CHRONICLE PHARMABIZ

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iPHEX technical sessions to brainstorm emerging trends

Shardul Nautiyal, Delhi

The inaugural session of iPHEX 2024 unfolding on August 28 at the International Exhibition & Management Centre (IEML) in Greater Noida, will be hosted at the elegant Banquet Hall, underscoring India's leading role as the "Pharmacy of the World" and will set the stage for a comprehensive exploration of industry advancements and collaborative opportunities.

The day's agenda also includes two significant panel discussions that will delve into critical industry issues. These sessions will dwell on emerging trends, challenges, and solutions in the pharmaceutical sector, reinforcing India's role in shaping the future of global healthcare.

The day will commence with a registration period from 09:00 AM to 10:00 AM, during which participants from across the globe will assemble and prepare for a day filled with high-level discussions and networking opportunities. The formal inauguration will begin with the traditional lighting of the ceremonial lamp and the welcoming of guests from 10:00 AM to 10:10 AM. This ceremony will be a symbolic gesture marking the start of the event and its significance.

Namit Joshi, Chairman of iPHEX 2024 and Vice Chairman of Pharmexcil, will deliver a welcome address. His speech will highlight the transformative impact of Indian pharmaceutical innovations and the critical role of international cooperation in advancing the industry.

S.V. Veeramani, Chairman of Pharmexcil, will follow with insightful opening remarks. Veeramani will discuss the evolving landscape of the pharmaceutical sector, focusing on regulatory updates and the importance of sustaining high industry standards through global collaboration and innovation.

Nitin Kumar Yadav, IAS, Joint Secretary EP-PHARMA, Department of Commerce, Ministry of Commerce

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IPHEX 2024, a hub for fostering innovation & collaboration

Terming IPHEX 2024 as a hub for fostering innovation and driving collaboration, leading, Ahmedabad - based pharma consultant, **DR SANJAY AGARWAL** in an interview with **SHARDUL NAUTIYAL** dwells on the pivotal milestones in the evolution of Indian pharma industry and its future prospects.

What are your key expectations for the 10th International Pharmaceutical Exhibition (IPHEX) 2024? As an event organized by Pharmexcil, how do you see it fostering innovation, collaboration, and driving insights in the industry?

As I look forward to the 10th International Pharmaceutical Exhibition (IPHEX) 2024, my expectations are high. This event, organized by Pharmexcil, is more than just an exhibition; it's a hub for fostering innovation, driving collaboration, and gaining crucial insights into our industry's future. I anticipate a showcase of groundbreaking technologies and new drug formulations that will redefine our approach to healthcare. But beyond the technology, it's the opportunities for collaboration that truly excite me. IPHEX 2024 is where partnerships are born, where industry leaders and innovators come together to share knowledge and forge alliances that will propel our industry forward. I see this event as a catalyst for meaningful discussions, deep dives into regulatory challenges, and an exploration of the global market dynamics that shape our work. This is where the future of pharmaceuticals will be mapped out.

Can you walk us through the evolution of the pharmaceutical industry? How has it transformed over the years, and what pivotal milestones have shaped its journey?

Reflecting on the evolution of the pharmaceutical industry, it's remarkable how far we've come. What started with the simple extraction of natural compounds has transformed into a sophisticated, technology-driven sector. The Industrial Revolution marked a turning point, bringing mass production and synthetic chemistry into the picture, and with it, a new era of drug development. Regulatory frameworks that emerged in the mid-20th century were crucial in standardizing safety and efficacy, laying the groundwork for today's stringent oversight. The biotechnology revolution of the late 20th century introduced us to biologics and gene therapies, while the Human Genome Project opened doors to genomics-based drug discovery. Now, in the 21st century, we're in the midst of a digital transformation. AI, big data, and IoT are not just buzzwords- they're reshaping how we discover, develop, and deliver medicines. This journey has been nothing short of extraordinary, with each milestone pushing the boundaries of what's possible.

From your perspective, what are the major regulatory compliance challenges that pharmaceutical companies, particularly MSMEs, are grappling with today?

In my view, regulatory compliance is one of the toughest challenges for MSMEs in our industry. The standards we must adhere to are incredibly stringent, and for smaller companies, meeting these standards can be a daunting task. The need for meticulous documentation, reporting, and continuous monitoring can overwhelm MSMEs, especially when resources are limited. Furthermore, the complexity of navigating different regulatory requirements across global markets adds another layer of difficulty. Compliance isn't just about ticking boxes- it requires significant investment in infrastructure, technology, and expertise. And let's not forget the cost. The financial burden of staying compliant, from audits to certifications, can be overwhelming for smaller firms trying to stay competitive.

What specific steps should the government take to enable Indian pharma companies to scale globally and consolidate their presence in international markets?

To truly enable Indian pharmaceutical companies to scale globally, I believe the government needs to take some decisive steps. Streamlining regulatory processes to align more closely with international standards is critical- this would make

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it easier for our companies to enter and compete in global markets. Financial incentives, such as tax breaks or subsidies, would also be a significant boost, especially for those investing in R&D and infrastructure. Moreover, negotiating favourable trade agreements could open up new markets and reduce entry barriers. We also need to focus on skill development, ensuring our workforce is equipped to meet the demands of an increasingly complex global market. These steps would not only help us scale but also consolidate our presence internationally, making Indian pharma a force to be reckoned with.

With profit margins tightening and compliance costs rising, pharmaceutical firms are finding it increasingly difficult to fund R&D for new drugs. What are your expectations from the government in terms of support for domestic pharmaceutical R&D?

With profit margins tightening and compliance costs on the rise, funding R&D has become increasingly challenging for many pharmaceutical firms. My expectation from the government is clear: more support for domestic R&D. This could come in the form of increased funding for both public and private research initiatives, particularly in high-risk, high-reward areas like novel therapeutic molecules and advanced drug delivery systems. Public-private partnerships could be a game-changer, allowing us to share knowledge, reduce costs, and accelerate innovation. Tax incentives for R&D investments would encourage more companies to take the plunge into uncharted territories. Additionally, simplifying and expediting the approval processes for new drugs could reduce the time and cost associated with bringing innovations to market. This support is essential if we want to remain at the forefront of global pharmaceutical innovation.

How would you describe the current transformative phase in pharmaceutical R&D, particularly in the development of novel therapeutic molecules and advanced drug delivery systems for therapeutic areas like diabetes, cardiology, and pain management?

We are currently in the midst of a transformative phase in pharmaceutical R&D, one that's redefining the future of medicine. Advances in genomics, proteomics, and synthetic biology are opening doors to novel therapeutic molecules that were once thought impossible. This is particularly evident in areas like oncology, immunology, and rare diseases, where targeted therapies are making a profound impact. At the same time, innovations in drug delivery systems, such as nanotechnology and controlled-release formulations, are improving the efficacy and safety of treatments, especially for chronic conditions like diabetes and cardiovascular diseases. The shift towards personalized medicine, where treatments are tailored to an individual's genetic profile, is not just a trend-it's the future. This is an exciting time in pharmaceutical R&D, and I'm eager to see where these advancements will take us.

How do you envision AI and IoT tools helping to lower the costs associated with traditional clinical trials and speeding up the drug discovery process?

AI and IoT are poised to revolutionize the way we conduct drug discovery and clinical trials. By leveraging AI-driven models, we can predict the efficacy of drug compounds with greater accuracy, reducing the need for costly and time-consuming lab experiments. This not only lowers costs but also speeds up the discovery process, allowing us to bring new treatments to market faster. In clinical trials, IoT devices enable real-time monitoring of patients, providing continuous data that improves the accuracy of trial outcomes. This can significantly reduce the duration of trials, saving both time and money. AI also enhances data management, automating the collection and analysis of trial data, which is crucial for regulatory submissions. In short, AI and IoT are game-changers, bringing efficiency, accuracy, and speed to a traditionally slow and expensive process.

Data integrity is crucial in the pharmaceutical value chain. Can you elaborate on its significance and the

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best practices to ensure its protection?

Data integrity is absolutely critical in the pharmaceutical value chain. Ensuring that data is accurate, complete, and consistent is not just a regulatory requirement—it's a matter of patient safety. Reliable data means that the drugs we develop are safe and effective, reducing the risk of adverse effects and building trust with patients and regulators alike. Best practices for ensuring data integrity include implementing robust data governance policies, using secure data management systems, and conducting regular audits. It's also essential to train employees on the importance of data integrity and ensure that everyone adheres to standard operating procedures.

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In an industry where data drives decisions, maintaining the highest standards of integrity is non-negotiable.

What are the key trends driving the growth of the domestic formulation and API markets? How do you foresee these trends shaping the industry in the future?

Several key trends are currently driving the growth of the domestic formulation and API markets, and I believe these will continue to shape the industry in the future. First, there's the rising demand for pharmaceuticals, driven by an increasing prevalence of chronic diseases and a growing population. This is particularly evident in therapeutic areas like diabetes, cardiovascular diseases, and oncology. Additionally, there's a strong push towards self-reliance in API manufacturing, reducing our dependency on imports. Government initiatives like the Production Linked Incentive (PLI) scheme are playing a crucial role here. Innovation in drug formulations, such as fixed-dose combinations and long-acting injectables, is also on the rise, enhancing patient compliance and treatment outcomes. Finally, the growing global demand for affordable generics is providing Indian pharmaceutical companies with significant export opportunities. These trends are setting the stage for robust growth in the years to come.

How is the pharmaceutical sector embracing sustainability, and what innovative practices are being implemented?

The pharmaceutical sector is increasingly embracing sustainability, and I'm proud to see the innovative practices being implemented. Green manufacturing is becoming a priority, with companies adopting environmentally friendly practices to reduce waste, conserve energy, and minimize the use of hazardous materials. The concept of a circular economy is also gaining traction, as the industry explores ways to recycle and reuse materials, reducing our environmental footprint. Sustainable sourcing is another area of focus, particularly in the case of biologics and natural products, where ethical sourcing practices are essential. Some companies are even committing to achieving carbon neutrality by investing in renewable energy and offsetting their carbon emissions. These practices are not just good for the planet- they're good for business, helping us build a more sustainable and responsible industry.

Finally, what are your thoughts on the future growth prospects of the Indian pharmaceutical industry?

When I think about the future growth prospects of the Indian pharmaceutical industry, I'm filled with optimism. Our expansion into global markets is gaining momentum, driven by our expertise in generics and biosimilars. Continued investment in R&D, particularly in novel drug discovery, biologics, and personalized medicine, will be key to maintaining our competitive edge. Government support, through proactive policies like the PLI scheme, is helping to boost domestic manufacturing and reduce our reliance on imports. The development of healthcare infrastructure in India, coupled with rising healthcare awareness, is also driving demand for pharmaceuticals. Lastly, the digital transformation of our industry, with the adoption of AI, big data, and IoT, is enhancing efficiency across the value chain. All these factors point to a bright future for the Indian pharmaceutical industry, one that's poised for sustained growth and global leadership. ◆

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Lewis King, Head of Business Development, Aspire Pharma Limited, United Kingdom, Dr. Nrusingh Prasad Mohapatra, Co-founder & Chief Scientific Officer, Nikoni Pharmaceuticals, USA, GM Khalilur Rahman, Managing Director, Chem Expertz Ltd, Bangladesh, Aman Madan, Managing Director-Neo Health, Australia, Margarita Kellerman, CEO, Osteo-Sibear Ltd, Russia, Asharaf Kurukkan Poil, Vice President – IBPC & Managing Director – Wellcare Group, Qatar and Dr. Anand Govindaluri, Group CEO, GOVIN Holdings, Singapore

The discussion will center around innovative approaches to expanding access to medical products and enhancing global healthcare delivery.

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