CPHI Americas

At the heart of Pharma

CPHI Americas Roundtable Round-Up: Reckoning with a new pharma landscape

CPHI Online

Insights from
CPHI Americas 2025
Investor Roundtable

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Introduction

CPHI Americas is the premier pharmaceutical trade show for the whole of the American pharmaceutical supply chain, from north to south. From May 20-22, 2025, the CPHI team welcomed exhibitors, attendees, speakers, and sponsors from around the world to the Pennsylvania Convention Center in Philadelphia, USA for 3 days collaboration and innovation.

At this year's CPHI Americas 2025, the CPHI Content team hosted a closed roundtable with industry experts to discuss the most pressing issues facing the pharmaceutical and healthcare industries today.

Conversations ranged from the value of global pharmaceuticals to the state of AI technology and Pharma 5.0, bringing together insight from different perspectives and a stimulating exchange of ideas. This report brings you a deep dive into the conversations had, and what experts from around the world are saying about issues affecting the pharmaceutical supply chain within the Americas and globally.

Vivian Xie,
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Prescriptions without borders: mapping the pharma battleground

"What manufacturing can be moved to the US, and what will this look like? What does cost efficiency mean in US terminology? Can we meet the efficiency, agility, and performance expected?"
Stella Vnook, CEO, Likarda

Though the show floor was abuzz with excitement, there was an undercurrent of uncertainty throughout the conference sessions at CPHI Americas 2025. Being hosted in Philadelphia, it was hard to ignore the current US administration's stance on trade disputes and discrepancies, and the pharmaceutical industry is not exempt.

Stella Vnook, CEO of Likarda, stated that, "We don't know what we don't know. It's not clear to which degree these tariffs are going to materialise. What it has prompted, though, is a reckoning with what manufacturing can be moved to the US, and what this will look like. What does cost efficiency mean in US terminology? Can we meet the efficiency, agility, and performance expected?" Several conference sessions touched upon the impact of President Trump's, including Gil Roth's session 'Market Dynamics Shaping CDMOs: Trends and Policies' and Claudia Lin's 'Biosecure Act: A Cure for Supply Chain Weakness or More Red Tape?', both participants in this year's roundtable. **Lin, Executive Vice President at Pharmatech Associates**, commented "One of the more depressing realities I see for the current environment of the US is the loss of leadership in true innovation and safe and efficacious drugs. While the Biosecure Act is really focusing on WuXi, few companies really have the kind of influence that WuXi has – the general lack of quality can maybe pass during early-stage development but when it's time for clinical production, trials, and late-stage development, few companies can scale like WuXi did."

Tariffs and regulatory uncertainties may drive innovation away from the US toward China, stated our roundtable. Of the 90 bioproducts approved in China, only 6 have received FDA approvals, reflecting FDA pushback on clinical trial design and manufacturing quality standards. Drug discovery is advancing rapidly through AI applications, but clinical development remains a significant bottleneck. There is a pressing need to accelerate development processes while keeping patients central throughout the entire journey, from diagnosis through routine care. **Archana Sah, Founder and CEO of AS Pharma Advisors**, explained "The real bottleneck lies at the door of clinical development, and has persisted and must be addressed if we're to bring these innovations to patients.Smart trial designs along with leveraging technological advancements like digital twin, wearable sensors, and decentralised trials in a fit for purpose approach,

"I worry with this news and the funding cuts with the [National Institute of Health] that we are losing ground with other countries – there's going to be a dearth of investment in innovation"

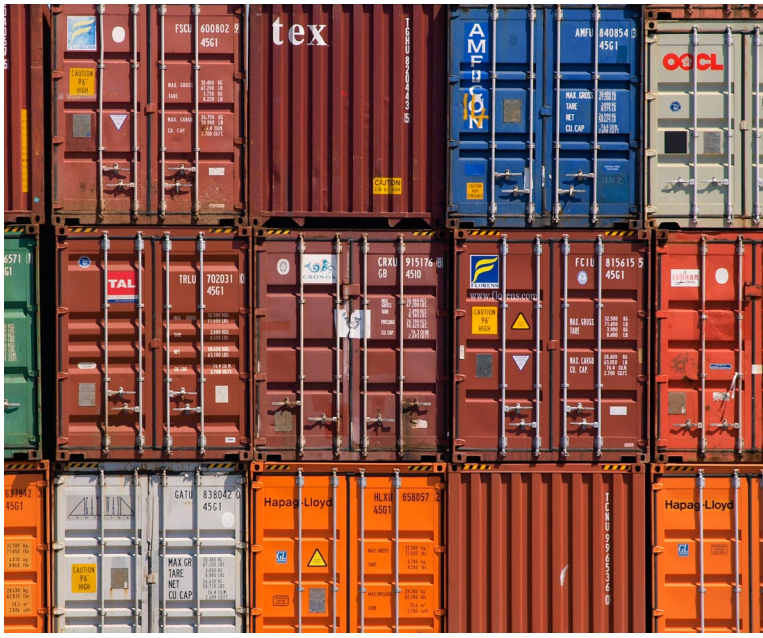
Archana Sah,
Founder and CEO,
AS Pharma Advisors

represent the future of pharmaceutical innovation, but are also being constrained by current regulatory policy and economic uncertainties. I do see early innovation work moving outside the US – when advising VC firms and investors, I'm frequently asked about investing in companies in countries like China. The concerning reality is that funding challenges affecting the NIH and academic centres, which have traditionally fuelled fundamental innovation, will likely slow progress. Consequently, some innovations will shift overseas, at least during uncertain times, potentially compromising the US' leadership position in research and early innovation."

In short, domestic or regional manufacturing is only viable if costs can be effectively managed. Large pharmaceutical companies are increasingly decentralising innovation across country centres to mitigate risks and leverage regional expertise. The need for diverse patient recruitment presents challenges in certain regions with homogeneous populations.

During CPHI Americas, the Trump administration signed an executive order for the Department of Health and Human Services (HHS) to pressure pharmaceutical manufacturers to align US pricing for all brand products on market that do not have a generic or biosimilar competitor with the lowest price out of 26 OECD countries. While some have taken the order with a grain of salt, **Cynthia Pussinen, CEO of Owl Bio Advisors**, said "I worry with this news and the funding cuts with the [National Institute of Health] that we are losing ground with other countries – there's going to be a dearth of investment in innovation."

Roth, President of the Pharma and Biopharma Outsourcing Association, responded "To me, it reminds me of the Clinton healthcare issue where the major pharma companies all decided they had to start expanding into other spaces, which is how you ended up with Merck Medco becoming a drug distribution company. Part of that expansion involved cutting down on R&D, and then 3 years later, there was a lag. In pharma, these things aren't immediate, and fortunately you do continue getting



blockbuster hits that can carry things through times like these."

Our roundtable experts were also wary of who would be the most affected by regionalisation and reshoring efforts for manufacturers: "Can it become more regionalised? Only by increasing costs, which to be blunt, innovators can absorb these costs while smaller biotechs and the generics industry will get hurt," Roth puts it plainly. "You can't move most of the commodity generic manufacturing to America, given the cost structures of that sector."

Sah concludes with her thoughts on the unpredictability and sometimes conflicting administration orders: "Most of large pharma have regional offices all over the country, so we may see those regional centres decentralising the innovation. Even with the DEPICT Act, which requires phase III pivotal trials to demonstrate diversity action plans (to regulatory bodies) to enrol diverse patients representative of hte prevalence of diseases globally (which makes sense scientifically and ethically), the current administration's stance on diversity may slow down this much needed scientific and ethical progress in clinical research and we may see some of the work shift outside the US."

Designing compliance: AI and regulatory intelligence in pharma

Artificial Intelligence holds tremendous potential to advance human health outcomes across the global healthcare ecosystem. However, significant questions remain about its practical applications, regulatory frameworks, and implementation strategies.

On the subject of regionalisation, the harmonisation of regulatory guidances across different nations, regions, and sectors continues to be an ongoing issue, especially as digital transformations with AI take place.

Progress in AI adoption varies significantly by country, as explained by **Dominick Romano, Founder of drainpipe.io:** "Technology oligarchs are creating a particularly problematic 'wild west' scenario in the pharmaceutical industry due to a lack of regulation. This regulatory vacuum creates too much variance and an uncontrolled market that's ultimately bad for business. I would say that Europe is actually pulling ahead in AI implementation because they have established laws that clarify risk profiles and compliance requirements for their jurisdictions. The excessive noise in the US market around these issues prevents clarity for decision-making and implementation, and in pharma specifically, we lack trustworthiness in our ability to design systems that map and understand variance in outputs. AI presents a combinatorial challenge of multiple inputs and outputs, which pharma is in fact well-equipped to handle given its existing frameworks. What we need in this region is to map existing guidelines, like ICH, to AI systems – something I've been working with one of the largest European pharma companies. By embracing these guidelines, you have a design space to resolve data with acceptable and measurable ranges. We urgently need process validation for AI in pharma to enable such an implementation."

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Dominick Romano,
CEO and Founder,
drainpipe.io

The harmonisation of AI regulations presents a complex challenge in the healthcare sector. There is an urgent need to map existing guidelines, such as those from the International Council for Harmonisation (ICH), with AI systems and develop robust process validation methodologies for AI applications in pharmaceuticals. Current US export controls are widely viewed as problematic within the industry, with many arguing that increased exports could drive down global pricing and improve access to healthcare technologies.

Artificial Intelligence holds tremendous potential to advance human health outcomes across the global healthcare ecosystem. However, significant questions remain about its practical applications, regulatory frameworks, and implementation strategies. The healthcare industry stands at a critical juncture where AI technologies are beginning to transform everything from drug discovery to patient care, yet the regulatory and implementation landscape varies dramatically across regions. Deploying strategic risk portfolios with unharmonised regulatory guidance has, as Romano put it, "shifted the culture to where these diverse risk portfolios in the US aren't diverse enough. We will have seven labs each with a particular culture, but doesn't produce the kind of diversity we need in AI right now to maintain a leading global position to innovate at the rate of a nation like China."

Optimistically, Sah mentioned current uses of AI in healthcare and pharma, though tentative, and its potential: "I definitely feel AI is being deployed in many hospitals – from an efficiency perspective, AI has real potential not just in clinical research, but also in real world clinical care. In France, they are integrated AI into patient clinic workflows and building efficiencies from the ground-up. In the US, hospitals like Mass General, MSKCC, and MD Anderson's have been incorporating AI as part of their workflows to build efficiency."

Latin American market potential and challenges

"In terms of efficiency in the biotech and experimental sectors of pharma, a lot of people are saying that there will possibly be a huge number of innovative products in the coming months."

Ricardo Castro, Vice President of Regulatory Affairs, Elysian Bio

A discussion on trends at CPHI Americas wouldn't be complete without a comprehensive conversation around the potential of the Latin American pharmaceutical market and supply chain.

Romano gave some context into the dynamics at play throughout the region: "Chile is in a really good position in South America, There's a couple of different things happening – Bolivia and Perui have been receiving massive shipments of drones from China and India, and it's putting pressure on technological innovation South America."

Ricardo Castro, Vice President of Regulatory Affairs at Elysian Bio, shed light on where in Latin America innovations in AI, pharmaceutical manufacturing, and supply chain efficiencies are taking place. "In terms of efficiency in the biotech and experimental sectors of pharma, a lot of people are saying that there will possibly be a huge number of innovative products in the coming months. However, in Latin America, we haven't developed an efficient system for these different products, which we might not even have in the next 5 years or so as it will be very costly. This has a lot of people wondering what efforts are there from an AI and intelligence perspective on the integration of a technology pipeline in the next 10 years."

"As far as AI is concerned, a lot of this uncertainty is coming from the fact that the United States is really the catalyst for this rise in the AI space," responded Romano. "From a mathematical standpoint, we lack the educational background to address some of these issues related to AI – for example, if you have a sequence of numbers, here in the US we are trained that this sequence is a point in some space somewhere. Other countries, like France and Sweden, however, are trained to look at these number sequences as lines. This changes the way we think about the numbers and can unlock different mathematical modalities which can change how we address the problems we're facing. This lack of educational diversity in the US has prevented us from coming up with certain regulatory or governance solutions to AI that would actually accelerate its adoption. None of what we are doing right now with AI is at the level of reliability needed for pharma."
Adopting the strategies of global pharmaceutical companies could provide a pathway for the US pharmaceutical landscape towards better AI integration, with Romano using his work at Boehringer Ingelheim to demonstrate: "In cooperation with our largest customer, we have developed a unique system that is providing inputs to their AI model that are validated and outputs that are validated, which is no different from a process validation step in pharma. But with AI workflows, you need to do this at every single stage, because each stage could present a compound error issue. Such companies are planning ahead 10 years, to 2035, because they know they need to adjust their entire IT infrastructure to support this. You have to think about how you represent the data across clinical trials in animals, to humans, and the regulatory aspect as well. There's a tremendous amount of data there. Do you have

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Vice President of Regulatory Affairs,
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the design spaces to map all this data? That's the problem that these companies are facing now."

In other aspects of the pharmaceutical industry, Castro listed some of the more prevalent areas of focus for the Latin American region, and cited significant unmet needs in oncology and capacity constraints limiting domestic service and export potential. Argentina, despite this, does show some of the strongest regional manufacturing capabilities, he states. "Depending on the country, the therapeutic area focus will differ," he said. "In Mexico, while it has the greatest need for oncological products, the most sold products are insulin, liraglutide, and semaglutides. For cancer, it's quite interesting because when you look at the numbers, the number of patients admitted to hospital in the US and EMEA is ten times higher than all Latin American countries combined. Yet, because products must come through the government, around 60-70% of oncology patients don't receive treatment. There is a lack of access because the market access itself is abysmal, and the treatment capacity in Mexico is not there. From 2018 to 2024, the health budget was cut by 50% in Mexico, with talks of reducing corruption and becoming more efficient, but the result is not what we need. From the perspective of companies in Mexico, they say 'we have capacity for market access in the US even though they don't have capacity to produce their own products'. The reason is because the government only pays for a certain number of units, but is not enough to supply the need in the entire nation. The private sector is growing, with more than 10% growth in the last 5 years because of COVID, but even specialist facilities in Mexico do not guarantee access to any of this medication. That is the way the system works in Mexico, and in countries like Colombia and Peru. Argentina has a little bit more market access because they have production capacity with APIs and biotechs like Chemo and MapScience. Other countries don't necessarily have that production capacity."

When asked whether market access might improve in Latin American countries, Castro was hesitant. "The owners of the company invest money in the supply needs for the [Mexican] government, or they invest

in the needs for the US. This is made more difficult with changes in regulations. In 2014, there were more than 70 biologic products. The Mexico drug regulator COFEPRIS has recently required that companies must support a comparability study – now, more than 90% of approved products at the moment will lose their registration because they cannot support the comparability data. For example, several companies in Mexico that produce biosimilars (previously referred to as biologic generics) generated over 10 billion pesos between 2005 and to 2014. However, none of that revenue has been invested in improving their dossier so when changes in regulations take effect, they must ask for help from authorities, since they remain the sole suppliers of these products. Even today, some of the products are still registered without having demonstrated biosimilarity."

Sah asked whether local governments encouraged local innovation and growth, citing India's own encouragement of local growth and development during the COVID-19 pandemic with in-grown vaccines. Castro responded that, "China and India are making great efforts to develop and integrate new technologies, designs, and processes to get the best products at lower costs. They are moving into continuous processing in biotechs and that is a huge step in the right direction. But even with that, there are companies that sell into China, such as Eli Lilly selling on their PD-L1s to China because they have the license that China doesn't have. I think there are a lot of companies in Latin America making good drug products, both biosimilars and generics. But there is a lack of knowledge and quality control despite our current submission and review process."

Pre-competitive collaboration for supply chain robustness

"I think there will be a lot of pre-competitive collaboration between all stakeholders, including pharma companies."
Archana Sah, Archana Sah, Founder and CEO, AS Pharma Advisors

The pandemic and recent policies have highlighted critical dependencies, with our experts citing over 70% of US-used APIs produced overseas. Complete self-sufficiency is unrealistic; strategic partnerships and diversification are recommended. "I think there will be a lot of pre-competitive collaboration between all stakeholders, including pharma companies," Sah comments. "This is where industry consortiums come into play, because as a pre-competitive collaboration unit, there can be representation from regulatory bodies, from pharma companies, from biotechs, and from patient advocacy boards. This multi-stakeholder, pre-competitive collaboration unit needs to share more than what it does in the name of pre-competitive sharing of information – a rising tide lifts all boats, after all. It will do pharma a lot of good to share information and data – that is going to be the engine for overcoming some of these hurdles we see with supply chain vulnerabilities, as opposed to each company trying to solve the same thing themselves."

The 'wild west' of AI could even benefit from such initiatives, Romano commented, stating "The ITU [International telecommunication unit] has been really helpful in their leadership, especially in the AI and health space. They've done some of the best research on AI for global health initiatives ranging from tuberculosis to AI for radiology and more. They're really working hard to present the technical documentation to the WHO."

Despite the holistic call for unity across borders, some remained skeptical of the US' ultimate goal. Vnook asked, "Are we gaining anything? I think that question remains to be seen because what we're experiencing is a tsunami wave. We're trying to figure out what to do while everything is still happening. It's difficult to say what America is going to gain and the best we can do is hypothesise on the US' intent."

"Part of the generic drug user fee includes a breakdown of every fee-paying facility to fit into user fee negotiations, and it lists about 100 US API sites against around 670 non-US API sites"

Gil Roth,
President,
Pharma and Biopharma Outsourcing Association

"Ultimately the intent is to reshore and have more self-reliance in medicine in general," Lin answered. "In the US, I noticed many API companies moving out of major cities for sustainability reasons. In order to get APIs at a certain price at a particular purity, you have to pollute the environment. That's when all the biotech companies moved in and the API companies moved abroad. But there will be a huge impact in bringing that back to the US."

"Part of the generic drug user fee includes a breakdown of every fee-paying facility to fit into user fee negotiations, and it lists about 100 US API sites against around 670 non-US API sites," Roth added. "The vast majority of these API sites do not say how much volume is coming from them. The CARES Act passed in early 2020 included the Reporting Amounts authority for the FDA, mandating every API and finished dosage form facility to report the volume of everything they're making each year. The draft guidance is terrible, especially from an API perspective – for example, filling part of a barrel would count the same as one full barrel. If you're starting with deficient information at the beginning, you end up with skewed ranges of what is actually being made where at any given time. That's why there's a push for supply chain transparency – currently there's a questionnaire throughout the US to every API supplier to gain clarity on what they make and howe much, which is tied to the Defense Product Act (DPA), making it mandatory. From what I hear, companies are being asked for information beyond their scope that may wind up providing the government with useless or unactionable information. That said, one of the issues that the FDA has run into is companies think they're sourcing from different API suppliers, but in reality it all comes from a single facility, with, say, five different generics relying on that one site. If that site goes down, everything goes."

Subhi Saadeh, Host of Let's Combinate (Podcast), offered his experience during the COVID-19 pandemic on supply chain collaboration. "After COVID, my experience working with CMOs and contract test labs was much more collaborative than one of secrecy and holding back. Maybe 5 years ago, you would get innocuous feedback from a supplier or CMO like the

way we apply this 50-year old sampling standard is proprietary – now there's a bit less of that and you see a lot more collaboration and sharing with sponsors.

During his Senate confirmation, the new FDA commissioner mentioned that one of his initiatives is to make NARCAN and EpiPen over the counter (OTC), which has the possibility to completely shift the way we do drug device development.

From a device point of view, your user and environment are the entire context you are designing around. If you're expanding that to OTC for devices that were designed for a specific user in mind, it can be quite a shift. But if you have collaboration between regulators and pharma and with the appropriate controls, you can certainly make that happen."

An inevitable shift or wake-up call? Concluding thoughts

Companies should view current tariffs as a wake-up call to diversify supply chains and invest in resilient manufacturing capabilities. The healthcare industry needs more precompetitive collaboration and data sharing to accelerate innovation while maintaining safety standards. Harmonisation of standards across regions is essential for efficient global development and deployment of AI healthcare solutions.

Continuous processing represents a significant advancement in pharmaceutical manufacturing that could improve efficiency and quality. Despite excellence in some areas, quality perception issues persist for Chinese products, requiring greater transparency and standardisation to build trust in the global marketplace.

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