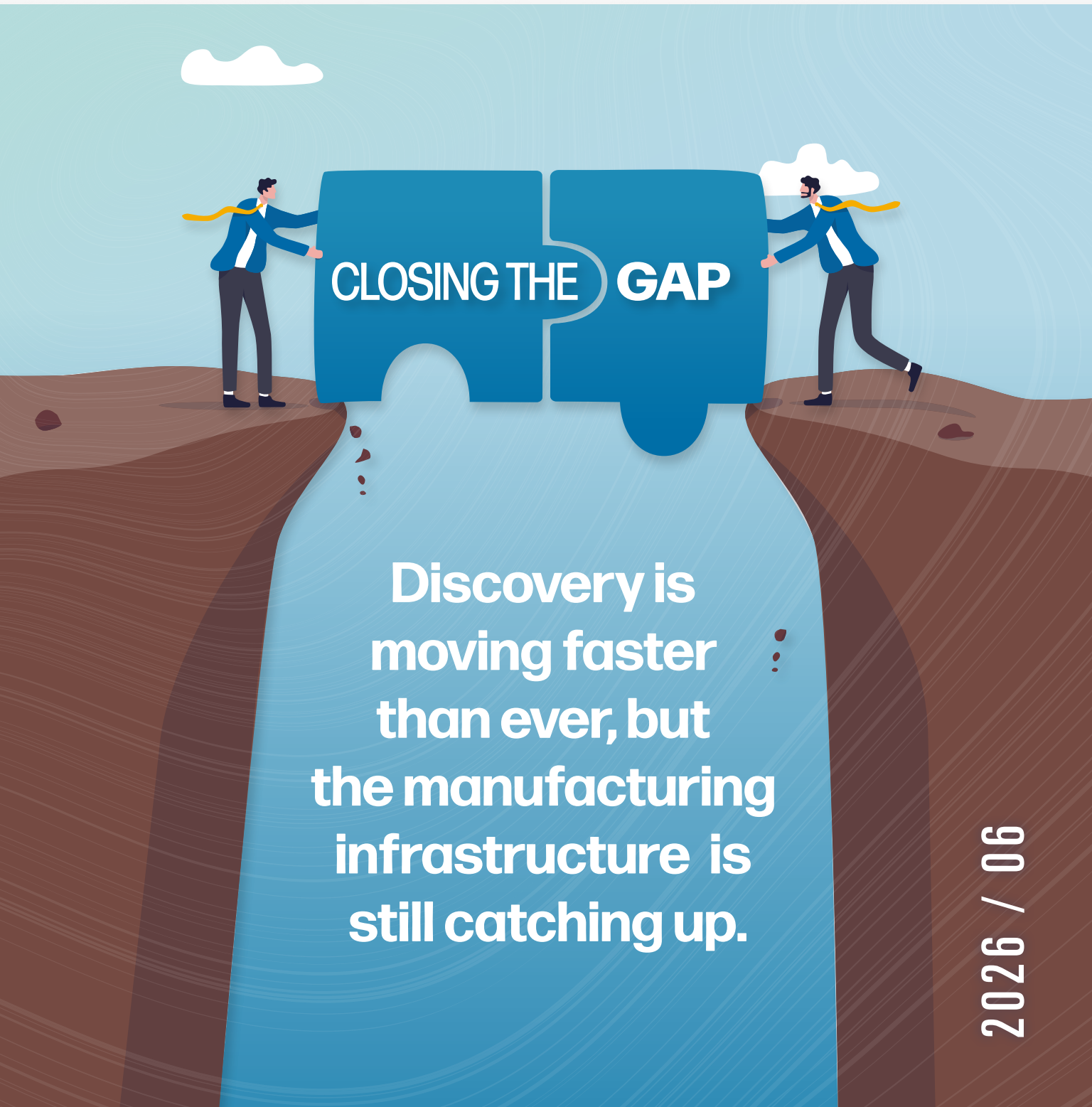
JUNE 2026 : VOLUME 1 : ISSUE 2

DISCOVERY INSIDER



Discovery is moving faster than ever, but the manufacturing infrastructure is still catching up.

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EXECUTIVE VICE PRESIDENT
Rob D'Angelo
rdangelo@labxmediagroup.com

VICE PRESIDENT OF CONTENT
Ash Board
aboard@labxmediagroup.com

EDITORIAL
Andrea Corona
acorona@drugdiscoverynews.com

Allison Whitten, PhD
awhitten@drugdiscoverynews.com

Bree Foster, PhD
bfoster@drugdiscoverynews.com

AUDIENCE ENGAGEMENT
Melissa Kay
mkay@drugdiscoverynews.com

CREATIVE SERVICES
Yuning Wang, PhD
ywang@drugdiscoverynews.com

Alejandra Manjarrez, PhD
amanjarrez@drugdiscoverynews.com

SALES DIRECTOR
Dana Sizing
315-956-0231
dsizing@drugdiscoverynews.com

ACCOUNT EXECUTIVE
Alex Comrie
315-956-0231
acomrie@drugdiscoverynews.com

ART DIRECTOR
Kristyn Reid
kreid@labx.com

OPERATIONS
Mikaela Swietlinska
mswietlinska@drugdiscoverynews.com

Jessie Huma
jhuma@drugdiscoverynews.com

Siobhan Swietlinska
sswietlinska@drugdiscoverynews.com

Kayla Van Volkenburg
kvanvolkenburg@drugdiscoverynews.com

SUBSCRIPTION SERVICES
ddnews@omeda.com
847-513-6029

editor's
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The gap is the story

Every issue, there's a thread that connects the stories even when we didn't plan it that way. This one has a clear one: the gap.

by **ANDREA CORONA**
SENIOR EDITOR

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THE GAP BETWEEN DISCOVERY AND MANUFACTURING. Between what science can do and what the infrastructure can support. Between early-stage promise and commercial reality. Between the tools we have and the complexity of the biology we're trying to understand.

We covered a lot of ground in this issue — SLAS, ASMS, INTERPHEX, CPHI Americas, Advanced Therapies Congress — and what kept surfacing across all of it wasn't any single technology or regulatory shift. It was this persistent distance between what drug developers know how to do and what the surrounding ecosystem is actually built to support.

At INTERPHEX, the conversation was direct about it: A 2025 analysis found that 74 percent of FDA complete response letters cited quality and manufacturing deficiencies. At CPHI, a panel on cell and gene therapy (CGT) made the same case from a different angle: The biology of CGT has largely arrived. What hasn't arrived yet is the manufacturing, commercial, and clinical scaffolding to deliver it at scale. And at SLAS Europe, even the AI conversation came back to this: The models are only as good as the data underneath them, and the data is only as good as how well the lab is actually connected.

What I find compelling about this moment is that the gap is closing. Perhaps not evenly, or without friction. Mass spectrometry platforms are pushing deeper into biopharma characterization. Lab orchestration is becoming a real discipline, incubators are getting more deliberate about connecting early-stage science to the capital and infrastructure it needs to survive. People are less interested in what AI might do someday and more focused on what it would take to actually make it work today.

There's also a funding story woven through all of this. What it takes to build a biotech in 2026 is different from what it took five years ago. Investors want commercial viability alongside scientific credibility, and the seed-stage shortfall remains real even as Series A and beyond start to recover. The industry may be resilient, but resilience requires acknowledging where the pressure actually is.

DDN has always covered the science. But in this issue, we're reminded why bridging the academic and industry perspectives matters. The researchers optimizing assays and the engineers designing modular cleanrooms are solving parts of the same problem. So are the investors, the incubators, and the chemistry, manufacturing, and controls teams quietly doing the work that determines whether any of the biology we're all excited about actually reaches a patient.

That's the story we're trying to tell. ■

Advanced Therapies Congress arrives with spring optimism in London

As the sector matures, London brought together global executives, start-ups, and researchers to confront the practical realities of scaling cell and gene therapies.

BY BREE FOSTER, PHD

CREDIT: ISTOCK.COM/ALIHAN USULLU

AFTER A LONG WINTER, THE Advanced Therapies Congress 2026 in March arrived with the first real promise of spring. Clear skies and unseasonably warm sunshine greeted attendees on day one — and, unusually for London, stayed put through day two — setting an upbeat tone for a meeting focused on momentum, scale, and maturity in cell and gene therapy.

More than 3,300 global executives gathered at ExCeL London to hear from 300 speakers, meet 100 startups, and take part in 10 content tracks spanning the full advanced therapy medicinal product (ATMP) value chain. The exhibition floor was busy throughout, with discussions ranging from viral vector capacity and automation to reimbursement frameworks and real-world evidence — reflecting an industry increasingly concerned with execution, not just innovation.

London proved a fitting backdrop. As part of the UK's life sciences' "Golden Triangle" with Oxford and Cambridge, the capital sits at the heart of a national ecosystem comprising 6,300 life sciences businesses, £80.7 billion in turnover, and more than 256,000 employees. The UK is home to over 130 advanced therapies companies, many clustered in the greater southeast, including university spinouts such as Orchard Therapeutics, Autolus, and MeiraGTx. This concentration is reinforced by deep integration between academia, industry, and the National Health Service, with multiple National Institute for Health Research Biomedical Research Centres and Academic Health Science Centres accelerating translational medicine.

During the congress, *DDN* spoke with leaders across the ecosystem, including Ruxi Comisel from eXmoor, Claudio Panzarella and Angelo Raggioli from ReiThera, Natalia Elizalde from VIVEbiotech, and Miguel Forte from Kiji Therapeutics, capturing a shared sentiment. Advanced therapies are entering a decisive phase, where scientific ambition must be matched by robust manufacturing, regulatory clarity, and sustainable access models. In London, against a backdrop of spring sunshine and dynamic conversation, the industry's trajectory was on full display — moving from promise to tangible progress. ■

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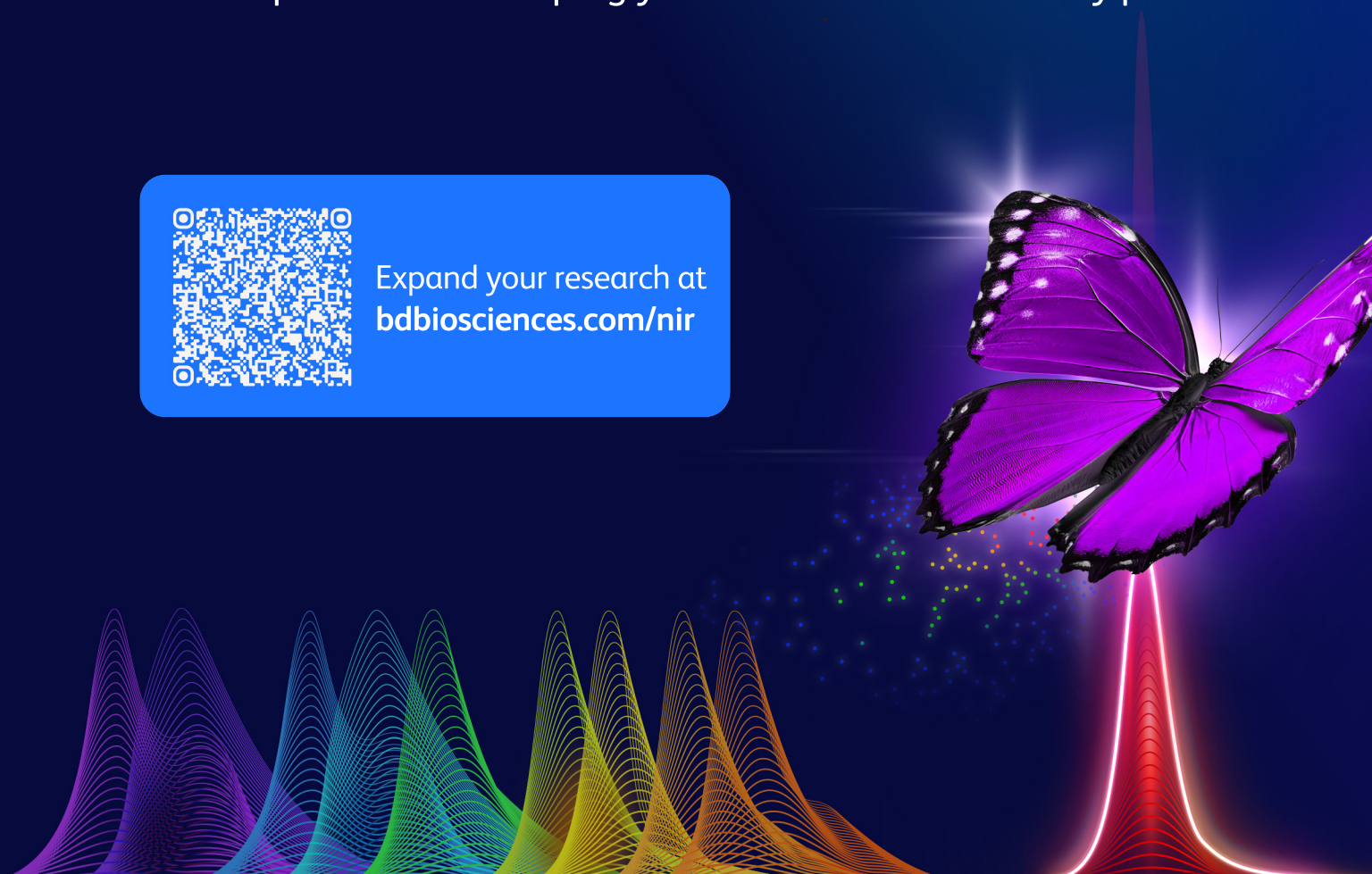


The gap between drug discovery and manufacturing narrows at INTERPHEX

What the conversations on that show floor revealed is that the hardest problem in drug development may not be finding new medicines, but building the infrastructure to make them reliably.

BY ANDREA CORONA

CREDIT: ISTOCK.COM/TOTOJANG

EVERY APRIL, THE JAVITS CENTER IN NEW York City becomes a temporary cross-section of the pharma industry. Researchers, engineers, regulatory specialists, and contract manufacturers converge on what has become one of the industry's most telling annual indicators of where the field's priorities and anxieties actually lie.

INTERPHEX 2026, which concluded April 23 after three days and more than 600 exhibitors, was no exception. What it reflected — in the themes dominating its 100-plus education sessions, in the debut of a dedicated contract outsourcing exchange, and in the record volume of manufacturing equipment on its show floor — was an industry wrestling with a problem that goes well beyond any single technology or regulatory challenge.

That problem is the gap between drug discovery and drug manufacturing. And in 2026, it is more consequential, and more visible, than it has ever been.

A pipeline that outpaces its infrastructure

The biopharmaceutical industry is in the midst of a productivity surge on the discovery side.

Artificial intelligence (AI) and machine learning (ML) tools are accelerating target identification, compound screening, and candidate optimization at a pace that would have been unrecognizable a decade ago. Multiomics approaches are generating richer biological datasets. Cell and gene therapies, bispecific antibodies, antibody-drug conjugates (ADCs), and RNA-based medicines are advancing through pipelines in categories that barely existed commercially 15 years ago.

But the infrastructure that translates those discoveries into medicines that can be manufactured consistently, at scale, and to regulatory specification has not kept pace. Chemistry, manufacturing, and controls (CMC) — the discipline that governs how a biologic or small molecule moves from laboratory synthesis to commercial production — remains, by some accounts, the most systematically underestimated function in drug development.

A 2025 independent analysis of more than 200 Complete Response Letters (CRLs) issued by the FDA between 2020 and 2024 found that 74 percent cited quality and manufacturing deficiencies as a contributing factor. These are not failures of discovery science, but instead shortcomings of translation — of the systems, processes, and infrastructure that connect a promising molecule to a manufacturable medicine.

The commercial stakes of that are, also, substantial. The global contract development and manufacturing organization (CDMO) market was valued at approximately $246 billion in 2025 and is projected to reach $588 billion by 2035, driven in large part by the inability or unwillingness of pharmaceutical and biotech companies to build all manufacturing capacity in-house. As pipelines grow more complex and the modalities entering development grow more diverse, the demand for external manufacturing expertise is accelerating, and the capability of that external infrastructure to handle what discovery is sending it is an open and pressing question.

Why CMC falls behind

The disconnect between discovery and manufacturing has structural roots. On the discovery side, the adoption of computational tools, high-throughput screening, and AI-driven design has dramatically compressed the timelines for identifying and optimizing candidates. On the CMC side, the equivalent digital transformation has been slower to arrive. A January 2026 report from the Association for Pharmaceutical Technology (APV) described CMC as remaining in a state of "digital infancy" relative to discovery, with traditional empirical approaches to drug product development increasingly becoming a bottleneck as pipeline diversity and complexity grow.

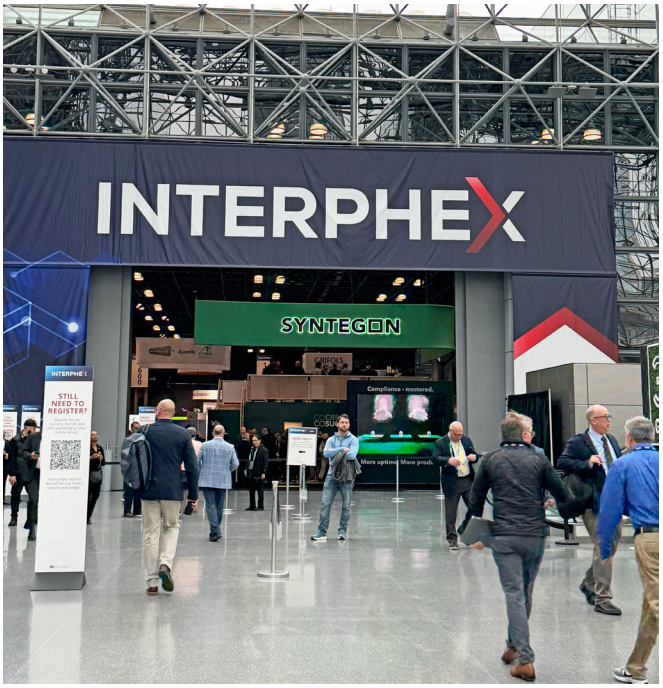
That asymmetry creates compounding problems. Candidates are advancing into development with limited CMC data packages, forcing manufacturing teams to characterize critical quality attributes (CQAs), establish control strategies, and develop scalable processes under compressed timelines and with incomplete product understanding. Process changes introduced during scale-up — changes that are scientifically necessary and regulatorily expected — require comparability assessments that must be conducted against a baseline of product knowledge that may not have been sufficiently established during early development. The result, too often, is the kind of late-stage manufacturing surprise that generates CRLs and delays approval by months or years.

Regulatory agencies have recognized the problem and have begun creating frameworks to address it. The FDA launched its CMC Development and Readiness Pilot program in 2023 specifically to help companies navigate and prioritize CMC resources earlier in development. ICH Q12, the international guidance facilitating the management of post-approval CMC change, introduced mechanisms for agreeing with regulators in advance on what data will be required to support anticipated manufacturing changes — reducing the unpredictability that has historically made late-stage process optimization so costly.

But guidance frameworks and regulatory initiatives can only go so far. The more fundamental challenge is building the scientific and analytical infrastructure to support genuine process understanding from early in development — and ensuring that the manufacturing questions that will determine a program's regulatory fate are being asked at the same time as the biological questions that define a candidate's potential.

Outsourcing as both solution and risk

For many drug developers, particularly the biotech companies that now populate the early stages of most therapeutic pipelines, the answer to manufacturing complexity is outsourcing. CDMOs offer access to specialized equipment, regulatory expertise, and manufacturing experience that would take years and significant capital to build internally. The growth of the CDMO market reflects the degree to which this model has become standard rather than exceptional.



CREDIT: ANDREA CORONA

INTERPHEX 2026 brought together the people, technologies, and ideas shaping the future of pharmaceutical and biotechnology manufacturing.

CREDIT: ANDREA CORONA

Industry leaders, researchers, and solution providers connected to explore the latest advances in drug development, manufacturing, and patient care.

But outsourcing transfers the manufacturing execution without necessarily transferring the manufacturing understanding. A biotech company that outsources process development to a CDMO is still responsible for the product knowledge that underpins its regulatory submission — for understanding which quality attributes are critical, how the manufacturing process affects them, and what data will be needed to support post-approval changes. The practical reality is that many early-stage biotech companies do not have that

expertise internally, which creates a dependency on CDMO partners that can be productive when the relationship is deeply integrated and problematic when it is not.

The COEX debut at INTERPHEX 2026 — a dedicated exchange for one-to-one connections between drug developers and contract organizations, which facilitated nearly 300 meetings across three days — reflects how central that relationship has become to how the industry functions. The question of how to find the right manufacturing partner, at the right stage of development, with the right capabilities for a specific molecule and modality, is no longer peripheral to drug development strategy. It is often one of the most consequential decisions a development organization makes.

What integrated infrastructure looks like

The most coherent response to the discovery-manufacturing gap is one that begins closing it early — treating manufacturing feasibility as a discovery-stage consideration rather than a development-stage problem. For biologics, that means characterizing the physicochemical and functional properties that will eventually define CQAs while the molecule is still being optimized, rather than after a candidate has been selected. For complex modalities including ADCs, bispecifics, and cell and gene therapies, it means involving process development expertise in candidate selection, since manufacturability is not separable from therapeutic viability.

Cleanroom infrastructure is one physical dimension of this shift. The global cleanroom technologies market, valued at approximately $11 billion in 2026, is projected to reach $17.7 billion by 2034, with the modular cleanrooms segment growing at a compound annual growth rate of nine percent — a trajectory driven by demand for flexible, scalable manufacturing environments that can accommodate the small-batch, highly variable production requirements of advanced therapies. Modular construction approaches that allow cleanroom capacity to be configured and reconfigured rapidly represent one answer to the flexibility that modern biopharmaceutical manufacturing requires.

Digital tools are another. The same AI and ML capabilities reshaping discovery are beginning to be applied to process development and manufacturing — to predictive modeling of how process parameters affect quality attributes, to real-time monitoring of critical process parameters during production, and to the computational comparability analyses that are required when processes change. That application is still early. As the APV report noted, the CMC community is in the early stages of transitioning toward digital design and quantitative formulation — integrating material and process data in ways that would allow process behavior to be predicted rather than empirically discovered at each scale.

Why the show floor matters

Events like INTERPHEX serve a function that papers and regulatory guidance documents cannot: They put the people working across the full pipeline into physical proximity and create conditions for the informal conversations that shape how the field moves. The connections made in a contract outsourcing exchange, the assessment of manufacturing equipment made hands-on rather than from a specification sheet, the education sessions that pull together regulatory, scientific, and operational perspectives on a shared challenge — these are the mechanisms through which the industry's collective understanding of complex problems actually develops.

"INTERPHEX 2026 reflected the momentum we're seeing across the pharmaceutical and biotech industries," Event Director Douglas Lugo said in a press release. "With increased participation from both attendees and exhibitors, along with the launch of COEX and expanded educational programming, this year's event created more opportunities than ever for meaningful connections, innovation, and business growth."

That momentum is real. But what INTERPHEX also reflects, in the volume and focus of its manufacturing-oriented content, is how much remains to be built. The discovery engine is running faster than it ever has. The manufacturing infrastructure catching what it produces is improving, but remains the less glamorous and less well-resourced half of an equation that determines whether any of the biology being discovered actually reaches patients.

Closing that gap — through the organizational decisions, partnership structures, and early-stage investment priorities that determine when and how manufacturing is considered is the work the industry is still in the middle of doing. ■

"The question of how to find the right manufacturing partner, at the right stage of development, with the right capabilities for a specific molecule and modality, is no longer peripheral to drug development strategy."

At AACR 2026, predictive models and integrated workflows took center stage

From 3D organoids to AI-enabled imaging, the tools reshaping how developers move from discovery data to reliable therapeutic predictions are maturing.

BY ANDREA CORONA

THE 2026 AMERICAN ASSOCIATION FOR Cancer Research (AACR) Annual Meeting, held April 17–22 in San Diego, surfaced a shift in how the cancer research community thinks about preclinical models and the tools that support them.

For drug developers, the signal was consistent across sessions: physiologically relevant models are becoming more tractable, AI-enabled analytics are making complex datasets more actionable, and the pressure to generate earlier, more reliable predictions of therapeutic outcomes is driving demand for integrated end-to-end workflows.

Kevin Quick, Vice President of platforms at Revvity, told *DDN* that the most consequential trend at AACR 2026 was the field's movement toward predictive preclinical models, enabled by converging advances in automation, data infrastructure, and imaging technology. "The field is moving toward predictive preclinical models, as automation and data infrastructure evolve to better support physiologically relevant models, such as 3D organoids and other advanced *in vitro* models," Quick told *DDN*.

Imaging advances are unlocking complex tissue models

A key enabler of that shift is high-content imaging. Quick pointed to advances in imaging speed, deeper tissue penetration, and improved resolution as making it increasingly feasible to extract meaningful data from complex 3D tissue models that were previously difficult to interrogate at scale. "Advances in high-content imaging are making it increasingly feasible to gain insights from these complex tissue models," he said. When combined with AI-enabled image analysis, those advances translate into faster, more reproducible, and more scalable readouts from the kinds of models that most closely approximate human tumor biology.

The practical implication for drug developers is significant. Organoids and other advanced *in vitro* systems have long promised a more biologically accurate window into therapeutic response than 2D cell cultures — but realizing that promise at the throughput and reproducibility required for drug discovery has remained a persistent

challenge. "AI-enabled image analysis further improves speed, reproducibility, and scalability of these complex data sets," Quick said. "Together, these advances are enabling earlier, more reliable predictions of therapeutic outcomes by combining high-content data with advanced analytics."

Tools are catching up to complex modalities

The third trend Quick identified at AACR 2026 concerns the tools infrastructure itself. Complex therapeutic modalities are placing new demands on preclinical research workflows that were not designed with their biological complexity in mind.

CREDIT: © 2026 AACR/TODD BUCHANAN

AACR 2026 drew cancer researchers and industry scientists to San Diego to examine how predictive models, high-content imaging, and data infrastructure are reshaping early-stage drug discovery.

Data quality over data volume

On the question of unmet needs in cancer drug discovery, Quick's response pushed back against the instinct to equate more data with better insights.

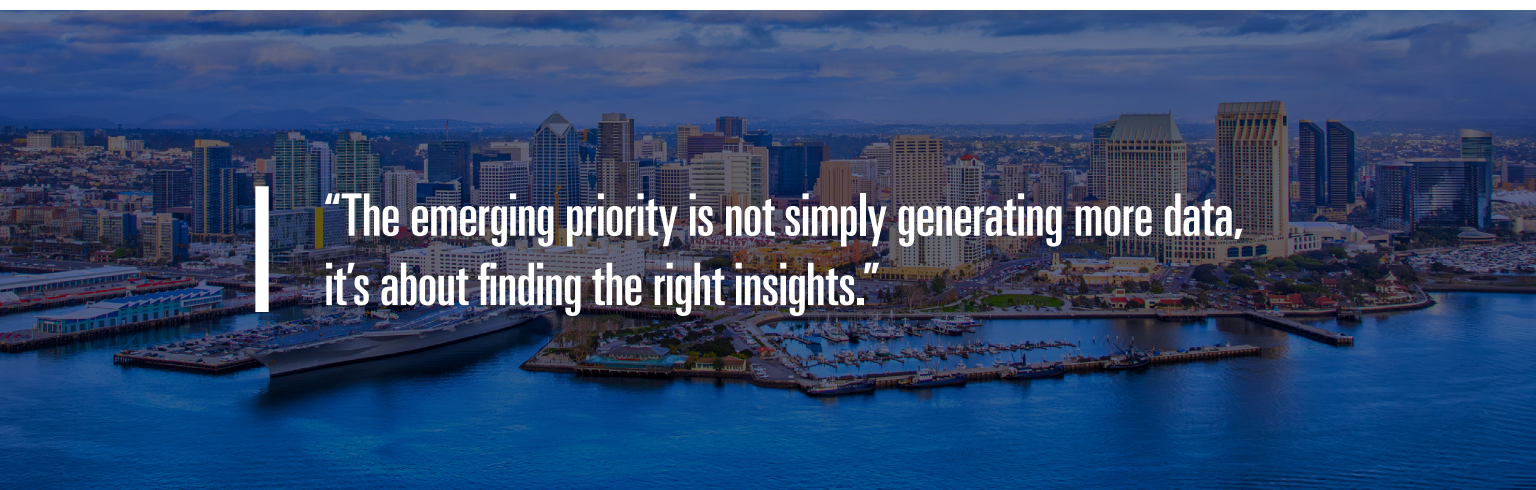
"A big challenge is moving from discovery data to reliable predictive models, making sure these models are fed high-quality, validated data as these datasets continue to be built out," Quick told *DDN*. "The emerging priority is not simply generating more data, it's about finding the right insights."

That framing echoes a broader concern in the field about AI readiness, that the value of data-driven approaches is bounded by the quality and diversity of the data underlying them, and that speed of data generation without validation creates noise rather than signal. "A promising approach to addressing these needs is through partnerships, so the data is properly validated while customers actively feed into the process," he said. "Data-sharing agreements further support this by enabling the development of co-tailored, end-to-end workflows, ensuring high-quality inputs to achieve high-quality outputs."

The tools available to characterize these modalities, model their mechanisms, and predict their behavior in patients need to reflect real-world biological complexity in ways that simpler assay systems cannot.

The response from the research tools space, Quick told *DDN*, is a shift toward integrated end-to-end workflows. "Combined with AI-enabled image analysis, this shift allows researchers to accelerate discovery and therapeutic innovation in cancer research."

A critical component of that integration is the relationship between *in vitro* and *in vivo* workflows. New approach methodologies — the emerging category of animal-free or animal-alternative testing strategies that includes organoids, organs-on-chips, and computational models — are increasingly being evaluated not as replacements for *in vivo* studies but as complements to them. "A key part of this is determining how new approach methodologies synergize with *in vivo* workflows to support validation, longitudinal studies, and regulatory confidence," Quick said — a question that will shape how predictive preclinical platforms are adopted and trusted in development decisions. ■



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Orchestration over automation at SLAS 2026

SLAS Europe 2026 showcased growing realism around AI in drug discovery, with attention shifting toward data quality, interoperability, and lab execution.

BY BREE FOSTER, PhD

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ACROSS SLAS EUROPE 2026, THE FOCUS was on AI and automation, but the tone was notably pragmatic. While AI featured heavily across keynote sessions and vendor demonstrations, the emphasis was less on future promise and more on present-day constraints. Conversations moved quickly beyond model performance and algorithmic novelty to the realities of laboratory execution: data quality, system reliability, and the challenge of connecting digital tools with physical experiments.

That shift reflects a broader recalibration underway in drug discovery. The fundamental challenge facing pharma has not gone away. As Jonathan Wingfield, a Business Development Specialist at TTP, told *DDN*, "The cost of bringing new drugs to market keeps rising, while the effective window of intellectual property is shrinking. That combination makes it much harder to recover the investment made in early discovery."

Rather than chasing ever more ambitious *in silico* predictions, many organizations are recognizing that the real bottlenecks sit elsewhere — in how experiments are executed, how data is generated, and how quickly teams can learn from results.

"We're starting to come out of the AI hype cycle, at least in the life sciences," Wingfield said. "AI can take you part of the way — particularly in early discovery — but once programs move into the clinic, the problems become much harder."

Instead, the growing consensus at SLAS Europe 2026 was one that treats AI not as a standalone solution, but as something that depends entirely on the infrastructure beneath it. Automation, connectivity, and reliable data generation are becoming the true enablers of change.

From automation to orchestration

For years, automation in the lab was largely synonymous with throughput. Liquid handlers, robotic arms, and screening platforms were deployed to move faster and process more samples. But that narrow definition is starting to break down. Today, the conversation has shifted from how fast individual systems can run to how well entire laboratories can function as connected, coordinated environments.

"The biggest change we're seeing is the move away from isolated, digitized labs toward fully automated, integrated environments," Paolo Concio, Senior Director of Global Commercial for Digital Science Solutions at Thermo Fisher Scientific, told *DDN*. "This represents a major step change — from standalone work cells operating independently to connected systems functioning as part of a coordinated whole. It requires the ability to link instruments, digital platforms, AI tools, and robotics into a seamless, continuous loop."

Crucially, this orchestration problem can't be solved by a single vendor or platform. Laboratories are inherently

heterogeneous environments. A single workflow may involve a dozen instruments from different suppliers, each generating its own data in its own format. "Customers are very clear about this," Concio said. "They already have infrastructure in place. They're not going to rip everything out and start again. The question is always: How does this new system fit into what I already have?"

That reality is driving a renewed emphasis on interoperability and open ecosystems. "Systems need to be designed to function within open ecosystems, capable of communicating and working across different platforms and technologies," explained Concio. "That shift toward connectivity and integration is what is now clearly emerging across the field."

Automation is no longer just about executing experiments. It's about moving seamlessly from hypothesis to experiment to data analysis, and back again. That broader interpretation of automation is beginning to redefine what a modern discovery lab looks like, and it sets the stage for where AI can deliver its most practical value.

AI in closed-loop labs

For all the attention AI receives in drug discovery, its real impact is tightly bound to the physical laboratory. Models don't learn in a vacuum. They learn through repetition — hypothesis, test, learn, repeat — and that cycle only works when digital intelligence is anchored to wet-lab reality.

"In discovery, you can generate huge numbers of candidates with AI," Marco Ravot-Licheri, Head of Digital for the Life Sciences Business at Tecan, told *DDN*. "But even the best models still contain assumptions. You have to test those hypotheses in the lab, bring the results back, and refine them. That feedback loop is non-negotiable."

Making that loop work requires a well-connected lab, where AI can also be effectively used in areas such as resource planning, data analytics, and workflow optimization. However, its performance drops significantly when data is fragmented or inconsistent.

"We need to bridge wet and dry lab environments, and we need the right application programming interfaces [APIs] in place — not just for instrument control, but also for analytics tools," said Ravot-Licheri. "You need those APIs to enable the closed loop."

A useful example of how this shift is already playing out can be seen in the evolution of lab analytics platforms. These systems were initially designed to monitor instrument performance and provide retrospective insight — essentially helping teams understand what went wrong after an experiment had already failed or deviated.

More recently, they have started to incorporate agentic AI capabilities that move them from reactive reporting to predictive intervention. "A scientist can now say, 'I'm about to start this run on this instrument,' and the system can look back across historical data, identify patterns, and flag potential risks before the run even begins," explained Ravot-Licheri.

This shifts the role of the system from post-hoc analysis to continuous monitoring and early warning, where emerging issues can be detected and acted on before they affect experimental outcomes.

Closed loops and human-centred labs

These developments point to a more significant trend in how discovery labs are designed and operated. As orchestration improves and AI becomes embedded in day-to-day workflows, the question is no longer whether laboratories can be automated — but how that automation should be structured, and who remains in control.

Rather than converging on a single model, SLAS Europe 2026 revealed two complementary paths emerging in parallel: closed-loop laboratories, where AI systems actively guide experimental cycles end to end, and human-centric labs, where automation and intelligence enable scientists to focus on higher-order interpretation, experimental design, and decision-making.

Within that framework, the future of the lab is not a simple choice between full autonomy and human control. "It depends on the application," Ravot-Licheri said. "Before there are clear use cases where self-driving labs make sense — environments where execution can be largely automated and scientists focus on interpreting results and designing the next question. But there are equally important contexts where labs remain fundamentally human-centric, with AI acting as an enabling layer rather than a replacement."

A connected foundation

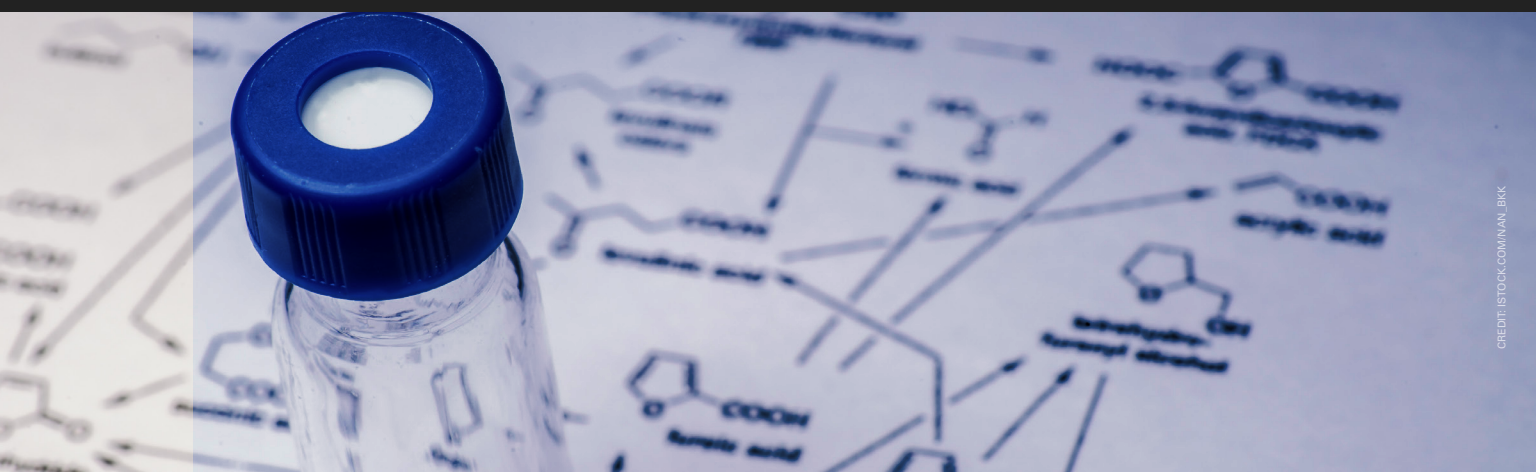
Across SLAS Europe 2026, the message that emerged most clearly was that AI is no longer being viewed as a standalone driver of transformation, but as something that is only as powerful as the laboratory it sits on top of. The most advanced models and algorithms still ultimately depend on whether experiments can be run reliably, whether data is captured in a structured way, and whether results can flow back into the next cycle of design and decision-making.

Overall, the impact of AI depends heavily on how automation is used to generate high-quality, real-world data. Without that foundation, AI on its own is unlikely to fundamentally change how discovery workflows operate. ■

At ASMS 2026, mass spectrometry stakes its claim

Sessions spanning chemoproteomics, AI-driven proteomics, biotherapeutic characterization, single-cell omics, and spatial multiomics all pointed toward mass spectrometry's growing role in drug discovery and development.

BY ANDREA CORONA



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THE 74TH ANNUAL CONFERENCE ON Mass Spectrometry and Allied Topics ran June 1–5 at the San Diego Convention Center, bringing together researchers across academia, industry, and government for four days of oral sessions, poster presentations, workshops, and exhibits. The program — spanning more than 40 concurrent oral sessions per day across topics from ion mobility instrumentation to clinical analysis, environmental contaminants, and cancer immunology — offered a cross-section of where mass spectrometry currently sits and where it is heading.

For drug discovery researchers in particular, the breadth of the ASMS 2026 program reflected a field in which mass spectrometry has become central not just to analytical characterization but to the biological questions that drive discovery. The conference opened with a plenary lecture from Benjamin Cravatt of The Scripps Research Institute, titled "Protein and Ligand Discovery on a Global Scale" — a framing that set the tone for a week in which the intersection of mass spectrometry with target identification, chemoproteomics, and therapeutic characterization was a recurring thread.

Chemoproteomics and drug target identification

Monday morning's dedicated session on chemoproteomics and protein probes brought together work from several groups applying mass spectrometry-based approaches to fundamental problems in drug discovery. Presentations included work from the University of Oxford on expediting the discovery of deubiquitinase inhibitors through activity-based proteomics, a large-scale chemoproteomic profiling study of clinical kinase inhibitors from the Technical University of Munich, and a live-cell chemoproteomic atlas of stereoselective ligand-protein interactions from Harvard Medical School.

Researchers from Talus Bioscience presented a platform for discovering covalent ligands against protein targets, while a team from Momentum Biotechnologies described a plate-format automated approach for drug target identification. The session also included work from University of California, Los Angeles using photochemical approaches to capture the state-dependent proteome.

The Tuesday morning drug discovery and development session ran parallel to quantitative proteomics, metabolomics, and biomarker analysis sessions, with presentations from Pfizer on standardizing proteomics frameworks for drug discovery, from AstraZeneca on antibody-drug conjugate (ADC) pharmacokinetic assays from preclinical to clinical deployment, and from Talus Bioscience on AI-guided screening for covalent modulators. A presentation from Amgen covered proteomic profiling of Cullin-Ring ligase activity across 28 human cell lines — directly relevant to the growing field of targeted protein degradation.

AI and informatics across the week

AI and computational tools appeared throughout the ASMS 2026 program, embedded within analytical workflows rather than treated as standalone topics. The Tuesday afternoon session dedicated to AI in mass spectrometry instrumentation and applications ran alongside sessions on biotherapeutic characterization and lipidomics. Monday morning featured a full session on multiomics integration and applications, with presentations covering large language model applications for pathway analysis, probabilistic modeling frameworks for multi-omics data integration, and tools for extending gene ontology analysis to lipidomics datasets.

Wednesday morning's informatics session covered innovations in computational mass spectrometry more broadly, while Thursday morning's informatics session addressed metabolomics, lipidomics, and glycomics — including AI-driven lipid identification pipelines and spectrum clustering approaches for largescale molecular networks. Throughout the week, data-independent acquisition (DIA) and its associated computational requirements appeared as a recurring methodological theme, with dedicated sessions and workshops on DIA for post-translational modifications, quantitative DIA data analysis, and DIA-based phosphoproteomics.

Biotherapeutic characterization

Biopharmaceutical development was well represented across the program. Wednesday afternoon's main hall session was dedicated to biotherapeutics, specifically proteins, antibodies, and ADCs. Tuesday afternoon included a parallel session on biotherapeutic characterization and quantitation. A Monday evening workshop focused on mass spectrometry approaches for characterizing complex biotherapeutic modalities, and a Tuesday evening workshop addressed the peptide renaissance and emerging analytical challenges for peptide-based therapeutics.

Within the biotherapeutic sessions, presentations addressed ADC pharmacokinetics, MHC-associated peptide proteomics workflows for immunogenicity assessment of monoclonal antibodies and adeno-associated viral (AAV) vectors, and longitudinal deep proteomic profiling of plasma during CAR-T therapy. A session on the detection of high-mass analytes covered charge detection mass spectrometry for AAV vector characterization throughout downstream purification — a technically demanding application with direct relevance for cell and gene therapy manufacturing.

Also featured in the exhibit hall were new instrument platform launches oriented toward biopharma applications, including platforms designed for broader dynamic range in complex samples, upgraded software for processing top-down proteomics data, and integrated workflows for oligonucleotide and mRNA therapeutic analysis.

Single-cell omics and spatial multiomics

Thursday morning's main hall session on single-cell omics reflected the maturation of mass spectrometry-based approaches for profiling individual cells. Presentations covered single-cell proteomics using affinity reagent-aided signal amplification, top-down proteomics of single human muscle cells integrating function and proteoform identity, mapping human brain development through single-cell proteomics, and surface proteome profiling at the single-cell level for immune cell antigen discovery in inflammatory disease — the last from Genentech.

A parallel Thursday morning session on the integration of multi-omics approaches included an end-to-end spatial multiomics approach for analyzing single tissue sections from the Pacific Northwest National Laboratory, a multi-omics analysis of molecular aging networks across ancestries and geographies from Stanford University, and a network-based proteomics framework for identifying multi-omic crosstalk in disease pathology.

Spatial approaches also appeared earlier in the week. Monday afternoon's imaging session was dedicated to spatially resolved omics, and Tuesday afternoon's biomarker session included a presentation on spatially driven lipid biomarker discovery at cellular, neighborhood, and functional tissue unit scales in human kidney from Vanderbilt University. Wednesday morning's imaging session covered pharmaceuticals, metabolites, lipids, and glycans.

Thursday morning's cancer and immunity session addressed mass spectrometry's role in immuno-oncology specifically, with presentations on quantitative mapping of tumor-NK immune synapses, surfaceome profiling of acute myeloid leukemia for immunotherapy target discovery from University of California, San Francisco, and deep learning approaches for discovering host neoantigens in immunopeptidomics.

Closing on scientific integrity

The conference closed Thursday with a plenary lecture on scientific integrity from Elisabeth Bik, a microbiologist and independent scientific integrity expert whose work has contributed to more than 1,600 retractions and 1,200 corrections across the scientific literature. Her inclusion as the closing plenary speaker — in place of the scientific discovery talks that typically anchor major conference closings — represented a deliberate statement from ASMS about the responsibilities accompanying the field's growing influence in biomedical research and drug development. ■

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Mass spectrometry platforms push deeper into proteomics and biopharma at ASMS 2026

New instrument launches from two major vendors at this year's conference reflected shared priorities: higher proteome coverage, richer characterization of complex biotherapeutics, and tighter integration of AI-driven software across analytical workflows.

BY ANDREA CORONA

CREDIT: ISTOCK.COM/SLAVKOSEREDA

THE EXHIBIT HALL AT THE 74TH ANNUAL Conference on Mass Spectrometry and Allied Topics in San Diego served as the backdrop for a wave of instrument and software announcements aimed squarely at the analytical demands of drug discovery and biopharmaceutical development. Two major launches — one centered on expanding Orbitrap platform capabilities, the other on advances in trapped ion mobility-based proteomics and proteoform analysis — reflected the field's continued push toward deeper biological characterization, higher throughput, and more integrated computational workflows.

Orbitrap expands across the development pipeline

Thermo Fisher Scientific announced three new Orbitrap mass spectrometry platforms at ASMS 2026, alongside a suite of AI-enabled software tools and integrated workflows spanning research, biopharmaceutical development, and applied testing.

For research applications, the company introduced the Orbitrap Tribrid Apex mass spectrometer, described in a press release as the company's most versatile and highest-performing Orbitrap Tribrid platform. The system incorporates three mass analyzers, an infrared laser option for alternative fragmentation, and a Direct Mass Technology mode. Complementary software releases included Proteoform Studio for top-down proteomics workflows, Proteome Discoverer 3.4 for managing larger proteomics datasets, and the acquisitions of MSAID — an AI-driven proteomics and machine learning software company — and Proteinaceous, which adds top-down and native mass spectrometry bioinformatics capabilities.

For biopharmaceutical development, the company unveiled the Orbitrap Excedion mass spectrometer, a platform designed for applications including drug metabolism studies, oligonucleotide analysis, and peptide analysis. The system features an enhanced dynamic range mode described as detecting three to five times more compounds in complex samples. Notably, the company announced that existing users will be able to upgrade to the Excedion Pro configuration without replacing their instrument. Supporting workflow components introduced alongside the platform included a metal-free ultra-high-performance liquid chromatography system engineered for sensitive biological molecules including short oligonucleotides, reversed-phase columns purpose-built for oligonucleotide, mRNA, and protein therapeutic analysis, and an oligonucleotide sample

preparation kit designed to streamline bioanalysis workflows. For later-stage regulated bioanalysis and quality control applications, the company also showcased the TSQ Certis triple quadrupole mass spectrometer, which the press release noted measures samples 15 percent faster and requires maintenance less than half as frequently as previous systems in complex matrices such as plasma.

Bruker advances proteoform analysis and high-throughput proteomics

Bruker's ASMS 2026 announcements centered on advances in trapped ion mobility-based platforms, with a particular emphasis on proteoform characterization, depth of proteome coverage, and the integration of top-down and native mass spectrometry capabilities into biopharma workflows.

The company announced major performance advances for its timsUltra AIP platform, reporting identification and label-free quantification of more than 10,000 proteins in cell line samples and more than 6,500 proteins at 500 samples per day using updated instrument configurations, new razor-PASEF acquisition methods, and Spectronaut 21 software. In a press release, researchers at University Hospital Tübingen and the University of Freiburg described applying the platform to formalin-fixed paraffin-embedded (FFPE) tissue biopsies in a translational oncology context, quantifying more than 10,000 proteins across clinical samples to identify pathway activity and tumor-specific resistance programs in cases where genomic analysis was inconclusive.

For top-down and native mass spectrometry, the company highlighted the timsOmni platform, which combines trapped ion mobility with trapped electron dissociation (ExD) fragmentation. An argon collision gas option was announced, described as improving collision-induced dissociation sensitivity by fourfold for biomolecules. A new partnership with Integrated Protein Technologies was also announced, interfacing that company's SampleStream automated buffer exchange system directly with the timsOmni platform to enable high-throughput intact and top-down biotherapeutic characterization workflows. In a press release, Phil Compton, CEO of Integrated Protein Technologies, said the combination was intended to make high-performance intact and top-down workflows more broadly accessible.

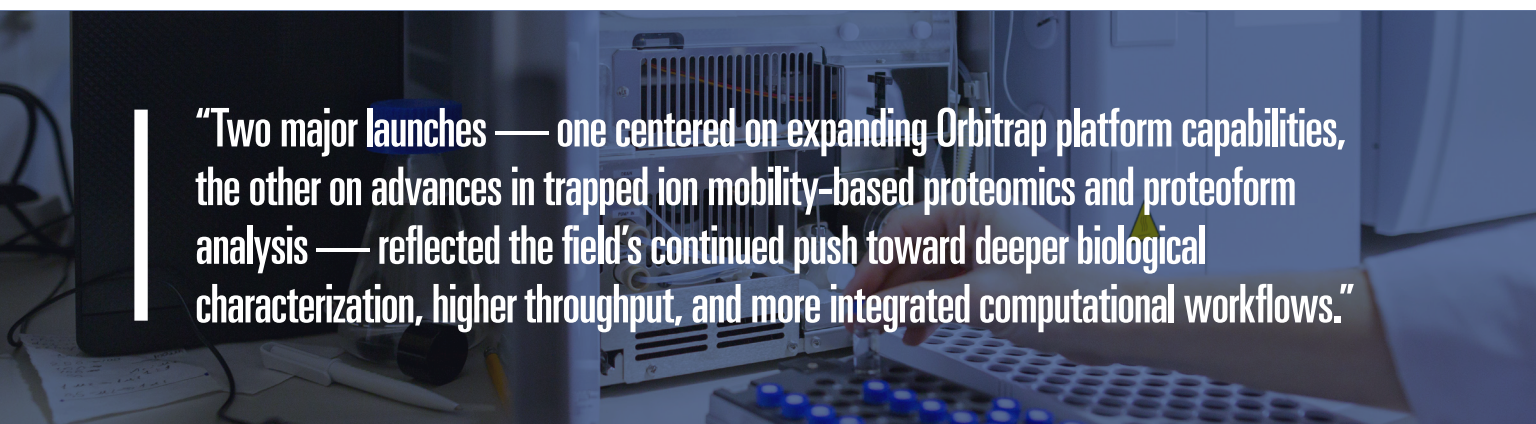
On the software side, Bruker announced releases of OmniScape 2027, ProteoScape 2027, and GlycoScape 2027. OmniScape 2027 includes LYRA, a *de novo* sequencing algorithm for top-down spectra that the company described as enabling ultrafast post-translational modification (PTM) screening across proteoform space. New glycoproteomics workflows incorporating complementary fragmentation modes were also announced, with MSFragger compatibility added for timsOmni trapped ExD acquisitions. In a press release, Alexey Nesvizhskii of the University of Michigan noted that the integration brings peptide-backbone sequencing and glycan-informative fragmentation into a single framework. A transformer neural network-based *de novo* peptide sequencing model called tims-Casanovo, developed in collaboration with academic groups at the University of Washington, Helmholtz Munich, and the University of Antwerp, was also described, with William Noble of the University of Washington noting in a press release that expanded training datasets improve its performance across applications including immunopeptidomics and antibody characterization.

The company also announced the timsMRMS, a platform combining trapped ion mobility separation with magnetic resonance mass spectrometry at resolving powers of one million to 10 million, targeting applications in energy industry research including petroleomics and dissolved organic matter characterization.

Shared directions

Taken together, the two sets of announcements at ASMS 2026 reflected several converging priorities in mass spectrometry instrument development. Both companies emphasized deeper coverage of complex proteomes, with high-throughput workflows capable of identifying proteins in the thousands. Both highlighted expanding capabilities for biotherapeutic characterization — particularly for complex modalities including oligonucleotides, mRNA therapeutics, glycoproteins, and antibodies — as a central development direction. And both integrated AI-driven software as a core component of their platform expansions, positioning computational tools not as add-ons but as necessary infrastructure for translating instrument performance into actionable biological and analytical conclusions.

The depth of biopharma-oriented content at ASMS 2026 more broadly — with dedicated oral sessions on biotherapeutic characterization, ADC pharmacokinetics, and immunogenicity assessment alongside instrument launches aligned to the same workflows — underscored how central mass spectrometry has become to the analytical infrastructure supporting biologics development across the pipeline. ■



"Two major launches — one centered on expanding Orbitrap platform capabilities, the other on advances in trapped ion mobility-based proteomics and proteoform analysis — reflected the field's continued push toward deeper biological characterization, higher throughput, and more integrated computational workflows."

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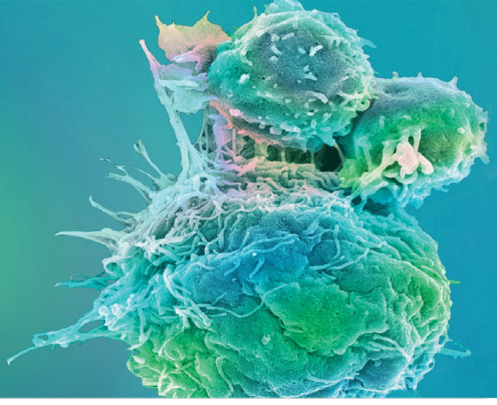
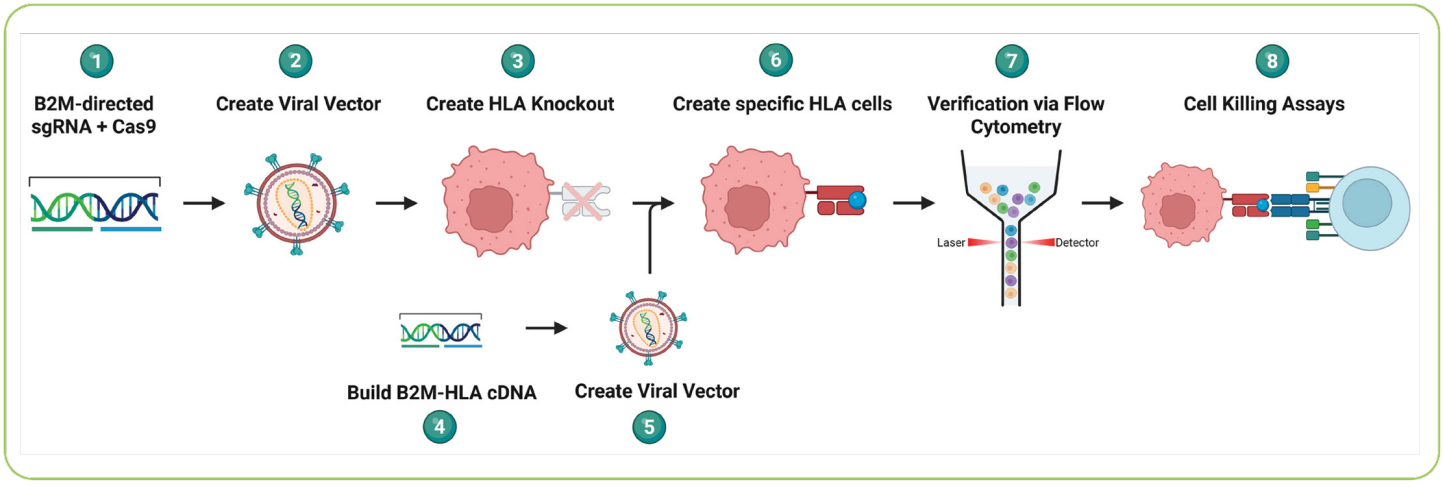


HLA-based cell therapy development workflow



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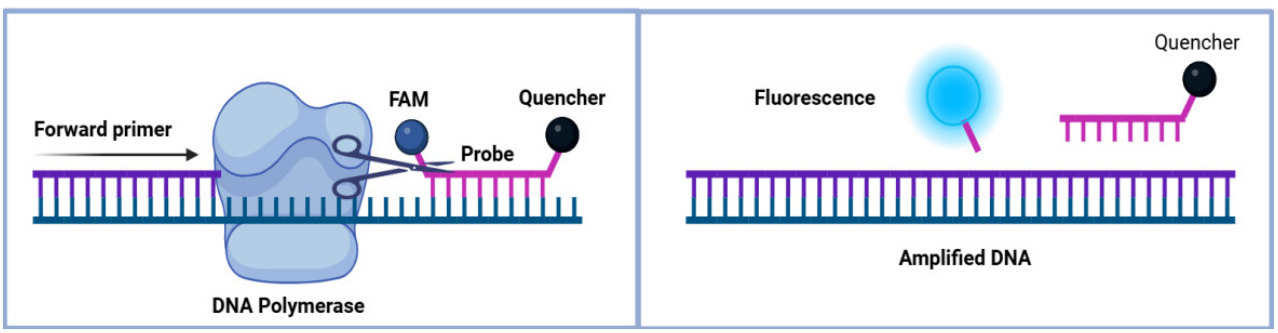
Recombinant proteins, antibodies, and other biologics are commonly generated in host systems such as *Escherichia coli (E. coli)*, Chinese hamster ovary (CHO) cells, or human embryonic kidney 293 (HEK293) cells. While purification workflows remove most contaminants, trace amounts of residual host-cell DNA can remain behind — creating both regulatory and experimental concerns.

For therapeutic products, agencies including the US Food and Drug Administration and the European Medicines Agency require manufacturers to carefully monitor residual DNA levels because carry-over genetic material may compromise product safety. Even in research settings, contaminating host DNA can interfere with downstream assays by triggering immune or cellular stress responses, potentially skewing experimental results.

To help researchers address this challenge, BPS Bioscience has launched a suite of highly sensitive Residual Host DNA Detection quantitative PCR (qPCR) Kits designed for rapid and specific detection of contaminating DNA from bacterial, hamster, and human host systems.

The kits use probe-based qPCR, in which a fluorescent 6-carboxyfluorescein (6-FAM)-labeled probe is cleaved during amplification by the 5′→3′ nuclease activity of Taq polymerase, generating a measurable fluorescent signal only when target DNA is present. This approach combines high sensitivity with strong specificity, enabling reliable detection of trace contamination.

Among the new offerings, the Residual HEK293 DNA Detection qPCR Kit detects human DNA concentrations as low as one femtogram per microliter by targeting human-specific Alu elements, while the Residual CHO DNA Detection qPCR Kit selectively identifies CHO-derived DNA without mammalian cross-reactivity.



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The Residual Host DNA Detection qPCR Kits use probe-based qPCR, where cleavage of a 6-FAM–labeled probe by Taq polymerase generates a fluorescent signal during DNA amplification.

The Residual *E. coli* DNA Detection qPCR Kit detects as little as five femtograms per microliter of bacterial DNA by targeting the 23S ribosomal RNA gene.

By pairing optimized reagents with validated protocols, these kits help streamline residual DNA testing workflows, allowing researchers to generate reproducible, high-confidence results without extensive assay development.

The biotech innovation ecosystem is at an inflection point

At CPHI Americas 2026, a session on the state of biotech innovation framed three forces reshaping how drugs are discovered, developed, and delivered: an accelerating policy environment, rising global competition, and the next frontier for gene editing.

BY ANDREA CORONA

CREDIT: ISTOCK.COM/NUTTAWAN JAYAWAN

CPHI AMERICAS 2026 OPENED ITS FIRST FULL day of programming in Philadelphia with a session that wasted little time situating the pharmaceutical industry within a world in active flux. Speaking Tuesday afternoon, Murray Aitken, Executive Director of the IQVIA Institute, offered a forward-looking read on where the biotech innovation ecosystem is heading — and what forces are driving it there.

The session's framing was broad by design. The biotech innovation ecosystem, Aitken argued, is entering a pivotal phase shaped simultaneously by new modalities, shifting investment priorities, accelerating AI adoption, and a global political environment that is actively rewriting the rules of scientific leadership.

The research-to-care gap is closing

One of Aitken's central observations was that the traditional distance between scientific discovery and clinical application is compressing in ways that have not been seen before. "The gap between what is research and what is care is narrower than ever," he said at the session. For drug developers working in discovery and preclinical stages, that compression can carry both opportunity and pressure: The expectation that experimental findings can be translated into actionable therapeutic strategies faster than the historical pace of the field would have suggested possible.

That narrowing is driven in part by the maturation of platforms — gene editing, cell therapy, RNA-based medicines — that have shortened the path from biological insight to therapeutic candidate. It is also driven by AI, which Aitken identified as a significant accelerant of the scientific progress underpinning the current pipeline.

A policy environment at record intensity

The regulatory and policy backdrop to all of this was described as unusually active. Aitken noted what he characterized as an "all time high of policy initiatives" across the major pharmaceutical markets — a volume of legislative and regulatory activity that reflects both the growing political salience of drug pricing and access and the geopolitical dimensions of pharmaceutical innovation.

Among the most consequential developments at the policy level, Aitken pointed to the European Union's emerging Biotech Act as an attempt to reclaim ground. The legislation, he suggested, is wrestling back some of what has happened over the past 30 years in the US contribution to biotech innovation, while simultaneously responding to the rise of China as a scientific and manufacturing power. That framing — Europe repositioning

itself relative to both the US and China — reflects a broader recognition that pharmaceutical innovation is no longer a domain with a single dominant geography.

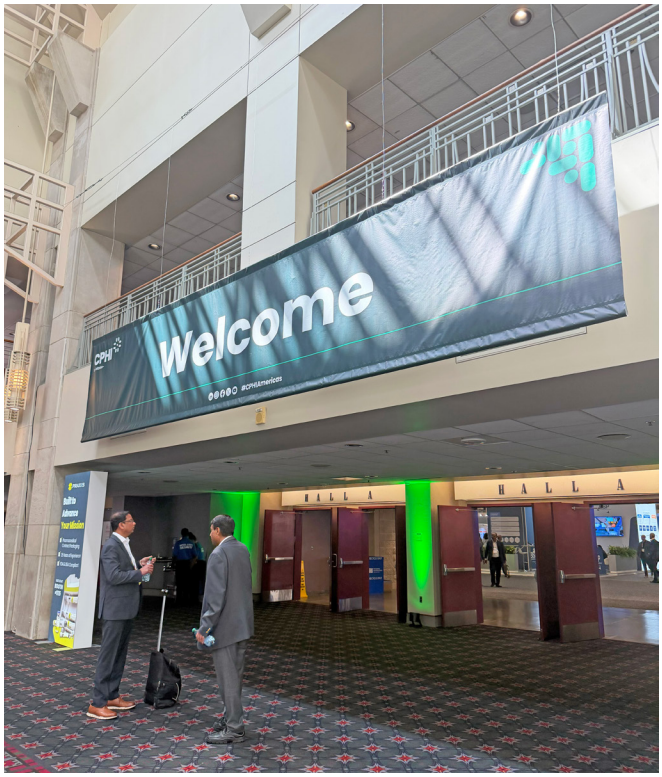
China's scientific ascent was a thread running through the discussion. Aitken noted that China is currently leading in certain dimensions of AI-driven scientific progress, and that governments and policymakers across major markets are actively shifting their stances in response — adjusting investment priorities, regulatory frameworks, and innovation incentives to account for a competitive field that looks fundamentally different from the one that prevailed even a decade ago.

Gene editing's next challenge: scale

Perhaps the most forward-looking element of the session concerned gene editing — a field that has moved from theoretical possibility to clinical reality with remarkable speed but that still operates largely within the constraints of rare disease indications. Aitken identified what he called the "next frontier" of the field: making gene editing apply to more than rare disease and making it relevant to large populations.

That is a different problem than the one the field has spent the last decade solving. The scientific and manufacturing challenges of delivering gene-editing therapies to patients with common diseases — at the volumes, price points, and delivery formats that large-scale adoption would require — are substantially greater than those involved in treating small patient populations with severe unmet need. Solving them will require advances not just in the editing technologies themselves but in the analytical, manufacturing, and delivery infrastructure that surrounds them.

For discovery researchers, Aitken's framing pointed toward the questions that will define the next phase of the field: how to move from proof-of-concept to population-scale relevance, how to navigate a policy environment that is simultaneously more active and more unpredictable than it has been in recent memory, and how to position discovery programs within a global competitive field that now includes serious scientific leadership from multiple geographies. ■



CREDIT: ANDREA CORONA

Attendees connect and collaborate at CPHI Americas, one of the industry's largest global events.

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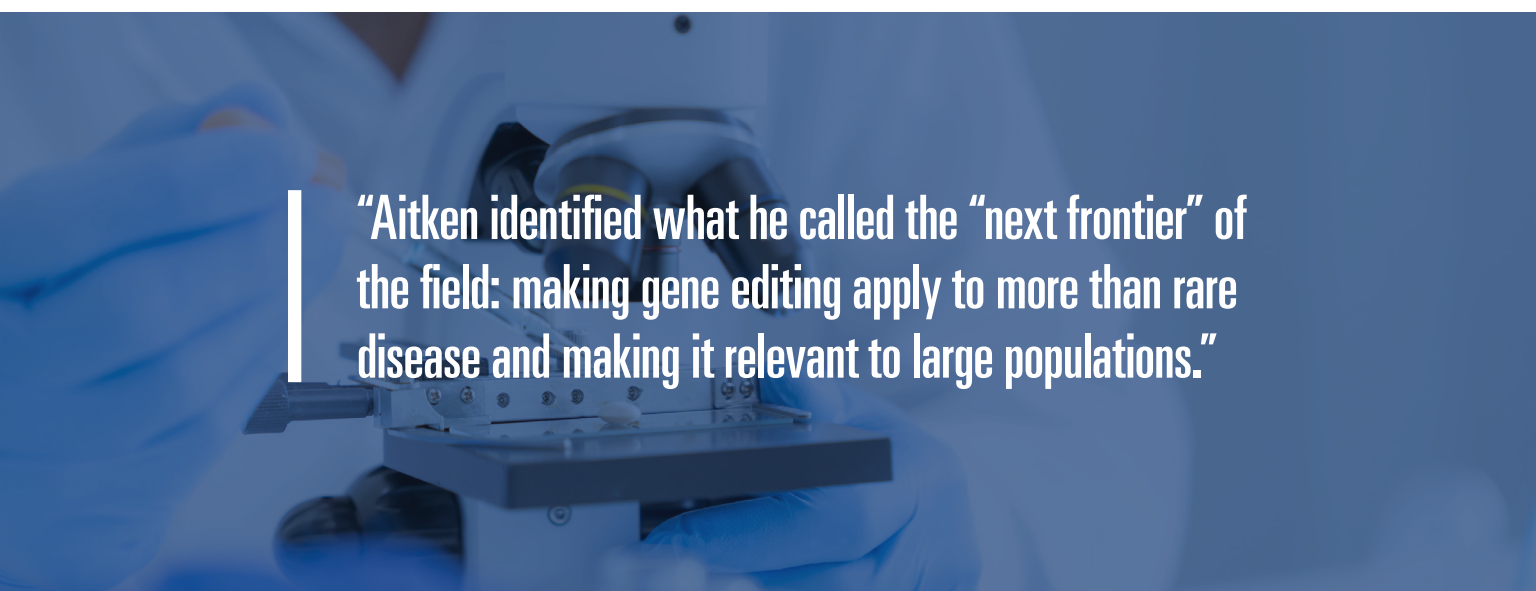
Industry leaders explore the latest innovations and partnerships shaping the future of pharma at CPHI Americas.



> "Aitken identified what he called the "next frontier" of the field: making gene editing apply to more than rare disease and making it relevant to large populations."

What it actually takes to fund a biotech in 2026

A CPHI Americas panel on fueling biotech breakthroughs surfaced something the industry has been circling for several years: the rules of early-stage company building have changed, the investors have changed, and the definition of credibility has changed with them.

BY ANDREA CORONA

WHAT MAKES A BIOTECH FUNDABLE has changed. That was the throughline of a panel at CPHI Americas 2026 in Philadelphia that brought together voices from early-stage investing, company leadership, and incubator management to take stock of where the biotech financing environment actually stands — and what it demands of companies trying to move through it.

Moderated by Jeff Buguliskis, Deputy Chief Editor of Outsourced Pharma, the session brought together Daniel Cohen, Managing Director and Global Head of Pharma Services at Morgan Stanley; Stella Vnook, Executive Chair and CEO of Kaida Biopharma; and Melina Blees, Site Director and Regional Director for the Tristate Area at BioLabs for Advanced Therapeutics Philadelphia. The session covered ground from seed-stage survival to the return of the Initial Public Offering (IPO) market, from the China question to the structural role of incubators in keeping early science alive. What emerged was a picture of an industry that has absorbed a significant recalibration and is now deciding what to do with what it has learned.

Science is not enough

Vnook, opened with a statement that landed as both diagnosis and warning: "Science is not enough."

It is a line that would have been almost unthinkable a decade ago, when the dominant model of biotech company formation ran directly from academic discovery through startup to clinical proof-of-concept — with investor appetite for novel science providing the fuel. That model, she argued, has been fundamentally disrupted. The definition of fundable has changed drastically. What was once a question of scientific credibility is now a question of commercial viability, and the two are no longer treated as sequential. "Investors expect both from day one."

The underlying shift is about who the buyer is. Where an exit strategy once meant an IPO or mergers and acquisitions (M&A) transaction and the end customer was a physician, the picture has been redrawn. M&A partners, patients, and commercial partners are now part of what an investor evaluates when they ask whether a company has thought through its full trajectory. The buyer has changed, and so has the language investors expect to hear. Companies still pitching in the terms of the old model are no longer speaking the language their funders understand, and that disconnect is increasingly what stalls a raise.

The derisking conversation has shifted in parallel. What the industry once considered a derisked asset — a clean Phase 1 readout, a validated target, a first-in-class mechanism — is no longer treated as such by investors.

The gap between what founders believe constitutes meaningful derisking and what investors are willing to recognize as such has widened. The IPO, once a viable near-term goal for companies with strong Phase 1 data, is now for many companies outside the realistic planning horizon. First-in-human trials are experiencing waves of delays driven by a combination of policy uncertainty, regulatory flux, and the collapse of capital availability that characterized the past few years.

And yet Vnook's read was not one of structural pessimism. "We are a very resilient industry," she said. "CDMOs will adjust and adapt. The growing pains are real, but the industry has absorbed disruption before." The question is not whether it survives but whether early-stage companies can make it through a funding gap that has become longer and more demanding than the one their predecessors navigated. That requires building credibility — not only credible science, Buguliskis noted in framing the session, but evidence in manufacturing, approval, and sometimes even patient impact — before asking investors to take the leap.

Capital is coming back — but selectively

Cohen offered a more market-oriented view. His read on the current moment was notably more optimistic than the mood that characterized the sector through most of 2024: The biotech funding environment is in genuine resurgence. The fourth quarter of last year was very strong. The first quarter of 2026 saw IPOs return. Multiple consecutive quarters of recovery in capital markets have restored something the sector badly needed — investor confidence that exits are possible.

"It's becoming a healthier market," Cohen said, "and it gives investors confidence to think about exit strategies." The return of the IPO market as a live option restores optionality for companies and their investors that had largely collapsed. When capital goes in and cannot get out, the entire risk calculus breaks down — and for a period, that is exactly what happened. The unwinding of that dynamic is what Cohen pointed to as the structural shift now underway.

Large pharma's response to its loss of exclusivity problem has accelerated this. The patent cliff facing major pharmaceutical companies has made M&A not just desirable but urgent — generating what Cohen called "Merger Monday," a sustained cadence of deal-making that has reactivated deal flow and given earlier-stage companies clearer visibility to potential acquirers. Capital that was locked in is finding exits. The mood among investors is shifting accordingly.

On the China question — a topic that has generated sustained noise around onshoring mandates, supply chain sovereignty concerns, and geopolitical risk — Cohen offered a counterintuitive read. "On one hand we hear a lot of noise and concern because of the partners in China," he said, "but we almost don't hear about it anymore." The practical operational concerns, in his view, have been absorbed and are being managed. The more significant development is scientific. With $500 billion in large pharma manufacturing capacity as a reference point for the scale of investment at stake, he pointed to a shift in how China itself is positioned: "China is no longer a me too market. They're becoming innovation protagonists." That framing — China not as a manufacturing dependency to be managed but as a genuine scientific competitor — has different implications for how Western biotech companies position themselves and where the next decade of innovation comes from.

The seed-stage gap and the infrastructure of survival

Blees, grounded the conversation in the practical realities facing companies at the very beginning of their journey. While the broader funding environment may be recovering at the Series A and beyond, the picture at seed stage remains harder. Companies are struggling to close early rounds. The distance in the funding spectrum — the space between initial formation and the kind of traction that attracts institutional capital — has not been filled, and pipeline worries among those working with pre-seed and seed-stage companies are real.

Venture capital's response to this has been a structural embrace of the incubator model. The logic is straightforward: Incubators reduce capital outlay, compress risk, and allow investors to evaluate companies under conditions that are more controlled than the open market. For the companies inside them, the value proposition is equally clear. "Incubators allow companies to put their capital and risk and comfort into the science itself instead of space and team," Blees said — concentrating the scarce resource of early capital on the work that actually creates value rather than on the operational overhead that surrounds it.

The practical implication is that incubators are shifting from community-building and service-provision models toward a more deliberate function: connecting companies to capital. That means more time spent on introductions, term sheet conversations, and investor relationship development, and less on the amenities and programming that defined the model in its earlier form. Companies that know how to use an incubator strategically — as a bridge to the next funding event rather than as a permanent home — are the ones finding the path forward.

Blees also pointed to an underutilized set of resources available to early-stage companies: free access to equipment, core facilities, and technology transfer programs that many founders are simply unaware of. Equipment manufacturers, she noted, are actively eager to partner with startups — offering access to platforms and workflows at no cost in exchange for the feedback and visibility that comes with working alongside companies at the frontier of what their instruments are asked to do. "Getting scrappy and creative about these resources," rather than trying to build internal capacity before the capital exists to support it, Blees added, "is increasingly what separates companies that survive the seed-stage gap from those that do not.

The need for live animal or comparable biological data as a threshold for the next funding conversation was another practical constraint she named. Companies that can generate that data through core facilities rather than proprietary infrastructure are able to meet the bar investors have set without the capital commitment that building that infrastructure requires. It is a bridge strategy, Blees acknowledged — but right now, bridges are what the sector needs. ■

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