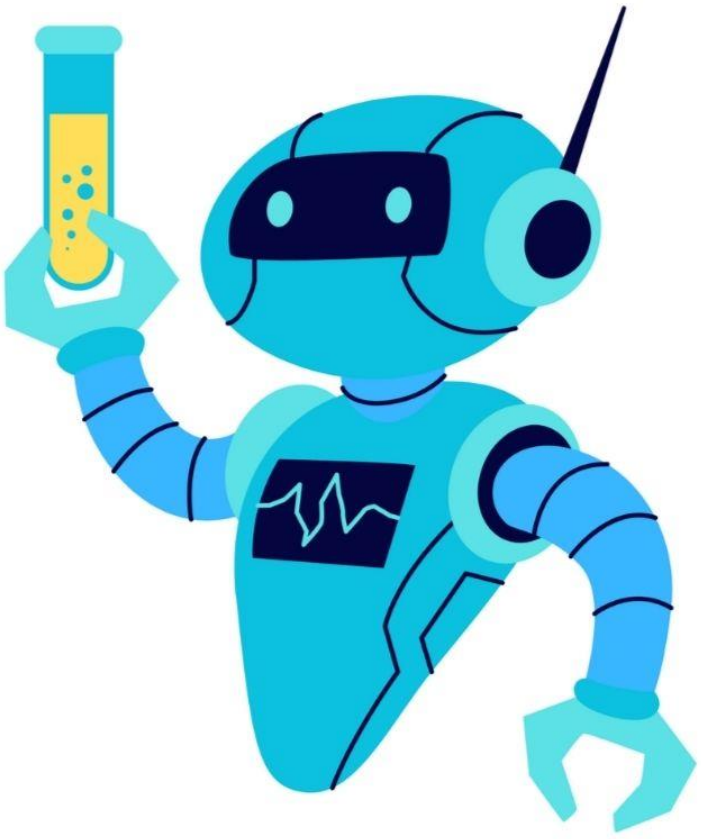
The Intelligent Laboratory

How AI, Automation & Digital Science Are Transforming Pharmaceutical Quality



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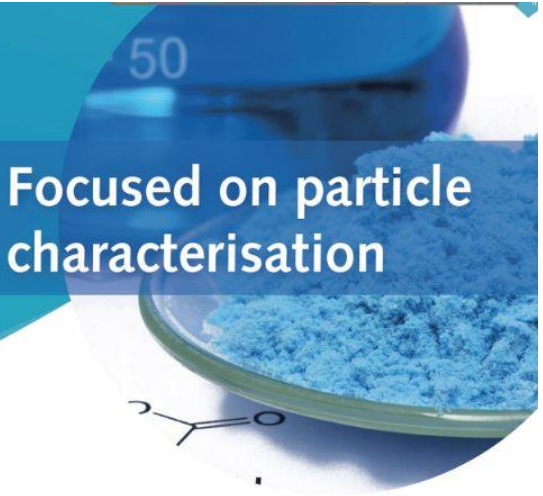

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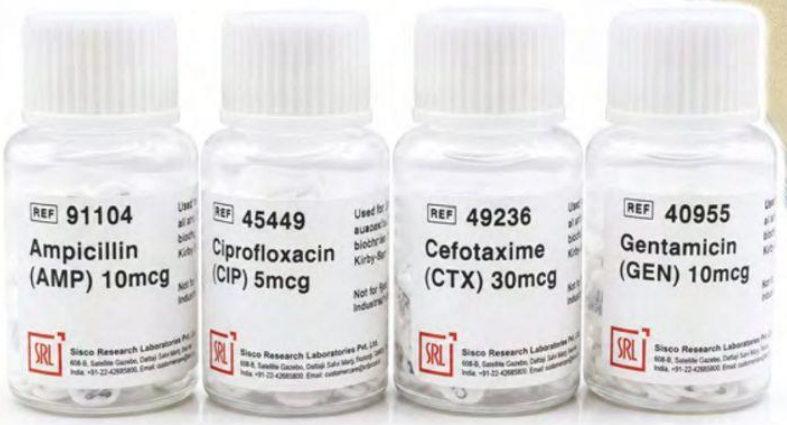

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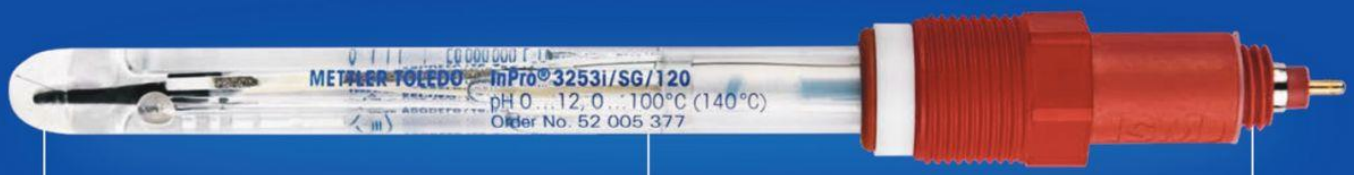
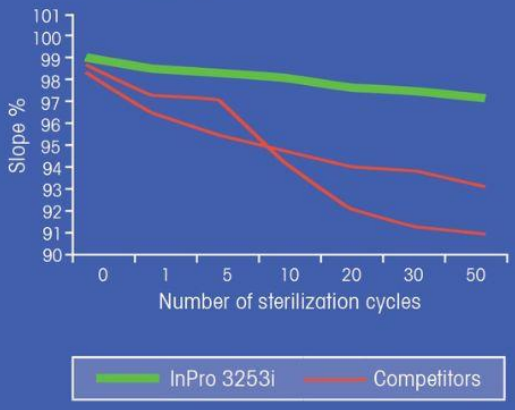
3 Reasons to Switch to ISM pH Sensors
For Bioprocessing



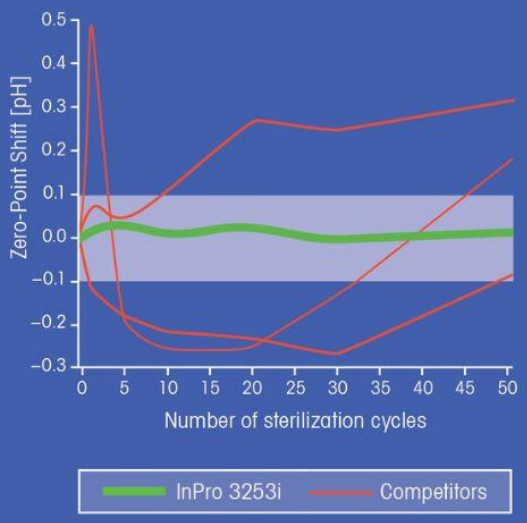
66 % Reduction in Calibration Requirements

- Most sensors are calibrated periodically: Based on a fixed schedule, not need.
- ISM predictive diagnostics use sensor output to ensure calibration only when needed.
- Specialized glass and reference system lead to low zero-point shift reducing the need for calibration.



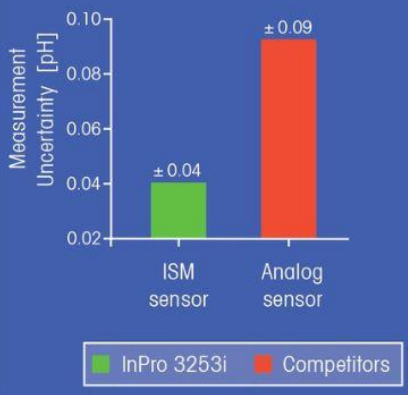
5 × Less Measurement Variability

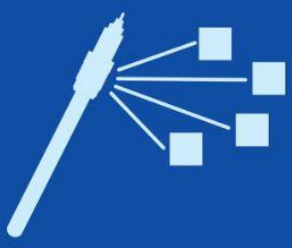
- Most sensors experience drastic zero-point shifts after a few autoclave cycles.
- Specially designed, rigorously tested ISM pH sensors keep their zero-point 5 × better, even after dozens of autoclave cycles.



120 % Improved Accuracy

- Analog pH sensors introduce up to 0.1 pH unit of error due to environmental factors.
- ISM pH sensors convert the signal to digital in the sensor, preventing interference.
- Algorithms mitigate temperature errors and buffer uncertainties.





What Is ISM?

Intelligent Sensor Management (ISM) is a **digital technology** that incorporates a microprocessor directly into sensors. This enables analog to digital signal conversion for greater accuracy and interference-free measurements, plus on-board storing of calibration data and predictive diagnostics.

Get Information and Pricing on the InPro 3253i:
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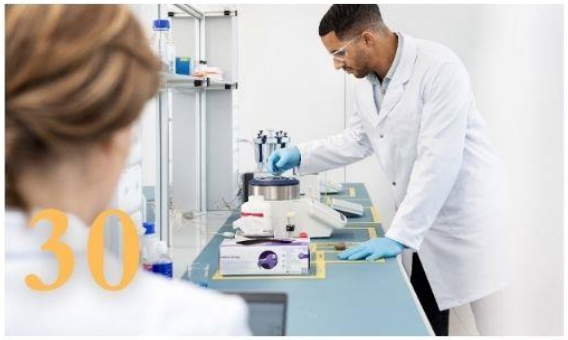
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Editor's Word

Dear 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 "**The Intelligent Laboratory: How AI, Automation & Digital Science Are Transforming Pharmaceutical Quality**" delving deep into its intricacies and uncovering the stories and people that make it an intriguing subject. Additionally, you'll find articles "**Pharmaceutical Quality by Design for Single-Use Components"**contributed by Ami Polymer, authored by Dr. Priyabrata Pattnaik, Chief Executive Officer-Ami Polymer that we hope will pique your curiosity.

As we embrace the digital age, Microbioz India continues to evolve to provide you with fresh, interactive experiences. Be sure to check out our website for additional content, multimedia features, and ways to connect with us through social media.

We value your feedback and insights, which drive us to continually improve and innovate. Your voices shape the direction of Microbioz India, and we appreciate the trust you place in us to be your source for Pharma, Bio-Pharma, Laboratory and Analytical Industry news and product launches.

Thank you for your continued support and loyalty. We look forward to embarking on this journey with you, exploring the worlds within the pages of Microbioz India, and sharing the stories that make our world so captivating.

Enjoy the read!

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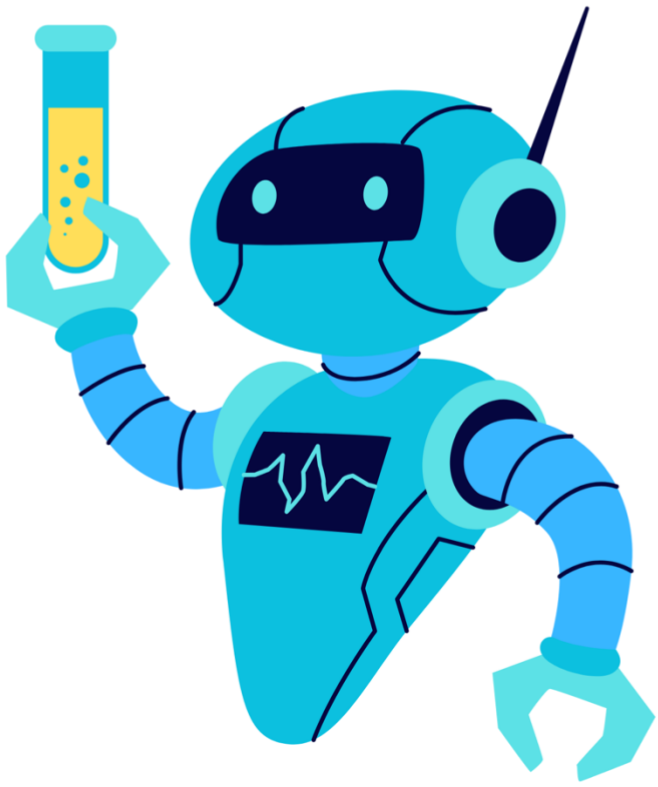
The Intelligent Laboratory

How AI, Automation & Digital Science Are Transforming Pharmaceutical Quality



Robotics now serve as the foundation for smart laboratories.

"The laboratory of the future won't simply generate data—it will understand it, predict outcomes, and drive better scientific decisions."

Some functionalities provided by automated robotic workstations include:

1. High-throughput screening
2. Sample sorting
3. Automated weighing
4. Liquid dispensing
5. Plate handling
6. Sample storage
7. Microbiology workflows

Once a robotic laboratory is set up, it can work at the same level of quality as humans, even for 24-hour shifts.

The Human Scientist Remains Central Smart laboratories do not mean the end of researchers. Smart laboratories simply shift the focus of research.

The researchers of the future will be working more on:

1. Research synthesis

2. Data analysis
3. Supervising AI
4. Research design
5. Understanding regulatory requirements
6. Managing innovations

Digital skills will be just as important as traditional research skills. The future laboratory researcher will be working with AI, not against it. There are still many challenges to implementing smart laboratories.

Some of these challenges have been barriers to adoption:

1. Very high costs
2. Old laboratory infrastructure
3. Data integration
4. Cybersecurity
5. Regulatory requirements
6. Workforce training
7. Change management

The most important part of digital transformation is the combination of advanced technology and a sustained commitment to improving the organization.

The Future Is Autonomous

Looking to the future, the laboratories of the pharmaceutical industry will be even more automated.

Some of the new technologies that are expected to be introduced include:

1. AI-driven autonomous experimental
2. Digital twins of laboratory workflows
3. Generative AI for lab documentation
4. Robotic laboratories with autonomy
5. Real-time release testing
6. Self-optimizing workflows
7. Quality-by-design platforms

All of these technologies will enhance the design and testing of new laboratory workflows with faster results and less risk.

Conclusion

The development of the intelligent laboratory is more than the application of new technologies.

It has the potential to modernize the entire practice of pharmaceutical science.

AI, automation, robotics, and digital networks are providing laboratories with the tools to construct flexible, data-centered environments.

Pharmaceutical companies have a lot at stake in the intelligent laboratory, and the stakes have drastically changed.

Rather than a competitive advantage, automation, and the rest of the intelligent laboratory, are crucial to the more efficient and compliant delivery of safe and effective pharmaceuticals to a global audience.

The digital transformation of the pharmaceutical industry is coming to the intelligent laboratory, and the laboratories that implement intelligent technologies first will shape the future of pharmaceutical quality.

Quality Without Compromise

The Next Generation of Pharmaceutical Analytical Technologies

"In today's pharmaceutical landscape, quality is no longer just a regulatory requirement—it is a strategic advantage driven by precision, innovation, and intelligent analytical science."

The pharmaceutical sector is transforming rapidly. Resulting from this transformation, analytical labs will likely need to provide results that are faster, more accurate, and more reproducible. Ranging from small molecules to biologics, cell therapies, gene therapies, and tailored medicines, modern pharmaceutical products require advanced analytical technologies and sophisticated methods that can detect even the smallest changes in the quality of pharmaceutical products.

Contemporary pharmaceutical analytical laboratories have even gone beyond traditional roles. These laboratories have become centers for innovations. The convergence of advanced instruments, automated processes, artificial intelligence, and digital data have made it possible to construct laboratories where the highest standards of safety, efficacy, and compliance with the regulations are built into each product.

The future of pharmaceutical analytical technologies is transforming the measurement, monitoring, and maintenance of quality during the entire life cycle of the pharmaceutical product. The innovations will allow pharmaceutical companies to achieve a high quality product while improving the speed of product development and the efficiency of operations.

The New Era of Pharmaceutical Quality

Quality is the most important aspect of pharmaceutical product manufacturing, and while this continues to be the case, the significance of quality in the recent years is rapidly evolving.

Regulatory authorities expect organizations to have a deep understanding of their products and processes. This understanding is to be verified by robust scientific evidence and is to be accompanied by continuous oversight.

This has led to the implementation of sophisticated analytical technologies that provide:

1. Better analysis
2. Faster processes
3. Greater reproducibility

4. Continuous monitoring
5. Improved data integrity
6. Predictive quality

Manufacturers are beginning to incorporate quality into the manufacturing process, rather than just assessing the quality of the final product.

Technological Advancement in Modern Laboratories

Current pharmaceutical labs are built around cutting edge sophisticated analytical tools that enable them to create and collect highly accurate data and produce highly reproducible results.

Some of these tools include:

1. High-Performance Liquid Chromatography (HPLC)
2. Ultra-High Performance Liquid Chromatography (UHPLC)
3. Gas Chromatography (GC)
4. Liquid Chromatography-Mass Spectrometry (LC-MS/MS)
5. Gas Chromatography-Mass Spectrometry (GC-MS)
6. Inductively Coupled Plasma Mass Spectrometry (ICP-MS)
7. Fourier Transform Infrared Spectroscopy (FTIR)
8. Raman Spectroscopy
9. Nuclear Magnetic Resonance (NMR)
10. UV-Visible Spectroscopy
11. Particle Size Analysis

Thermal Analysis

12. X-ray Diffraction (XRD)

Pharmaceutical Quality Assurance technologies assess a range of products from identity to unstable, to pure and contaminated, to stable.

High-Resolution Mass Spectrometry:

See Beyond the Ordinary High-Resolution Mass Spectrometry (HRMS) has revolutionized an entire industry.

Now, laboratories use HRMS to determine the quality of a product to a greater extent by detecting, for example, impurities or degradation.

Some of the main uses of HRMS include:

1. Impurity profiling
2. Extractables and leachables analysis
3. Biomarker identification
4. Biopharmaceutical characterization
5. Stability studies
6. Nitrosamine detection
7. Structural elucidation

Because of how sensitive HRMS is, it is a great tool for ensuring safety and supporting regulations, while also improving and expediting the pharmaceutical development process.

Process Analytical Technology (PAT): Quality You Can See

One of the most significant changes in the industry was the shift from testing the end product to analyzing processes as they occur.

With Process Analytical Technology (PAT), companies can analyze the important parameters of the production process as it is being completed.

Commonly used PAT technologies include:

1. Near-Infrared (NIR) Spectroscopy
2. Raman Spectroscopy
3. Online particle size analysis
4. Process sensors
5. Automated sampling systems

Because PAT analyzes processes in real-time, it is possible and common for the production process to be modified to eliminate wasted resources from the process and to reduce the number of failed batches. Additionally, PAT helps improve the consistency of the production process.

Automation in the Pharmaceutical Sector

Many modern laboratories analyze tens of thousands of samples weekly. As a result, labs are becoming more efficient with:

1. Automated Sample Preparation
2. Robotic Liquid Handling
3. Automated Dilutions
4. Intelligent Scheduling
5. Barcodes for Sample Tracking
6. Digital Workflow Management

Because automation minimizes the need for human involvement, reproducibility is also improved. Scientists can also spend more time analyzing results, rather than preparing samples and completing other routine lab tasks.

AI in Pharmaceutical Science

AI is now an integral part of pharmaceutical analytical science.

AI has the capability to:

1. Rapidly Analyze Large Datasets
2. Identify Trends
3. Detect Anomalies
4. Analyze Data to Make Decisions

AI is even capable of performing chromatographic peak integration, spectral interpretation, and method optimization. One of the greatest impacts of AI in laboratories will be the improvement of quality assurance.

Digital Laboratories and Data Integrity

Laboratories are becoming more digital and connected. Consequently, systems that were once based on paper documents are becoming integrated systems that are secure and digital.

Today's laboratories in the pharmaceutical industry use:

1. LIMS
2. ELNs
3. CDS
4. QMS
5. MES

Because modern digital systems eliminate the need to record results by hand, they reduce errors and facilitate a complete audit of results.

Digital systems of record comply with data integrity requirements of regulatory agencies.

Analytical Challenges of Biopharmaceuticals

The growth of biologics and biological therapeutics has introduced a number of challenges for analysis.

Unlike conventional small molecule therapeutics, biologics, which are complex, require advanced characterization.

Analytical technologies that monitor biologics include:

1. Capillary Electrophoresis (CE)
2. Multi-Angle Light Scattering (MALS)
3. Dynamic Light Scattering (DLS)
4. Bio-layer Interferometry (BLI)
5. Surface Plasmon Resonance (SPR)
6. High-resolution LC-MS

These technologies help to analyze the structural heterogeneities of proteins, their aggregation and glycosylation, and the molecular interactions and stability of the product.

Adapting to New Regulations

Regulatory authorities continue to focus on the analytical and data integrity of higher standards.

Though advanced technologies can assist laboratories with ongoing compliance, they must be implemented within the existing frameworks that have made significant investments.

These frameworks must address:

1. Data integrity (ALCOA+)
2. Validation of methods
3. Qualification of systems
4. Risk-based quality management
5. Electronic audit trails
6. Validation of computerized systems
7. Continuous process verification

Analytical Technology with Simplified Compliance

Next generation analytical technology seamlessly incorporates quality controls into laboratory workflows.

Sustainability in Analytical Science

Modern laboratories are integrating sustainable practices into analytical methodologies.

Green analytical chemistry is characterized by:

1. Decreased solvent usage
2. Miniaturized techniques
3. High energy efficiency of instruments
4. Automation of waste disposal
5. Laboratory supplies and packaging that are environmentally friendly

Manufacturers increasingly recognize that both sustainability and superior level analytical services can be provided.

Smart Analytical Laboratories

The analytical laboratories of the future will be completely integrated environments, with communication between equipment, automation of workflows, and quality decisions supported by advanced predictive analytics.

Examples of innovations that facilitate this include:

1. Digital twins of laboratory operations
2. Fully autonomous analytical laboratories
3. Laboratory environments hosted in the Cloud
4. AI-based assistance for the development of laboratory techniques
5. The advanced quality of analytics and the Internet of Things (IoT) for predictive quality and the real-time release of tested materials.

Pharmaceutical companies will benefit greatly from the investment in these technologies that will improve the ease of regulatory compliance.

They gain:

1. Quicker product development
2. Better efficiency in manufacturing
3. Lower operational costs
4. Increased laboratory productivity
5. Improved regulatory readiness
6. Improved patient safety
7. Increased Confidence in Analytical Results

As the pharmaceutical industry improves its analytical methods and speeds up its processes, the emphasis on analytical excellence and capability will define competition in the industry.

Conclusion

The level of quality in pharmaceuticals is being revolutionized. With the innovative analytical technology available, all processes of drug development and manufacturing are undergoing this transformation.

Organizations now have the benefit of advancements in high-resolution systems and intelligent automation, as well as the use of digital labs and the increasing integration of AI.

The evolution of these technologies in the last decade has made great strides, and now even more unimaginable projects are becoming a reality.

Pharmaceutical **Quality by Design** for Single-Use Components

Dr. Priyabrata Pattnaik
Chief Executive Officer
Ami Polymer

The last two decades have seen major changes in the biopharmaceutical industry. The importance of single-use systems (SUS) has grown from being specialty tools in a lab to critical infrastructures in the development and large-scale production of vaccines and biologics.

Bioprocessing Components Can No Longer Be Treated as Commodity Plastics

A modern-day bioprocess can have in excess of hundreds of single-use components such as tubing, connectors, clamps, bags, filters, and other molded components, as well as commercial assemblies and customized fluid transfer systems.

While these systems are referred to as consumables, they carry a significant burden on product quality, manufacturing reliability, compliance to regulations, and safety of the end-user. Potential issues with any one of these systems can halt production of a million-dollar batch, cause concern for leachables, and impose an integrity risk to the manufacturing process. Even a minor disruption to the supply chain of any one of these plastic products can result in delays in providing much-needed therapies to the patients.

Because of this burden, biopharmaceutical companies have begun to view suppliers of these single-use components as quality-driven partners for manufacturing plastic components in contrast to plastic molders of the past.

This emerging view has led to the increasing application of the principles of Quality by Design (QbD) to the manufacturing of consumables. QbD, which originated in pharmaceutical development and was formalized in the International Council for Harmonisation (ICH) guidelines, describes a science- and risk-driven approach to the design and manufacture of products and processes to ensure quality.

For producers of bioprocessing consumables, QbD gives the opportunity to create predictable quality and robust manufacturing with a high degree of confidence from regulators and differentiates competitively in a sustainable manner. Producers of single-use bioprocessing components will not gain the market advantage by producing the cheapest components.

The advantage will go to producers of single-use components who understand the materials, processes, risks, variability, and lifecycle of their components.

Targeting Biopharmaceutical Clients

Traditionally, some producers of single-use components were manufacturers of plastics, rubbers, and other extrusions and mouldings. Their core capabilities were efficient manufacturing, cost and time to market, and expertise in fabrication and molding.

These will continue to be important, however biopharmaceutical clients are expecting more. Today, supplier qualification processes will assess a variety of criteria, including, but not limited to, quality and change control, traceability and risk, validation, data integrity, and regulatory acceptance.

This is not without reason. Biopharmaceutical clients are more and more expecting their suppliers to adopt quality by design philosophy, as single-use components are interacting with drug substances and conducting critical operations in sterile environments.

The industry is adopting the philosophy of "quality cannot be inspected into a single-use component." It must be designed both in the component and the manufacturing process.

Understanding QbD in Single-Use Components

QbD in single-use components encompasses a structured development process with an end goal in mind that focuses on the science and quality of the process to manage risks.

For consumable manufacturers, QbD refocuses from finding flaws to minimizing them. Instead of saying, “Did this part pass the inspection?” QbD asks (a) what part of the process is most important to the customer? (b) what factors and/or features of the process impact the response? (c) what is the acceptable range of variability? and, (d) how can the process best define and control the acceptable response? a big theory of QbD is developing a scientific methodology to design and control a process with the end goal of having predictability, reliability, and assurance.

Identifying CMAs (Critical Material Attributes)

Material selection is the first step in designing a single-use component. In the pharmaceutical QbD framework, Critical Material Attributes (CMAs) are the dimensions and/or characteristics of the raw material that dictate the quality of the final product.
The CMAs of a single-use component can include (a) polymer characteristics (those that affect molecular weight distribution, melt flow index, density and other polymer characteristics), (b) polymer mechanical properties (tensile strength, elongation, flexibility, compression resistance, and others), (c) an extractable and leachable chemical profile and other properties (chemical compatibility, oxidation resistance, and others), (d) biocompatibility (those tested per USP <88> and ISO 10993 including the cytotoxicity), and (e) effects of various methods of sterilization (gamma, e-beam, autoclaving, and others).

A QbD based supplier does not just buy some resin from an authorized supplier. Rather, they gain an understanding of how different material attributes impact the performance of the product. This understanding is the basis for material requirements, supplier assessments, incoming inspections and other operational processes.

Critical Quality Attributes (CQAs) for Single-Use Components

CQAs are features of a product that impact performance and therefore must be controlled. Examples include:

1. Dimensional Characteristics: sizes and shapes of product features.

2. Functional Characteristics: integrity to leak, withstands pressures, flow and connection performance.

3. Surface Characteristics: Surface finish, roughness, and cleanliness

4. Biological Characteristics: Assurance of sterility, levels of endo-toxins, and bioburden.

5. Chemical Characteristics: View of extractables, and identity of the material.

Manufacturers must expend hard resources to understand which of the CQAs and/or attributes actually impact the customer experience. When using a Quality by Design (QbD) approach, these resources and efforts are placed on the most impactful CQAs, which are determined using a risk based methodology.

Critical Process Parameters (CPPs)

With a deep understanding of CQAs, the manufacturers' next step is to understand the variables of the process that impact the CQAs. These variables are called Critical Process Parameters (CPPs). For injection molding, temperature, pressure and time can be critical process parameters.

The same concepts of QbD apply to CPPs in that the information and understanding of CQAs and CPPs is used to impact process variables to ultimately impact the performance of the product rather than controlling variables simply because it is the norm.

Design of Experiments: The Engine of Process Understanding

DotE (Design of Experiments) is considered to be one of the most important tools that aid QbD (Quality by Design). The traditional techniques of process development require one to painstakingly make adjustments to the process, using trial-and-error to reach the desired process. DoE in contrast, gives a systematic scientific order to the understanding of main effects, interaction effects, the basis of variability, and the sensitivity of the process.

To illustrate, consider the molded connector. This may be investigated using a fractional factorial design to examine the effects of molding temperature, the effects of injection pressure, and the effects of the length of the cooling time. The data generated would allow the identification of critical factors, interaction effects, the adequate and acceptable limits of the process, and the robustness of the process. The result of this study would provide a scientifically justified design space which is far better than the arbitrary limits of the operating conditions.

Mold Validation: Moving Beyond Tool Qualification

In conventional manufacturing of plastics, the acceptance of a mold is usually a compliance check of the mold's dimensional conformity. In contrast, the requirements of bioprocessing are significantly advanced.

Mold validation in bioprocessing should address the question of consistency (can the mold produce acceptable parts repeatedly?), variability (will the performance of the mold remain consistent across different operators, shifts, and equipment?), molding capability (will the mold maintain the required specifications under normal conditions of production?), and mold life (will the performance of the mold be acceptable for the entire life of the tool?). Once molds are validated, they serve the role of quality assets as opposed to simply production equipment. This is highly relevant because even minor variations in tool design can influence the performance of sterile assembly significantly.

Process Validation in Single-Use Manufacturing

Pharmaceutical manufacturers routinely validate production processes. Customers increasingly expect consumable suppliers to follow similar principles. Process validation generally includes:

- *Stage 1: Process design* - understanding process variables and risks.
- *Stage 2: Process qualification* - demonstrating reproducible performance under controlled conditions.
- *Stage 3: Continued process verification* - ongoing monitoring during commercial production.

Applying this framework to component manufacturing improves consistency while strengthening customer confidence. Validation shifts discussions from claims to evidence.

Process Capability: Quantifying Manufacturing Excellence

Quality organizations increasingly use process capability metrics to assess manufacturing performance. Two commonly used metrics include Cp and Cpk. These indicators quantify how well a process operates relative to specification limits. A capable process exhibits low variability, stable centering, and predictable output.

Many pharmaceutical customers increasingly expect evidence that critical dimensions are manufactured within statistically capable processes. Process capability demonstrates scientific process control, manufacturing maturity, and reduced quality risk. It transforms quality conversations from subjective opinions to objective data.

Statistical Process Control: From Reactive to Predictive Quality

One of the most important transitions in modern manufacturing is moving from defect detection to defect prevention. Statistical Process Control (SPC) provides this capability. SPC uses real-time data to identify trends before defects occur. Control charts, trend analysis, process capability studies, pareto analysis, and statistical alarms are common tools used in this context.

For single-use component manufacturers, SPC may monitor critical dimensions, weld strength, pressure resistance, leak test performance, and material properties rather than discovering problems after production is complete, SPC enables proactive intervention. This reduces scrap, rework, customer complaints, and batch failures. Most importantly, it creates a culture of continuous quality improvement.

Lifecycle Quality Management

A common misconception is that quality ends once a product is released. In QbD philosophy, quality management extends throughout the product lifecycle. Lifecycle quality management includes (a) material lifecycle control, covering supplier qualification, material monitoring, change notification, etc., (b) process lifecycle control, covering process trending, revalidation, equipment maintenance, etc., (c) product lifecycle monitoring, covering customer feedback, complaint analysis, performance monitoring, etc., and (d) continuous improvement, covering CAPA implementation, risk reduction, process optimization, etc.

The objective is maintaining a state of control throughout the commercial life of the product. This approach aligns closely with regulatory expectations and customer requirements.

Change Control: A Critical Differentiator

One of the greatest concerns among biopharmaceutical manufacturers is uncontrolled change. A seemingly minor modification involving resin supplier, or mould insert, or assembly process, or sterilization provider may trigger requalification, risk assessments, regulatory filings, and validation activities.

QbD organizations implement rigorous change control systems that evaluate potential impact before implementation. Such systems provide customers with transparency, predictability, and confidence. In many cases, strong change control programs become decisive factors during supplier selection.

Risk Management as a Core Quality Discipline

QbD and risk management are inseparable. Risk assessments help prioritize resources toward areas with greatest potential impact. Common methodologies for risk assessment are failure Mode and Effects Analysis (FMEA), hazard analysis, risk ranking, and fault tree analysis. Risk-based thinking enables organizations to focus on critical dimensions, critical materials, critical suppliers, and critical processes. Rather than attempting to control everything equally, resources are directed toward the variables that matter most.

Connecting Engineering Decisions to Business Outcomes

Quality investments are sometimes viewed as costs. Leading organizations understand they are strategic investments.

It is important to consider the financial consequences of a single component failure, which could be either batch rejection, or manufacturing downtime, or investigation costs, or regulatory scrutiny, or customer dissatisfaction, or lost market share, or all and few of these.

Conversely, robust QbD programs generate measurable business value, in terms of reduced cost of poor quality (fewer defects and complaints), improved manufacturing efficiency (lower scrap and rework), faster customer qualification (scientific evidence accelerates supplier approval), stronger customer retention (confidence strengthens partnerships), premium market positioning (quality leaders compete on value rather than price alone). The economic impact often far exceeds the cost of implementing advanced quality systems.

Why QbD Differentiates a Company from Conventional Plastic Moulders

Perhaps the most important strategic implication of QbD is market differentiation. Traditional moulders typically compete on cost, capacity, and lead time. These factors remain important but are increasingly insufficient in biopharmaceutical markets.

A QbD-driven manufacturer competes on scientific understanding - deep knowledge of materials and processes, regulatory readiness - alignment with pharmaceutical expectations, predictable performance - data-supported reliability, risk reduction -lower operational uncertainty, lifecycle support - partnership throughout product life.

The distinction is profound. A conventional moulder sells parts. A QbD-driven supplier delivers confidence. As biopharmaceutical manufacturing becomes increasingly sophisticated, confidence becomes a highly valuable product.

The Future of Single-Use Manufacturing

The next generation of bioprocessing suppliers will increasingly resemble pharmaceutical manufacturers in their quality philosophy. Digital quality systems, real-time process analytics, predictive quality monitoring, advanced process capability management, AI-driven quality intelligence, and digital twins for process optimization are current emerging trends.

Customers increasingly expecting suppliers to demonstrate Process understanding of statistical control, scientific validation, and lifecycle management.

Organizations that embrace these principles early will establish sustainable competitive advantages. Those that continue operating as conventional plastics manufacturers risk being excluded from high-value biopharmaceutical supply chains.

Conclusion

The rapid expansion of single-use technologies has fundamentally elevated the role of consumable manufacturers within the biopharmaceutical ecosystem. Single-use components are no longer simple plastic parts; they are critical enablers of product quality, manufacturing efficiency, regulatory compliance, and ultimately patient safety.

Quality by Design provides a powerful framework for meeting these elevated expectations. By systematically understanding Critical Material Attributes, Critical Quality Attributes, Critical Process Parameters, mould behaviour, process capability, statistical control, and lifecycle performance, manufacturers can build quality into their products rather than attempting to inspect defects out of them. More importantly, QbD transforms the strategic identity of a company. It shifts the organization from being viewed as a commodity supplier to being recognized as a trusted quality partner.

In an industry where the consequences of failure can be measured in millions of dollars and potentially impact patient lives, that distinction matters enormously.

The future winners in single-use manufacturing will not simply be the companies that mould components most efficiently. They will be the companies that combine engineering excellence, scientific rigor, pharmaceutical quality thinking, and lifecycle quality management to deliver confidence at every stage of the bioprocessing journey.

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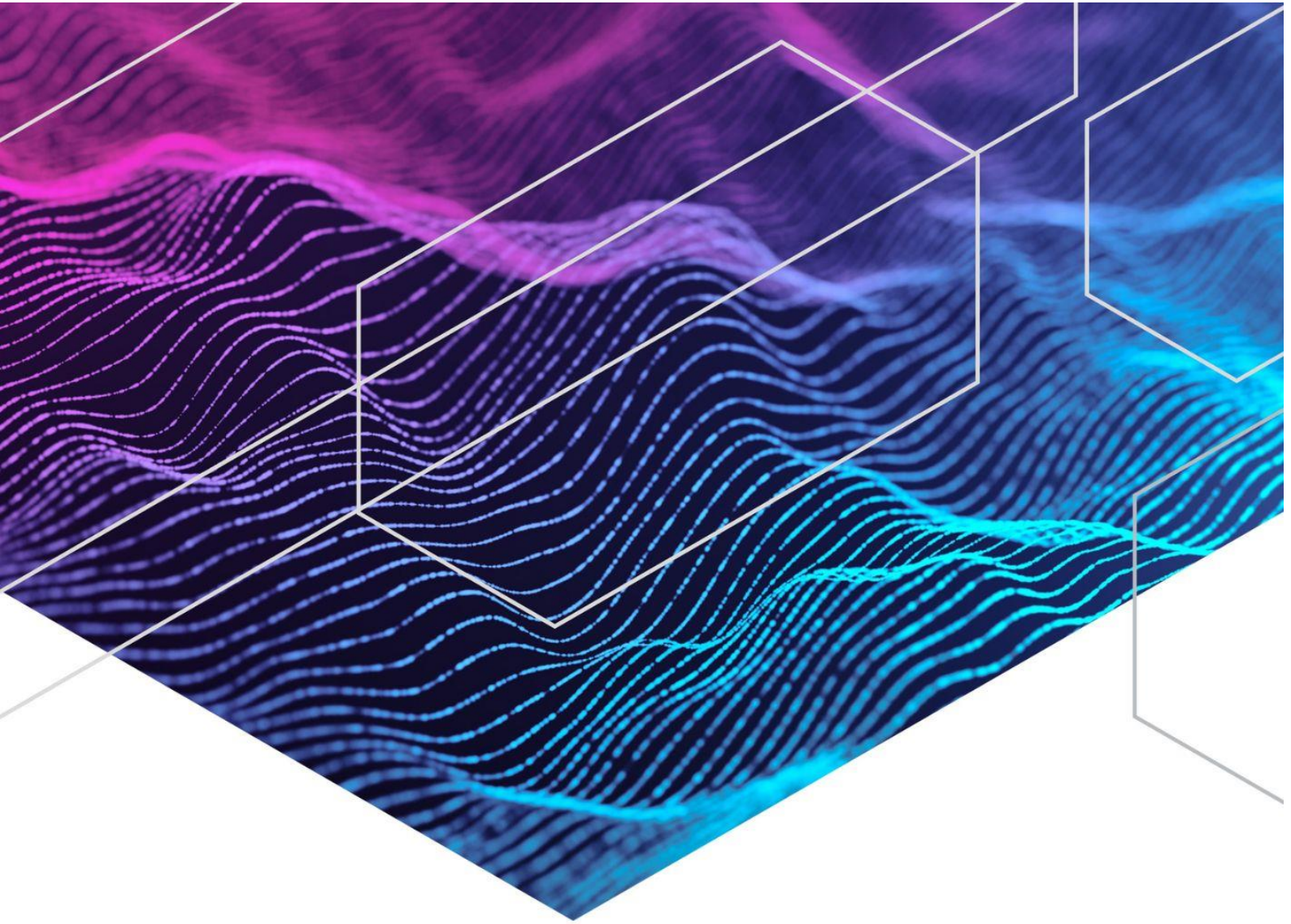

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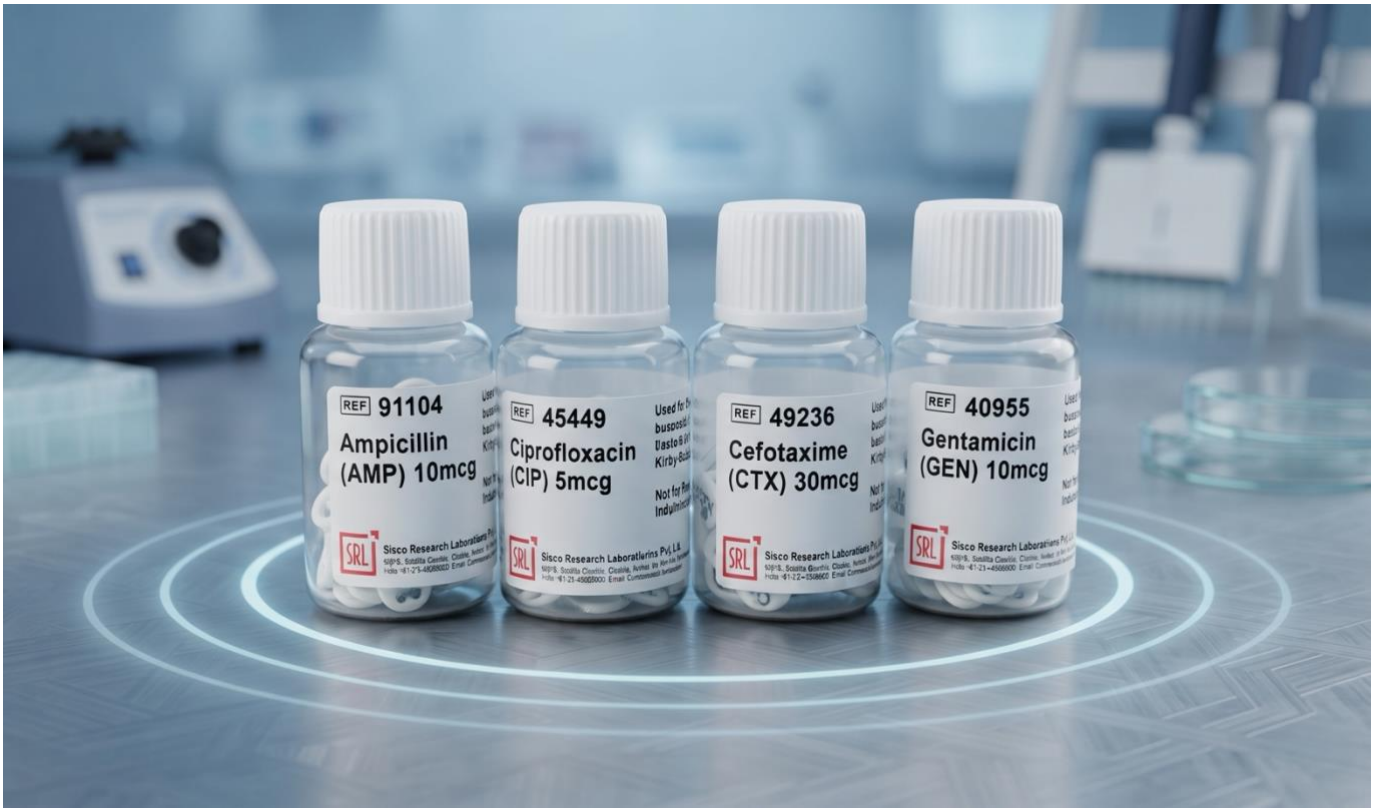

SRL Expands Microbiology Portfolio with AST Discs

Strengthening their microbiology offerings, Sisco Research Laboratories Pvt. Ltd. (SRL) has just launched Advanced Antibiotic Susceptibility Testing (AST) Discs. **These AST Discs are designed to support accurate, reliable, and reproducible antimicrobial susceptibility testing, meeting the performance expectations of modern microbiology laboratories.**

SRL AST Discs, which are designed for use with the universally accepted Kirby-Bauer Disc Diffusion Method, allow laboratories to perform antimicrobial susceptibility testing with confidence. **These AST Discs comply with the Clinical and Laboratory Standards Institute (CLSI), ensuring dependable performance in diffusion across various laboratory applications.**

SRL AST Discs are manufactured to ensure consistent quality and reliable performance in antimicrobial susceptibility testing.

The discs are made with high-quality, even-thickness filter paper, containing specified quantities of the antibiotic, and are coded with precision screen printing.

Their AST Discs are offered with the following antibiotics, among others:

1. Ampicillin 10 mcg,
2. Colistin 10 mcg,
3. Nalidixic Acid 30 mcg,
4. Vancomycin 30 mcg **and many more...**

Designed to support advanced microbiological testing, the new AST Discs are applicable in multiple laboratory environments, including

1. Clinical Microbiology Laboratories
2. Pharmaceutical Quality Control Laboratories
3. Diagnostic Laboratories
4. Research and Development Laboratories

The launch of the new products supports SRL's commitment to provide reliable microbiology solutions that help address the needs of laboratories by providing advanced solutions to professionals in health care, pharmacy, and research.

About SRL

For over 50 years, Sisco Research Laboratories Pvt. Ltd. (SRL) has earned a prominent position in India's professional marketplace.

With three advanced manufacturing units, SRL has the capacity to produce over 10,000 products. Each of these units is certified for quality under ISO 9001:2015 and is compliant with GMP, FDA, and CE regulations. SRL has established itself as the preferred supplier for buyers in over 15 industry sectors. These include pharmaceuticals and biotechnology (and related areas), healthcare, agriculture, oil and gas, consumer products, research and development, and areas related to and including science and technology. SRL has the ability to undertake and manage product development on its own, and as a result, has a continuous flow of newer and innovative products that have positive recognition from the scientific community. SRL is committed to the empowerment of laboratories and industries with a team of more than 500 authorized distributors and dealers.

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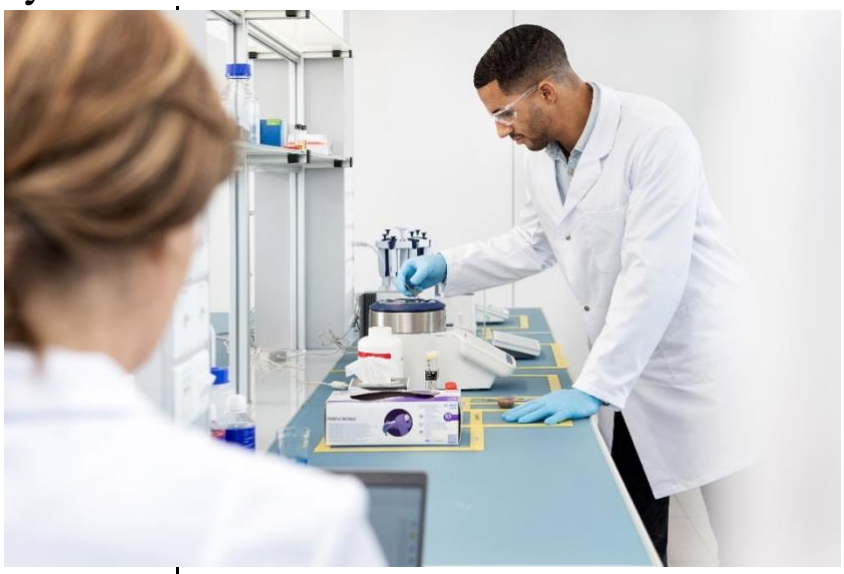
e: marketing@srlchem.com

The Lean Lab Approach: Revolutionizing Laboratory Efficiency and Productivity

In today's fast-paced and resource-conscious world, laboratories are under increasing pressure to deliver high-quality results quickly and cost-effectively. One powerful strategy that has emerged to meet these challenges is the Lean Lab approach, which adapts the proven principles of Lean Manufacturing to the unique environment of laboratories.



What is Lean?

Lean principles originated in manufacturing with the goal of maximizing value by eliminating waste. While traditionally applied on production floors, these principles are highly adaptable to laboratories. Lean in the lab focuses on streamlining workflows, standardizing equipment, optimizing workspaces, minimizing non-value-adding activities, and fostering employee engagement.

Core Benefits of a Lean Lab

Implementing Lean methodologies in the laboratory offers several key benefits:

1. Consistent and predictable lab performance
2. Reduced lead times and operational costs
3. Clear understanding of lab capacity and resource needs
4. Enhanced productivity and customer service
5. Improved right-first time (RFT) results
6. A culture of proactive continuous improvement

The goal is to minimize non-value-adding activities and achieve more with less, using tools such as the 5S methodology, waste reduction frameworks, and progress metrics.

The Nine Steps to Lean in Laboratories

1. **Housekeeping – Keep It Simple:** A well-organized lab environment streamlines work and boosts efficiency.
2. **Value-Stream Mapping – Minimizing Overproduction:** Analyze and optimize workflow steps to reduce or eliminate unnecessary activities.
3. **Workload – Reduce Waiting Time:** Minimize delays by ensuring a steady supply of critical materials and resources.

4. **Optimizing Laboratory Workflow:** Design the lab layout to reduce unnecessary movement, optimize sample flow, and place equipment logically.
5. **Performance Management:** Focus on preventing errors and improving accuracy through error reduction strategies and automated data management.
6. **Optimizing Equipment Performance:** Maintain and calibrate equipment regularly to prevent defects and ensure reliability.
7. **Maximizing Laboratory Personnel Skills:** Invest in training and flexibility to unlock the full potential of the team.
8. **Optimizing Chemical and Material Inventory Management:** Manage inventory effectively to reduce waste, control costs, and maintain safety.
9. **Continuous Improvement Process – Trust Your Staff:** Empower employees to drive ongoing improvements, fostering innovation and accountability.

Conclusion

Adopting Lean Lab principles transforms laboratory operations by creating an environment focused on efficiency, quality, and continuous improvement. By streamlining processes, engaging staff, and eliminating waste, laboratories can enhance productivity, reduce costs, and deliver reliable results faster.

The Lean Lab approach is not just a methodology but a culture shift that equips labs to meet the demands of modern science and industry with agility and excellence.

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 METTLER TOLEDO is available at www.mt.com.

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Alembic Pharma gains after partner NATCO receives USFDA tentative nod for Olaparib tablets

Alembic Pharmaceuticals rose 1.71% to Rs 839.50 after the company announced that its partner, NATCO Pharma, has received tentative approval from the US Food and Drug Administration (USFDA) for Olaparib Tablets in strengths of 100 mg and 150 mg.

The approved abbreviated new drug application (ANDA) is therapeutically equivalent to the reference listed drug (RLD), Lynparza Tablets, 100 mg and 150 mg, marketed by AstraZeneca Pharmaceuticals LP, for the indications specified in the approved labelling.

Under the partnership arrangement, NATCO Pharma will manufacture the Olaparib tablets, while Alembic Pharmaceuticals will distribute the product in the United States.

Olaparib, marketed under the brand name Lynparza, is a targeted cancer therapy belonging to the class of PARP inhibitors. It is indicated for the treatment of certain types of ovarian, breast, pancreatic and prostate cancers by preventing cancer cells with specific genetic mutations, such as BRCA or HRR mutations, from repairing damaged DNA.

The company said the Paragraph IV (Para IV) patent litigation related to the product is ongoing. According to IQVIA, Olaparib Tablets, 100 mg and 150 mg, had an estimated U.S. market size of approximately $1.4 billion for the 12 months ended March 2026.

With this approval, Alembic Pharmaceuticals now has a cumulative total of 244 ANDA approvals from the USFDA, comprising 224 final approvals and 20 tentative approvals. Alembic Pharmaceuticals is a vertically integrated research and development pharmaceutical company. It manufactures and markets generic pharmaceutical products all over the world. Its research and manufacturing facilities are approved by regulatory authorities of many developed countries, including the USFDA.

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The company's consolidated net profit jumped 29.19% to Rs 202.70 crore in Q4 FY26, compared to Rs 156.89 crore posted in Q4 FY25. Revenue from operations grew 4.41% year on year (YoY) to Rs 1,847.72 crore in the quarter ended 31 March 2026.

Alembic Pharma Falls 2% on USFDA Warning Letter

Alembic Pharmaceuticals shares slipped as much as 2% on Tuesday, 14 July, touching a day low of Rs 814.55 on the NSE.

The fall came after the company disclosed a USFDA warning letter tied to its Vadodara bioequivalence facility. The letter is dated 10 July, 2026. Alembic said it became aware of the communication on 12 July.

According to the company, the warning letter relates to a clinical investigator involved in a bioequivalence study at the Vadodara site. It follows a USFDA inspection carried out at the facility between 3 and 7 March, 2025.

Alembic clarified that the observations concern the Informed Consent Form used during the study. The company also said these observations are not related to data integrity.

Based on its initial assessment, Alembic said the warning letter does not restrict operations at the bioequivalence facility. The company does not expect any material financial impact at this stage either.

It added that it is now working closely with the clinical investigator. The goal is to prepare a response for the USFDA within the prescribed timeline.

A clinical investigator oversees a research study from start to finish. Their job includes preparing the study protocol, monitoring participant safety, and reporting results once the trial wraps up.

Coming to the stock price, shares were trading at Rs 824.05 on the NSE at 13:16 pm. That's down 0.84% from Monday's close of Rs 831.05.

The stock touched an intraday high of Rs 834.75 earlier in the session before slipping into negative territory. Alembic Pharma is down 20.04% over the past year and remains well off its 52 week high of Rs 1,044.80.

Cipla Arm Receives One USFDA Observation at New York Facility

Cipla's wholly owned subsidiary, InvaGen Pharmaceuticals, received one Form 483 observation after a routine USFDA inspection at its New York manufacturing facility

InvaGen Pharmaceuticals Inc., a wholly owned subsidiary of Cipla, received one inspectional observation from the US Food and Drug Administration (USFDA) following a routine inspection at its manufacturing facility in Central Islip, Long Island, New York.

Shares of Cipla Ltd. closed at Rs 1,418.7 apiece on Friday, 17 July, on the National Stock Exchange, after declining by 0.76% in the intraday session.

Routine cGMP Inspection & One Form 483 Observation

According to the company's exchange filing, the inspection was a routine current Good Manufacturing Practices (cGMP) inspection conducted at InvaGen Pharmaceuticals' manufacturing facility in Central Islip, Long Island, New York.

The inspection commenced on July 13 and concluded on July 17, 2026.

At the conclusion of the inspection, the USFDA issued one observation in the Form 483 to the manufacturing facility.

A Form 483 is issued when investigators identify conditions that may require corrective action and does not, by itself, indicate a final regulatory action.

Cipla said it will work closely with the USFDA and is committed to addressing the observation comprehensively within the stipulated timeline.

"On conclusion of the inspection, the Company has received 1 (one) inspectional observation in Form 483. The Company will work closely with the USFDA and is committed to addressing this comprehensively within the stipulated time," the company said in its regulatory filing.

In a separate filing, the company announced the schedule for the release of financial results for the first quarter of fiscal 2027. The results will be announced on 23 July 2026, following which the company will conduct an earnings conference call to discuss the financial performance of the company.

"The Company will host an earnings conference call at 1600 hrs IST (1830 hrs SST/HKT, 1130 hrs BST, 0630 hrs US ET), during which the leadership team will discuss financial performance and take questions," the company said in the exchange filing.

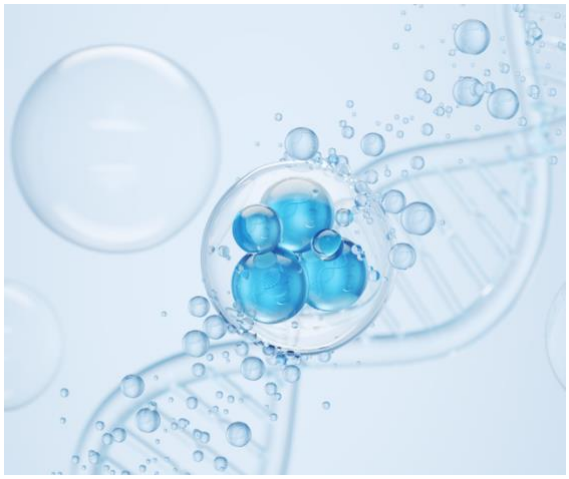
India Accelerates mRNA Vaccine Manufacturing with New Biopharma Investments

India is witnessing a major expansion in mRNA vaccine manufacturing as leading pharmaceutical companies announce fresh investments in advanced biologics facilities. The initiative aims to strengthen domestic capabilities for pandemic preparedness while expanding exports to South East Asia, Africa, and the Middle East. Several manufacturers are upgrading GMP production lines equipped with single-use bioprocessing systems, automated fill-finish technologies, and advanced quality control laboratories. The investments are expected to reduce dependency on imported vaccine technologies and improve manufacturing flexibility. Government-backed incentives under pharmaceutical manufacturing initiatives continue to attract multinational collaborations. Industry experts believe these developments will significantly improve India's position in the global vaccine supply chain.

Demand for thermostable vaccine formulations and rapid-response manufacturing platforms is also encouraging companies to invest in next-generation production technologies.

Singapore Emerges as Regional Hub for Cell & Gene Therapy Manufacturing

Singapore continues to strengthen its position as one of Asia's premier destinations for advanced cell and gene therapy manufacturing following several new facility expansions announced by international biopharmaceutical companies.



The country's highly developed regulatory framework, skilled workforce, and advanced biomedical ecosystem have attracted significant investments in viral vector production, CAR-T manufacturing, and personalized medicine.

Industry analysts expect demand for contract development and manufacturing organizations (CDMOs) specializing in advanced therapies to grow rapidly over the next five years as more therapies move toward commercialization.

Collaborations between academic institutions and pharmaceutical manufacturers are accelerating innovation in precision medicine across South East Asia.

Malaysia Expands Pharmaceutical Packaging Capacity for Regional Exports

Malaysia's pharmaceutical sector is experiencing robust growth as several manufacturers invest in high-speed packaging and serialization facilities designed to meet increasing export demand throughout ASEAN markets.

The new investments include automated inspection systems, track-and-trace technologies, and sustainable packaging solutions that comply with evolving international regulatory standards. Industry leaders indicate that pharmaceutical packaging is becoming increasingly important as biologics, specialty medicines, and temperature-sensitive products require enhanced protection during transportation.

The country also aims to strengthen its position as a preferred pharmaceutical manufacturing destination by improving supply chain resilience and digital manufacturing capabilities.

Thailand Expands Clinical Research Infrastructure for Global Drug Development

Thailand is rapidly becoming a preferred destination for multinational pharmaceutical companies seeking high-quality clinical trial sites supported by experienced investigators and modern healthcare infrastructure.

Recent investments are improving patient recruitment capabilities, digital clinical trial management systems, and decentralized research models designed to accelerate study timelines.

Regulatory agencies are working closely with industry stakeholders to streamline clinical trial approvals while maintaining stringent ethical and patient safety standards.

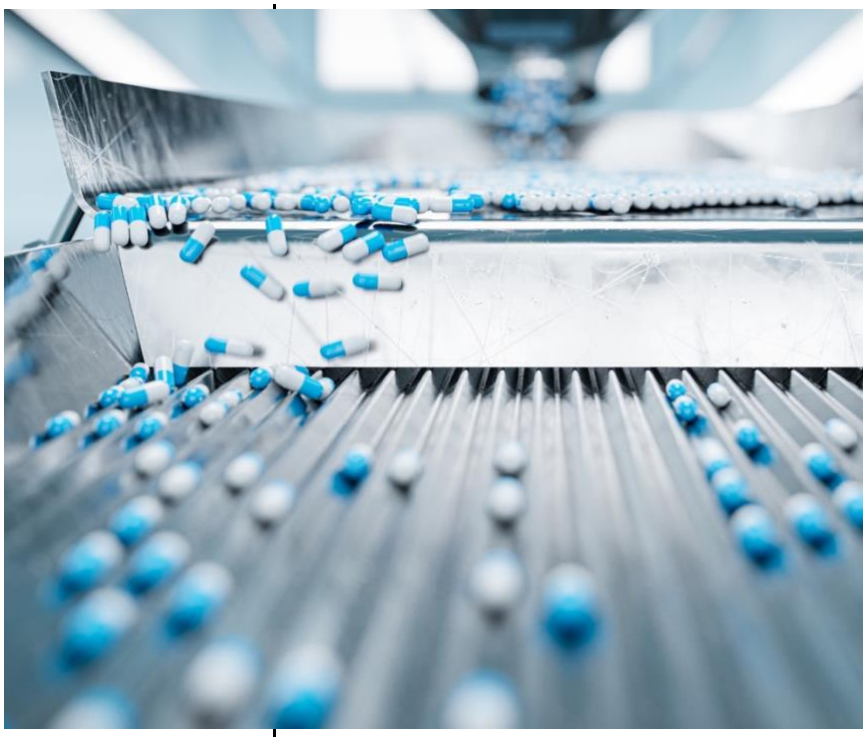
Experts believe Thailand's growing expertise in oncology, infectious diseases, and metabolic disorders will attract additional global pharmaceutical research programs.

Indonesia Strengthens Local API Manufacturing to Reduce Import Dependence

Indonesia has announced fresh initiatives to increase domestic Active Pharmaceutical Ingredient (API) production as part of a broader strategy to strengthen pharmaceutical self-reliance and improve healthcare security.

Several manufacturers are investing in advanced chemical synthesis, fermentation technologies, and environmentally sustainable production methods to support local medicine manufacturing. The expansion is expected to improve supply chain resilience while reducing vulnerability to international raw material disruptions experienced in recent years.

Industry observers anticipate stronger collaborations between government agencies, universities, and pharmaceutical companies to accelerate technology transfer and workforce development.



ASEAN Digital Quality Transformation Gains Momentum Across Pharmaceutical Manufacturing

Pharmaceutical manufacturers across South East Asia are increasingly adopting AI-driven quality management systems, electronic batch records, digital laboratories, and predictive maintenance technologies to improve operational efficiency.

The digital transformation is helping companies reduce deviations, improve data integrity, and strengthen compliance with global GMP expectations while accelerating product release timelines.

Cloud-based manufacturing execution systems and laboratory information management systems (LIMS) are becoming standard investments among both multinational and regional pharmaceutical manufacturers.

Experts believe digital manufacturing will become one of the biggest competitive differentiators for pharmaceutical companies operating across the ASEAN region over the coming decade.

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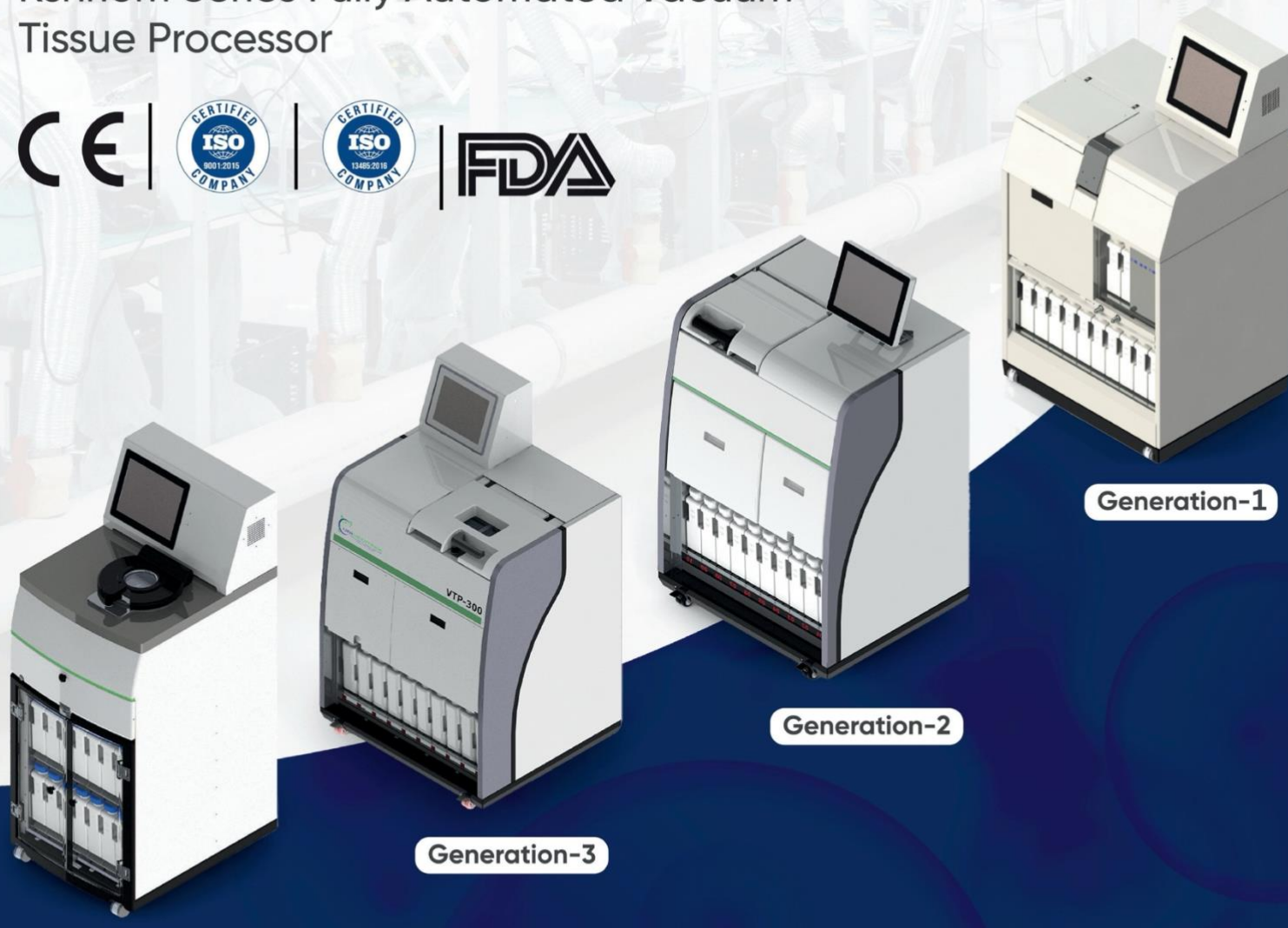

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USFDA Grants Accelerated Approval to Vera Therapeutics' Trutakna™ for IgA Nephropathy

The U.S. Food and Drug Administration (USFDA) has granted accelerated approval to **Trutakna™ (atacicept-vymj)** developed by **Vera Therapeutics** for the treatment of adults with primary Immunoglobulin A Nephropathy (IgAN). The therapy represents an important advancement for patients at risk of progressive kidney disease.

Trutakna is the first FDA-approved therapy designed to simultaneously inhibit both BAFF and APRIL, two proteins involved in abnormal immune activation associated with IgAN.

Clinical studies demonstrated meaningful reductions in proteinuria, an important indicator of kidney disease progression.

Researchers believe the approval reinforces growing industry interest in precision immunology and targeted biologic therapies for rare renal diseases. Additional post-marketing studies are planned to evaluate long-term renal outcomes.

Merck Secures USFDA Approval for Lipfendra™— First Oral PCSK9 Cholesterol Therapy

Merck & Co. has received USFDA approval for **Lipfendra™ (enlicitide)**, becoming the first oral PCSK9 inhibitor available for lowering LDL cholesterol in patients who require additional lipid control beyond statins.

Clinical trials showed LDL cholesterol reductions approaching 60%, offering physicians an oral alternative to injectable PCSK9 therapies. Industry experts believe the approval could significantly expand access to advanced cholesterol management.

The approval is expected to intensify competition in the cardiovascular market, with several pharmaceutical companies advancing next-generation lipid-lowering medicines.

Natco Pharma Receives USFDA Tentative Approval for Generic Olaparib Tablets

Natco Pharma has received tentative approval from the USFDA for its generic version of **Olaparib Tablets**, expanding its oncology portfolio for the U.S. market. The announcement has strengthened investor confidence and highlights the company's growing presence in complex generic oncology medicines.

Olaparib is widely used in the treatment of ovarian, breast, pancreatic, and prostate cancers carrying specific genetic mutations. Once patent exclusivity conditions are met, Natco will be positioned to commercialize its generic product in the United States.

The development further demonstrates the increasing success of Indian pharmaceutical companies in obtaining USFDA approvals for high-value specialty medicines.

Gilead Advances Next-Generation HIV Research with Long-Acting Therapies

Gilead Sciences continues to strengthen its leadership in HIV innovation through research on long-acting prevention and treatment options, including **Yeztugo™** and **Sunlenca®**. The company is also collaborating on weekly oral HIV treatment strategies aimed at improving patient adherence.

Researchers are focusing on therapies requiring fewer annual doses while maintaining long-term viral suppression. Long-acting medicines are expected to transform HIV management worldwide by reducing treatment burden. The competitive landscape continues to evolve as several pharmaceutical companies accelerate research into curative approaches, immune-based therapies, and gene-editing technologies.

USFDA Highlights Strong Pipeline of Novel Drug Approvals During 2026

The USFDA has continued to approve innovative therapies across immunology, rare diseases, dermatology, hepatology, and endocrinology, reflecting sustained momentum in pharmaceutical innovation. Among the notable approvals are **Icotyde™**, **Lynavoy™**, **Yuviwel™**, and **Loargys™** for significant unmet medical needs.

Industry analysts report that the number of novel drug approvals during the first half of 2026 remains comparable to previous high-performing years, demonstrating continued investment in breakthrough drug development.

Pharmaceutical companies are increasingly prioritizing biologics, targeted therapies, gene medicines, and precision diagnostics to support future product pipelines.

USFDA Introduces New Regulatory Initiatives to Accelerate Drug Development

The USFDA has announced updated regulatory initiatives designed to accelerate innovative drug development through more efficient clinical trial designs and expanded use of advanced statistical methodologies. The new framework encourages greater use of digital technologies, streamlined clinical development pathways, and modern evidence-generation strategies.

Regulatory experts believe these changes could reduce development timelines while maintaining rigorous standards for safety and efficacy. Pharmaceutical companies are expected to increasingly adopt adaptive trial designs, real-world evidence, and AI-supported analytics.

The updated regulatory approach is anticipated to benefit biotechnology companies developing treatments for oncology, rare diseases, neurological disorders, and precision medicine.

2Mag bioMIX Technical Spec: Precision Cell Culture Stirring

Efficient mixing is a vital activity in most cell culture, biotechnology, and pharmaceutical research. The 2Mag bioMIXdrive 2, unlike other magnetic stirrers, is optimized for cell culture and other sensitive laboratory applications. It provides maintenance-free, wear-free, and heat-free stirring.

Maintenance-Free and Wear-Free Technology

The bioMIXdrive 2 is based on a proprietary magnetic drive technology that, because there is no mechanical wear, provides a long-term solution without the need for maintenance. The stirring occurs quickly and without vibration and is designed to limit shear stress.

Ultra-Flat Design with Dual Stirring Positions

The bioMIXdrive 2 has an ultra-flat stainless steel body and fits within laboratory incubators. It provides two stirring positions and is designed to handle sample volumes from 5 mL to 5,000 mL, increasing versatility.

Precise and Gentle Mixing

The stirring speed for the bioMIXdrive 2 can be adjusted in the range of 5–250 rpm. At lower speeds, the stirring is performed in a smooth and controlled fashion, allowing mixing which is both thorough and gentle, and which will not adversely impact delicate cell cultures, nor the accuracy of the experiment.

Designed for CO_2 Incubators

The stirring performance of the bioMIXdrive 2 can be utilized for research performed in a CO_2 incubator.

It is designed to perform its function without providing any heating, ensuring that the incubation environment is not disturbed.

The stirrer functions dependably between -10°C and +50°C, performing extremely well between 0 and 100% RH. This makes the device suitable for continuous operations in the most demanding environments.

Product Showcase

Key Features

- Maintenance-free and wear-free magnetic drive
- Ultra-flat design with two stirring positions
- Stirring volume: **5–5,000 mL**
- Speed range: **5–250 rpm**
- Heat-free continuous operation in CO_2 incubators
- Operates from **-10°C to +50°C** at **100% humidity**
- Ideal for cell culture, biotechnology, pharmaceutical, and microbiology laboratories

To know more:

https://srico-labworld.com/2mag-ag/cell-culture-stirrers/biomixdrive-2/

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SRICO's product range includes Analytical Instruments, General Laboratory equipment and consumables. The products represented by us are supplied/supported across India through our own branch offices and residential representatives spread across India.

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Non-invasive real-time liquid flowmeters

Biotech Fluidics offers a range of non-invasive flowmeters for real-time, non-invasive monitoring of liquid flow.
Measuring liquid flow rate has traditionally been served by devices such as volumetric flow meters despite their significant limitations. Based upon the measurement principle of heat dispersion – Biotech Liquid Flow Meters offer unprecedented time resolution thereby providing new insights into flow variation and inconsistency. Compact in size, each Biotech Flow Meter comes with easy-to-use PC software enabling continuous accurate recording, monitoring, and storage of measured flow rate data.

Operating in real-time, with current flow rate displayed on the integral OLED display, users can spot transient pulsations helping them gain a detailed understanding of the flow stability of the device they are monitoring. Biotech Flowmeters are highly dependable and designed to be compatible with most solvents and liquid reagents.

Operating up to liquid flow rates of 650mL per minute, with a resolution of 0.02 mL per minute, the Biotech High Flow Meter is an ideal process optimization tool for monitoring preparative chromatographs used to produce larger quantities of pure compounds.

With an extended flow rate range of up to 40 mL/min, the new Biotech Semi-Prep Flow Meter is the perfect tool for continuous monitoring and validation of pumps serving both straight and reverse phase preparative HPLC, flash and continuous processing systems as well as bioreactor feed pumps.

Designed to operate over the range 1µL to 5mL per minute - the Biotech HPLC Flow Meter comes pre-calibrated and can be connected inline to continuously measure inline flow rates of liquids from pumps serving HPLC and GPC/SEC systems as well as flow chemistry reactors.

Operating over the flow range 0.01 to 80 µL per minute, with a resolution of 1nl per minute, the Biotech Micro Flow Meter is the perfect tool for precise monitoring of extremely low flow rates such as are encountered in UHPLC, LC/MS and micro- / nanoscale bioprocessing applications.

To learn more about the real time flowmeters range from Biotech Fluidics please visit https://www.biotechfluidics.com/products-sensors-flowmeter/ or contact the company on + 46 300 56 91 80 / + 1-612-703-5718 / info@biotechfluidics.com.

LigoLab and MarginLogic Health AI Partner to Automate Laboratory Data Entry

The integration uses artificial intelligence to capture data from paper requisitions, aiming to reduce manual entry and speed up laboratory processing.

LigoLab and MarginLogic Health AI have announced a marketplace agreement to integrate artificial intelligence-powered optical character recognition (OCR) technology into laboratory workflows.

The partnership allows clinical laboratories, reference labs, and pathology groups to automate requisition intake and accessioning within LigoLab's laboratory information system (LIS) and revenue cycle management informatics platform.

The integrated solution uses artificial intelligence to capture, interpret, and validate data from requisitions, physician orders, insurance cards, and patient demographics. Validated orders are then transmitted into the LigoLab platform. According to the companies, the integration results in faster accessioning, fewer manual keystrokes, and more efficient laboratory operations.

"Requisition intake and accessioning is where laboratories lose time and accuracy before a specimen even reaches the LIS," says Jenny Bull, LigoLab's success director, in a release. "Pairing MarginLogic Health AI's OCR with our platform lets high-confidence orders flow straight through, so staff can focus on the exceptions instead of retyping what should already be structured data."

Unlike traditional OCR solutions that convert images into text, the MarginLogic Health AI technology uses contextual artificial intelligence to understand clinical documents. The system recognizes handwritten and printed requisitions, validates extracted information, and flags ambiguous fields for human review.

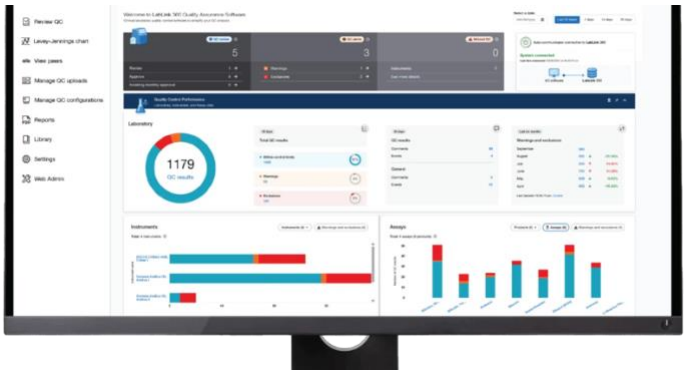
High-confidence requisitions are processed with minimal manual intervention, while lower-confidence fields are routed for review to ensure accuracy.

"Laboratories shouldn't lose hours retyping what a document already contains. Our AI reads a clinical requisition the way an experienced accessioner would — interpreting context, validating what it captures, and flagging only the fields that genuinely need a human," says Ammar Darkazanli, CEO and president of MarginLogic Health AI, in a release.

The partnership is intended for laboratories that receive volumes of faxed, handwritten, or paper requisitions. Even organizations with electronic ordering often process non-integrated orders that require manual entry. Beyond operations, the partnership aims to improve financial performance by increasing demographic accuracy and reducing transcription errors, which can minimize claim issues and denials.

The integration complements existing laboratory interfaces. Electronic orders from provider electronic health records continue to flow through established connections, while the AI technology automates the processing of paper-based and non-integrated requisitions. MarginLogic Health AI solutions are currently available to LigoLab customers.

Thermo Fisher Scientific Launches New Quality Assurance Software



The digital tool is designed to simplify quality control workflows and speed up decision-making in clinical laboratories.

Thermo Fisher Scientific has introduced LabLink 360 Quality Assurance software, a new digital solution intended to help clinical laboratories simplify quality control (QC) workflows and accelerate decision-making.

The software aims to improve visibility into QC performance and help staff proactively manage operations. According to the 2025 Westgard Global QC Practices Survey, one in three laboratories experience out-of-control QC events every day, and 75% of labs repeat controls during troubleshooting, which increases workload and delays results, according to a release from Thermo Fisher Scientific.

Automating Quality Control Review

LabLink 360 consolidates QC data and automates routine review steps. The software uses data visualizations and a centralized dashboard to bring QC metrics into a single view.

The platform also includes built-in peer group benchmarking, which allows for real-time comparison directly within daily workflows. For organizations with multiple locations, the software provides oversight across multi-site and referral networks. These features allow issues that previously required manual cross-referencing to be identified, prioritized, and resolved faster, according to the company.

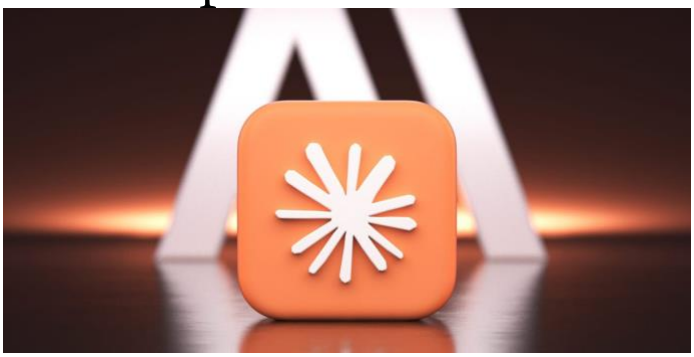
"Clinical laboratories are being asked to do more with less," says Anuj Dhingra, vice president and general manager, niche diagnostics, clinical diagnostics division, Thermo Fisher Scientific, in a release. "LabLink 360 extends our MAS portfolio into the workflow itself, giving laboratory staff the data and automation they need to focus on what actually requires their expertise."

Integration with Automation Workflows

The software is designed to work with the MAS Quality Controls portfolio. It adds a workflow and analytics layer that supports integration with MAS Max Load & Go Automation Workflows, which are used in high-volume and automated testing environmentts.

Global availability of the software will be phased according to local regulatory and market requirements, according to the company.

Revvity Connects Signals Research Platform to Anthropic Claude



The collaboration enables scientists to access data and scientific knowledge through an artificial intelligence workbench.

Revvity Signals Software has joined Anthropic's directory for Model Context Protocol (MCP) connectors, allowing scientists to access research and development data through the artificial intelligence model Claude.

The integration includes access to Claude Science, an artificial intelligence workbench for scientific research. Through the connector, Claude can access information via an intelligence layer, which helps researchers search and analyze complex research and development data using natural language, according to a press release from Revvity.

"Signals AI was designed to help scientists transform connected R&D data into understanding, decisions and action," says Kevin Willoe, president of Revvity Signals Software, in a release. "By joining Anthropic's MCP ecosystem, we're extending the reach of our Signals AI beyond our Signals One platform and enabling researchers to combine Claude's reasoning capabilities with the governed data, ontology-driven scientific context and trusted knowledge managed across the entire Revvity Signals offering."

The integration complements a recently launched framework that embeds artificial intelligence capabilities across the Signals One platform. The new connector allows scientists who use Claude to securely access their connected data and scientific context from the software platform.

By connecting the artificial intelligence to the software platform, scientists can access organizational knowledge, experimental data, and scientific context through natural language interactions, according to the press release. The company states the system is intended to maintain traceability and scientific precision while helping researchers act on complex data.

The collaboration aims to combine artificial intelligence capabilities with scientific workflows to help accelerate research and development, according to Revvity. Scientists can now use Claude to interact with connected knowledge managed across the software business's offerings.

Labcorp Launches RNA-Based At-Home Colorectal Cancer Test Nationwide

The test detect signs of colorectal cancer and precancerous growths using a home collection kit.

Labcorp announced the nationwide availability of ColoSense, an RNA-based at-home screening test for colorectal cancer approved by the Food and Drug Administration (FDA).

Offered through a commercial collaboration with test developer Geneoscopy, the test expands Labcorp's range of colorectal cancer screening solutions. The test is now covered for eligible Medicare and Medicare Advantage beneficiaries following an update to the National Coverage Determination by the Centers for Medicare & Medicaid Services in June, with additional commercial coverage also available.

ColoSense uses RNA-based technology to detect biomarkers associated with colorectal cancer and advanced adenomas, which are precancerous changes that may be an early indication of disease. The test aligns with stool-based RNA screening approaches recognized in the American Cancer Society colorectal cancer screening guidelines and is included as a recommended screening option in the National Comprehensive Cancer Network guidelines.

"Labcorp is focused on improving colorectal cancer screening rates by offering at-home options consumers are more likely to complete," says Brian Caveney, chief medical and scientific officer at Labcorp, in a release. "With ColoSense now available nationwide, we're expanding access to an FDA-approved screening option that delivers advanced science and a more streamlined, easier-to-use collection experience."

The test is available through healthcare providers for adults aged 45 to 85 at average risk. It is not intended for individuals with a history of colorectal cancer or certain high-risk conditions. In clinical performance evaluations, the test demonstrated 93% sensitivity for colorectal cancer in average-risk individuals and achieved 100% sensitivity for stage I colorectal cancer, according to the company.

"ColoSense reflects years of scientific innovation focused on improving how we screen for colorectal cancer at home," says Matt Sargent, chief commercial officer at Geneoscopy, in a release.

The collection kit is delivered directly to the consumer's home and features a design that eliminates the need to separate or mix the stool sample. Labcorp research indicates that among users of at-home screening tests, 41% were uncomfortable preparing the sample, and 34% said the process felt messy.

Geneoscopy provides patient navigation support to help individuals understand their results and follow recommended next steps, including a colonoscopy after a positive result. Labcorp notes that ColoSense is a screening test and does not replace diagnostic colonoscopy.

Thermo Fisher Unveils AI-Driven Orbitrap™ Mass Spectrometry Workflow at ASMS 2026

Thermo Fisher Scientific has introduced its latest AI-powered mass spectrometry workflow during ASMS 2026, integrating advanced Orbitrap technologies with intelligent software designed to accelerate proteomics, biopharmaceutical characterization, and biomarker discovery. The launch highlights the growing role of artificial intelligence in analytical laboratories.

The newly introduced platform combines enhanced spectral interpretation, automated peptide identification, and streamlined data processing to improve laboratory productivity while reducing manual review.

One of the major highlights is the integration of AI-assisted software capable of identifying complex proteins with greater confidence, supporting pharmaceutical research, biologics development, and precision medicine applications.

Researchers can now process significantly larger datasets while maintaining high analytical sensitivity, making the system particularly valuable for multi-omics research and next-generation drug discovery.

Industry experts believe AI-enabled analytical instruments will become standard across pharmaceutical quality control laboratories over the next few years.

The launch also reflects Thermo Fisher's continued investment in digital laboratory transformation and cloud-enabled scientific workflows.

Agilent Launches Infinity III LC Series with Smart Diagnostics

Agilent Technologies has officially launched its new **Infinity III LC Series**, introducing intelligent troubleshooting, guided maintenance, and automated workflow optimization for pharmaceutical analytical laboratories. The new system debuted as one of the headline product launches showcased during Pittcon 2026.

Agilent Technologies

The Infinity III family includes upgraded HPLC systems designed for pharmaceutical quality control, food safety testing, environmental analysis, and academic research laboratories.

A key innovation is the built-in **InfinityLab Assist Technology**, which continuously monitors instrument health, provides predictive diagnostics, and minimizes laboratory downtime.

The new Hybrid Multisampler introduces Feed Injection technology that improves chromatographic performance, especially for challenging solvent conditions.

Agilent has also expanded its consumables portfolio with new inert HPLC columns and advanced bioseparation columns to support oligonucleotide, biologics, and protein analysis.

Analytical laboratories are expected to benefit from faster method development, higher reproducibility, and reduced maintenance requirements.

SCIEX Introduces AI-Enhanced OS 5.0 Software for ZenoTOF Platforms

SCIEX has launched the latest **SCIEX OS 5.0** software featuring integrated AI-powered workflow automation for its ZenoTOF mass spectrometry systems, providing laboratories with faster data interpretation and simplified analytical workflows.

SCIEX
The power of precision

The software incorporates intelligent peak detection, automated calculations, and enhanced reporting capabilities that significantly reduce manual processing time.

Developed for pharmaceutical, biotechnology, clinical research, and environmental laboratories, the platform enables scientists to obtain higher confidence results with improved operational efficiency.

The updated interface also improves laboratory compliance through standardized reporting and secure data management features.

AI-assisted data analysis is expected to improve productivity for laboratories handling high-throughput analytical testing and complex biologics characterization.

Industry analysts view this launch as another important milestone in the transition toward autonomous analytical laboratories.

Shimadzu Launches AI Performance Concierge for Next-Generation LC-MS

Shimadzu Corporation has introduced its latest intelligent laboratory platform featuring **AI Performance Concierge** technology designed to simplify LC-MS operation and predictive maintenance. The innovation was demonstrated during recent analytical science conferences.

The software continuously monitors instrument health, predicts maintenance requirements, and assists laboratory personnel with automated troubleshooting recommendations.

Shimadzu has also integrated advanced Peak Intelligence capabilities that automatically optimize chromatographic peak detection and improve quantitative analysis.

SHIMADZU
Excellence in Science

The system significantly reduces routine instrument monitoring while improving uptime for pharmaceutical quality control laboratories.

Researchers performing metabolomics, food safety, toxicology, and clinical research are expected to benefit from increased analytical efficiency.

Digital automation continues to reshape modern laboratories by minimizing operator intervention and maximizing instrument utilization.

Bruker Expands Multi-Omics Portfolio with Advanced Spatial Biology Solutions

Bruker has unveiled new mass spectrometry and spatial biology technologies designed to strengthen multi-omics research, pharmaceutical biomarker discovery, and precision medicine applications. The launches were among the major highlights at ASMS 2026.

The latest instruments provide higher sensitivity, improved molecular imaging resolution, and faster acquisition speeds for complex biological samples.

Researchers can now combine proteomics, metabolomics, and spatial imaging data within integrated analytical workflows to generate more comprehensive biological insights.

The systems are expected to accelerate translational research across oncology, neuroscience, and immunology.

Enhanced software capabilities further improve laboratory automation, data visualization, and AI-assisted interpretation.

Industry experts anticipate growing adoption of spatial biology technologies as pharmaceutical companies increasingly invest in precision therapeutics.

Waters and Industry Partners Advance AI-Powered Mass Spectrometry Data Platforms

Waters Corporation, together with several leading analytical technology partners, has highlighted new AI-enabled data management platforms aimed at improving mass spectrometry workflows, laboratory collaboration, and scientific data reuse.

The initiative was showcased during ASMS 2026. The platform supports intelligent processing of historical mass spectrometry datasets while improving reproducibility across multiple laboratories.

Researchers can combine analytical datasets from different instruments to enhance biomarker discovery, pharmaceutical development, and regulatory research.

Waters™

The initiative supports FAIR (Findable, Accessible, Interoperable, and Reusable) scientific data principles, encouraging greater collaboration throughout the life sciences community.

The new digital ecosystem is expected to improve laboratory efficiency while reducing redundant experimentation and accelerating scientific discoveries.

Industry leaders believe cloud-connected analytical laboratories supported by AI will define the next generation of pharmaceutical and biotechnology research.

Selection **Guide**

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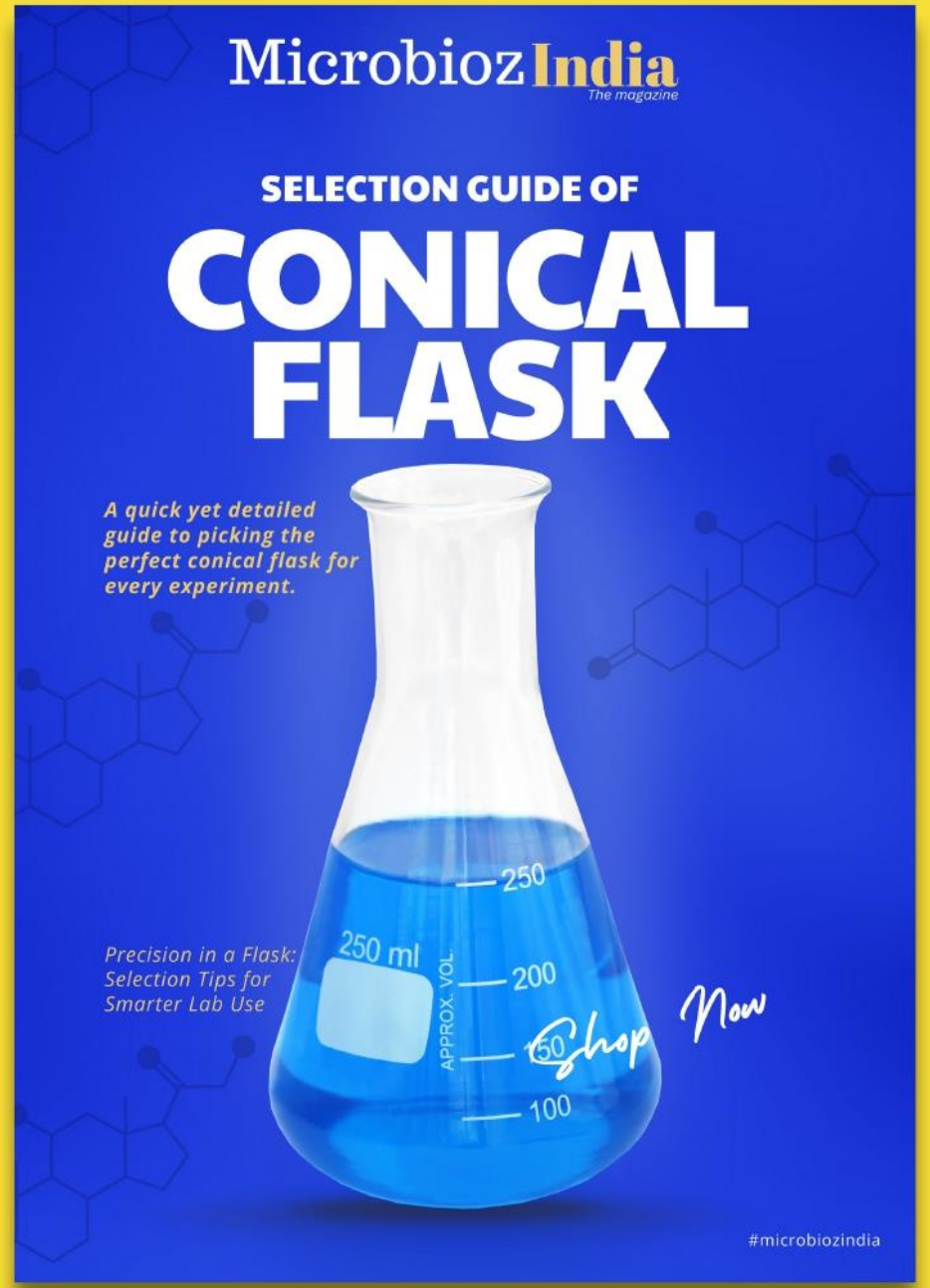

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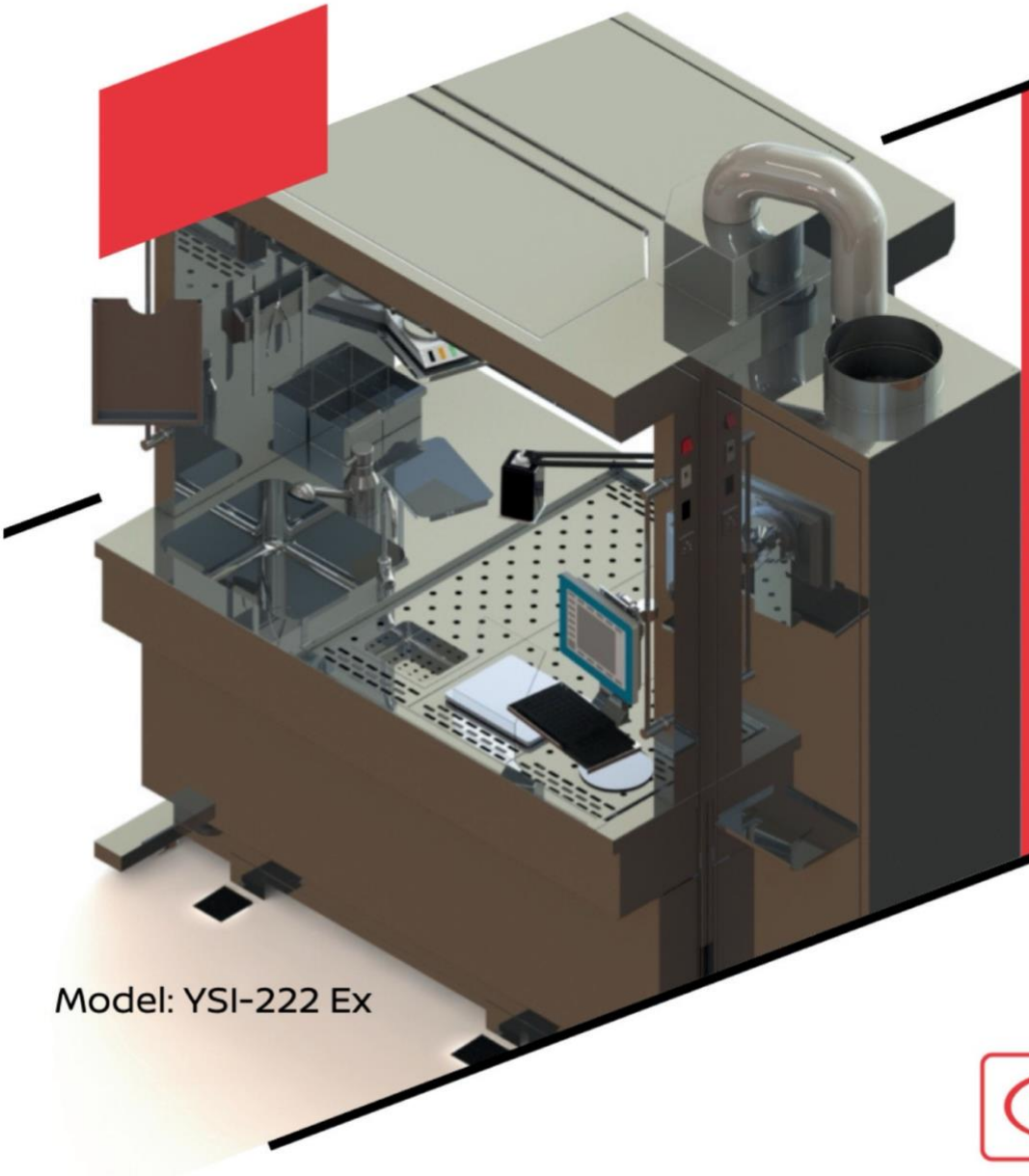

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