



OPPI

Organisation of Pharmaceutical Producers of India



भारत के लिए

# ANNUAL SUMMIT 2023 REPORT

Date: 23rd November, 2023

भारत के लिए





## भारत के लिए

Map not to scale

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## Acknowledgements



The Organisation of Pharmaceutical Producers of India (OPPI) would like to thank all our partners and stakeholders for their participation and insightful contribution to the deliberations of our Annual Summit, organized this year under the theme, भारत के लिए.

We extend our heartfelt appreciation to the distinguished government officials who graciously spared valuable time from their demanding schedules to join us. Their insightful perspectives not only enrich our understanding but also promise substantial contributions to the ongoing enhancement of the pharmaceutical sector and ensure that it is fit for the future and the new reality that we live in.

We express our sincere gratitude to Shri. Sudhansh Pant, Secretary, Ministry of Health & Family Welfare, Government of India, for honoring the Annual Summit with his distinguished address.

We thank Shri. R. P. Singh, Joint Secretary, Department of Pharmaceuticals; Prof. Y K Gupta, Principal Advisor India Strategy Development – Global Antibiotics Research and Development Partnership (GARDP) & President of AIIMS Jammu; Dr. Rajeev Singh Raghuvanshi, Drugs Controller General of India, CDSCO, Government of India; Ms. Supriya Devasthali, Director, Department for Promotion of Industry and Internal Trade (DPIIT); Dr Akshay Jain, Joint Director, National Health Authority, Ministry of Health & Family Welfare, Government of India; Mr John Cabeca, United States Intellectual Property Counselor for South Asia, U.S. Patent and Trademark Office (USPTO) American Embassy – New Delhi to honor the occasion with their esteemed presence.

We would also like to take this opportunity and extend our thanks and gratitude to the Department of Pharmaceuticals (DoP), Invest

India, Pharmaceutical Research and Manufacturers of America (PhRMA), International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), Japan Pharmaceutical Manufacturers Association (JPMA), and National Health Authority for the sustained support and partnership in making the OPPI's Annual Summit a success.

The support of multilateral organizations, international government entities, academia, private sector leaders, and civil society has been invaluable. We thank the officials of Pfizer Ltd., Indegene, Eversana, Bristol Mayers Squibb, Merck Specialities, Bayer Pharmaceuticals Pvt. Ltd., K&S Partners, Apeejay Styra Svran Group, among others for their support.

## Executive Summary



The theme for the OPPI Annual Summit organized on 23 Nov 2023 was “भारत के लिए”. Today, we are at a unique crossroads in the journey of healthcare and pharmaceuticals in India. The theme “भारत के लिए”- “For India,” carries with it the profound message that the health of a nation is the cornerstone of building a better world, and it echoes the sentiments of the G20's vision – “One World, One Family.” It embodies a collective commitment to the betterment not only of India but also of the global community as a whole.

The year 2023 marks a significant moment in our collective history. As the nation gears up towards India@100, we have a responsibility, a vision, and a mission. The Summit included discussions envisioning the healthcare landscape 25 years into future, transitioning not only from ‘Make in India’ to ‘Discover in India’ but also advancing from

volume-centric to value-centric innovation in the pharmaceutical sector. The Summit also focussed on the contribution of Government (Central and States), corporates, academia, patient advocacy groups, and all other stakeholders involved in the healthcare ecosystem. OPPI and its member companies have been steadfastly contributing to the country's healthcare ecosystem since pre-independence, demonstrating an unwavering dedication to patient safety and the delivery of high-quality care. The association's advocacy decisions, patient-centric approach, and overall efforts are consistently guided by the overarching principle of “भारत के लिए”. The association is collaborating with the government stakeholders and other partners to find innovative solutions for unmet medical needs and to address the nation's healthcare challenges. In alignment with the visionary leadership of the Hon'ble Prime Minister Shri Narendra Modi-ji,

OPPI is wholeheartedly committed to the clarion call of ‘Jai Vigyan and Jai Anusandhan’—emphasizing the pivotal role of science and research in shaping a robust and progressive healthcare future for the nation.

### Summit discussion tracks

The OPPI Annual Summit 2023 captured discussions across the following themes:

- Future of healthcare in India: Fast-forward 2047 - reimagining healthcare 25 years into the future
- Moving from volume-based to value-based innovation in pharmaceuticals
- Ease of Doing Business: Mapping the journey towards India @100

A futuristic report “Reimagining pharma and healthcare for India@100: भारत के लिए” was also released at the event.

# Inaugural Session

## Guests Of Honour Addresses

### Shri. Sudhansh Pant

Secretary, Ministry of Health & Family Welfare, Government of India



In the Indian healthcare sector, a historical and revolutionary step was the launch of the game changing Ayushman Bharat scheme by the Hon'ble Prime Minister in 2018. The scheme comprises of two pillars. The first focuses on establishing health and wellness centers to strengthen the nation's primary healthcare system, especially in the rural areas. For the first time, 12 diagnostic tests became available, and they remain accessible in over 1.6 lakh health and wellness centers nationwide. The healthcare centers at primary level for the first time started providing screening for non-communicable diseases such as hypertension,

diabetes, and cancer. Additionally, free drugs and diagnostics, and wellness and yoga sessions were introduced. This marked a shift from curative approach to a more preventive and promotive one. The second component of the Ayushman Bharat initiative is the Pradhan Mantri Jan Arogya Yojana (PMJAY) – the largest health insurance scheme globally that offers annual health insurance of up to INR 5 lakhs to over 12 crore families below poverty line families. Over the past five years, approximately six crore individuals have received free treatment for

major diseases in large hospitals under the scheme. Currently, more than 27,000 hospitals are empanelled in PMJAY, with the central and the state governments having spent over INR 70,000 crore. This has significantly reduced out-of-pocket expenses from 69% about 13 to 14 years back to around 39% to 40% today, putting more money in the hands of the people as government assumes responsibility of healthcare to a large extent. In terms of healthcare education, the number of medical colleges has doubled in the last 8 to 9 years, increasing from less than 400 to

over 700. The MBBS seats have more than doubled from 50,000 to over a lakh during the same period. Postgraduate MD, MS, DNB seats have seen a 125% increase in just 7-8 years, growing from 30,000 to 70,000+. This has led to a substantial 60% growth in the overall healthcare workforce, including nursing, pharmacists, allied healthcare professionals, doctors, and dentists.

In the realm of vaccinations, India set a world record during

COVID-19 by administering over 2.2 billion vaccine doses under the government program. Significant efforts are also underway in drug regulation, aiming for India to provide the highest quality assurance as the global pharmacy. Initiatives like the implementation of a revised Schedule M and the finalization of a new drug regulation act are in progress.

As a future focus, multinational companies should prioritize

innovation for diseases which are specific to India. While the SDG goal aims to eliminate TB by 2030, India's Prime Minister has set an ambitious target of eradicating TB from the country by 2025, emphasizing the need for research and developing vaccines. Lastly, to address the challenge of affordability of innovative medicines, multinational firms are urged to develop pricing mechanisms allowing access to innovative drugs during their patent protection period in countries like India.

### Shri. Ravindra Pratap Singh

Joint Secretary, Department of Pharmaceuticals



Indian pharmaceutical industry is currently valued at approximately US\$50 billion, with an expected growth rate of around 10-12%. In the healthcare sector, there is a mandate to provide adequate and affordable healthcare to all, and the pharma industry plays a crucial role in achieving this goal.

Presently, around eight out of the 20 largest global generics companies are based in India. More than 55% of our exports are to highly regulated markets, and around 90% of World Health Organization (WHO) prequalified Active Pharmaceutical Ingredients (APIs) are sourced from India. Country also meets

about 65-70% of WHO's vaccine requirements. We also have the highest number of USFDA approved plants outside the US, highlighting the industry's manufacturing capacity and quality standards. Looking ahead to 2047, there is a need for significant growth. Indian pharma industry is currently third

in terms of volume and 11th in terms of value. By 2047, we need to move to the top 5 in terms of value. The industry also should explore markets where its presence is currently limited, such as Japan, China, and Latin America. Similarly, on the medical devices side, reducing import dependence is critical. We should target to meet over 50% of our needs through the domestic medical device industry by 2047.

Collaboration in the industry, particularly during the COVID-19 pandemic, enabled indigenous manufacturing of important drugs such as remdesivir and tocilizumab. This collaboration

needs to continue, with focus on high-value drugs like complex drugs, orphan drugs, biopharmaceuticals, and precision medications. The industry should target new drugs and high-quality devices at par with the global standards.

All important futuristic aspects for growth of the industry are being covered in this summit. Innovation is critical for future growth of the industry. We also need to keep pace with the global regulatory standards. We need to tackle the emerging challenges like antimicrobial resistance (AMR) and non-communicable diseases (NCDs).

Pharma R&D spend in the US and China is around US\$50-60 billion and US\$15-20 billion respectively. In India, the industry is spending around US\$3 billion in R&D. There is a need for increased investment. Government recently announced a scheme for promotion of research and innovation in pharma and medtech. The scheme is aimed at strengthening research institutions and fostering industry-academia linkages.

Efforts towards creating an ecosystem include schemes for bulk drug parks, medical device parks, and clusters. The department is also implementing production linked incentive (PLI) schemes for bulk drugs, pharmaceuticals, and medical devices to incentivise production and create global champions. The PLI schemes for pharmaceuticals focus on biopharmaceuticals, complex excipients, phytopharmaceuticals, autoimmune drugs, and anticancer drugs.

Looking forward to 2047, industry needs to focus on backward integration of manufacturing facilities. We have large scale manufacturing capacities, but the raw material and the APIs are still sourced from outside. We are also looking at attracting more Foreign Direct Investments (FDIs) – In the automatic route, 100% FDI is presently allowed for greenfield projects and 74% for brownfield projects.

We also need to adopt sustainable manufacturing practices with reduced emissions, waste generation, and energy and water consumption.



Felicitatation of Shri RP Singh by Mr. Suresh Pattathil

## Shri. Dr. Rajeev Singh Raghuvanshi

*Drug Controller General of India, CDSCO, Government of India*



The Indian pharmaceutical industry is recognized as the “pharmacy of the world” due to its significant achievements. It contributes over 20% of the global generics supply by volume and serves approximately 60% of the global demand for vaccines. It has the distinction of having the largest number of U.S. Food and Drug Administration (USFDA) compliant pharma plants (more than 600 as of Oct’22) outside of the US.

Total trade is expected to reach from US\$50 billion today to US\$130 billion in the next 7 years. All of this achievement is largely due to India’s leading position in the global generics market.

**Need for shift from volume- to value-driven products:** To maintain India’s leadership position, there is a need to move at a fast pace in achieving the transition from volume- to value-driven products. Not doing this can not

only challenge country’s historical leadership position in the pharma industry but it is also important to meet the growing patient needs in India, encompassing a large number of patients with rare diseases.

**Potential areas for value play:** Complex generics hold great potential to drive future value. They involve more difficult production processes and therefore face less competition. Another big play that is coming in India is the biotherapeutics, including biosimilars, cellular therapy, and gene therapy. Based on statistics from CDSCO, we can see that things are moving in the right direction in India. There is also success in discovery research, but we need to do more.

The global clinical trials (GCT) is another area where we see huge opportunity and movement. In last 1.5 years, CDSCO statistics show 50% increase in GCT applications and 30% increase in approvals of GCT applications. We are now working on optimizing the

processes and regulations for GCT approvals in consultation with the industry.

Another good area is digital health or digital medicines. A lot of activities have happened in this area in India over the last five years, and now we have started seeing products coming out some of which are being integrated with the National Health System. We are seeing good movement in the diagnostics area as well. Digital health is important not only from the value or revenue potential, but also because of its potential to enable healthcare delivery to the last mile with respect to the patients sitting at the farthest corner of the country.

**Volume- to value-shift enablers:** This transition requires a change in mindset, encouraging innovative thinking, and a move away from the generic model. There are signals that things are moving in the right direction, but to be successful, it needs to be a mass movement in the

country similar to what we saw for the generics model.

Second is the need for the industry to invest more money into the R&D. This is crucial for the shift towards value-driven products, and an increasing number of companies are contemplating and initiating such investments.

Third area is the need for very focused outcome-based collaborations between industry and academia, especially in the field of discovery research. We have developed very focused academia in the last 10-15 years in this country. We have best Technology Institutes (IITs), Management Institutes (IIMs), Information Technology Institutes (IIIT), National Institutes around biologics, genetics, etc.

We are very strong in technology, in pharma manufacturing infrastructure, and on the clinical

side (from practice to clinical trial knowledge). We now need to strengthen our play at the interface of technology and clinical. To enable this, strong collaboration at industry-to-industry level (Tech industry and pharma industry) is required, which is not happening so much today.

Given that value play is inherently global, maintaining a strong emphasis on quality is imperative for success in the global market. The quality philosophy has to get integrated in our thinking and in our systems.

Government is also taking a lot of initiatives to support and enable the volume to value shift. Policies are being made around this shift, such as the recent R&D policy released by DoP to promote innovation, PLI schemes and infrastructure support to promote the medical device industry, and lots of other financial incentives.



Felicitations of Shri. Dr. Rajeev Singh Raghuvanshi

A lot of regulatory streamlining and rationalizing is also taking place, such as Medical Device Rules 2017, Clinical Trial Rules 2019, the upcoming New Drug and Cosmetics bill. A regulatory digital platform is also under development that will replace Sugam. Centre, State, and every stakeholder in the pharma value chain will be part of this digital ecosystem.

**Future direction and positive signals:** By now 58 biotherapeutics have been approved, including biosimilars, some monoclonal antibody-based drugs, some mRNA vaccines. Over 50% of the activity has been in the last two to three years.

Nine C&GT products have already been approved, including the recently approved CAR-T therapy developed by Bombay IIT startup in Oct'23. There are 37 clinical trials in Cell and gene therapies (C&GT) at different stages (Ph1, Ph2, Ph3) running at this point – which is a good number for a country like India which just started in this space. There are 36 INDs at different stages of clinical trials, and 10 have already been approved. Ten INDs have already been approved.

We have all the ingredients for success already in place – strong academics, strong technology background, strong infrastructure in pharma manufacturing, strong global network and recognition, successful healthcare stakeholder ecosystem, and strong clinical knowledge. The time is ripe to leverage these assets for a successful transition to value-based healthcare, aiming for the projected US\$130 billion target.

## Key Takeaways

### Mr. Suresh Pattathil

President – OPPI & Managing Director and General Manager, AbbVie India



The theme of OPPI Annual Summit i.e., “भारत के लिए”- “For India,” carries with it the profound message that the health of a nation is the cornerstone of building a better world, and it echoes the sentiments of the G20’s vision – “One World, One Family.” It’s a vision that encapsulates our collective commitment to the betterment of not just India but also the global community.

The year 2023 marks a significant moment in our collective history. As the nation gears up towards India@100, we have a responsibility, a vision, and a mission. We are poised to transform healthcare, not just for today but for generations to come. Our summit, with its forward-looking conversations, seeks to reimagine

healthcare 25 years into the future. We are not merely talking about ‘Make in India’ but ‘Discover in India’; we are transitioning from volume-based to value-based healthcare.

As we reflect on the journey of OPPI and its member companies, we take pride in serving the healthcare ecosystem of India since pre-independence. We have remained unwavering in our commitment to patient safety and providing quality care. Our advocacy decisions, our patient commitment, and our work are always underpinned by one guiding principle - keeping our approach, “भारत के लिए,” at the forefront of everything we do.

In line with the clarion call of our Hon’ble Prime Minister,

Shri Narendra Modi-ji, for ‘Jai Vigyan and Jai Anusandhan,’ we are resolute in our pursuit of innovation. We are actively seeking solutions for unmet medical needs, engaging in collaboration with government stakeholders, and co-creating with partners to address our nation’s healthcare challenges. We aim to enhance the economic and health impact of our great country.

Our priority is ‘भारत के लिए,’ and our endeavor is to enhance the economic and health impact for India. Our member companies are deeply committed to enabling access, driving innovation, supporting health systems, and making strategic investments for the development of the pharmaceutical industry in India. We recognize

that our business growth ultimately leads to a growing economic and health impact for the nation.

We acknowledge the need to explore innovative solutions that sustainably enhance access while ensuring a conducive environment for R&D investments. This involves embracing calculated risks that drive innovation. Our intent is to improve care delivery, reach the last mile, and create a sustainable and conducive environment for our

business to grow multifold. This growth, in turn, attracts more investments from pharma MNCs, further strengthening our nation's healthcare infrastructure.

We firmly believe that introducing innovative programs with commercially viable business models is the key to building local, sustainable capabilities for healthcare, including education, infrastructure, and drug development. It is these capabilities that will truly increase access and

ensure that our mission of 'भारत के लिए' remains steadfast.

This is a reminder that every step we take, every decision we make, should be driven by the welfare of our nation. Our commitment to innovation, collaboration, and access is the cornerstone of the change we seek. Together, we shall build a healthier, brighter future for India and, in doing so, play a significant role in shaping a better world for us all.

## Mr. Anil Matai

Director General, OPPI



The OPPI Annual Summit has consistently united diverse stakeholders who share a common vision—creating sustainable healthcare solutions for the patients of our beloved nation. Our Annual Summit has become a platform where the brightest minds, the most dedicated innovators, and

the most passionate advocates of healthcare come together under one roof to engage in transformative conversations.

This year, our Annual Summit underlined the paramount role health plays in shaping the destiny of nations and the world. It is

not merely a thematic choice; it's a call to action, an invitation to collectively envision the future and the profound impact healthcare will have on our nation and the world 25 years from now.

Today, as our great nation races towards India@100, this Summit

shone a spotlight on the invaluable contributions of Government, both at the central and state levels, corporate entities, academia, patient advocacy groups, and all other stakeholders involved in the healthcare ecosystem. It's about acknowledging the collective power of partnership and innovation in addressing the healthcare challenges that confront our nation.

Our member companies have been stalwarts in India's healthcare ecosystem, serving the nation even before independence.

Their unwavering commitment to patient safety and the pursuit of quality care is a testament to their dedication. As an association, we have consistently prioritized the well-being of our country, embodying the spirit of "Bharat Ke Liye." We have been fueled by innovation, working tirelessly to find solutions for unmet medical needs, forging partnerships with government stakeholders, and co-creating with like-minded partners to tackle our nation's healthcare challenges head-on.

We stand in unity with the clarion call of our Hon'ble Prime Minister Shri Narendra Modi-ji, who beckoned us all with "Jai Vigyan and Jai Anusandhan."

The discussions centered on the future of healthcare in India, ease of doing business, and how can we shift the needle from Make in India to Discover in India. These conversations not only explored the current state of healthcare but will help in actively shaping the future of healthcare in India and the world.

## Capturing the spirit of भारत के लिए



Scan QR code to watch the video

# Report Release: Reimagining Pharma And Healthcare For India@100 - BharatKeLiye

Recognized as the ‘pharmacy of the world’ for several decades, the Indian pharmaceutical industry has garnered global acclaim, particularly for its leadership in the generic drugs sector. Impressively, it commands over 20% of the global generics supply by volume and addresses approximately 60% of the worldwide demand for vaccines.

Beyond its global impact in improving health outcomes, the Indian pharmaceutical industry plays a pivotal role in propelling the country’s economic growth and generating employment.

EY and OPPIs report titled ‘Reimagining pharma and healthcare for India@100 – Bharat Ke Liye’ highlights the potential ambition for the pharmaceutical and healthcare sectors by 2047. According to recent reports, the industry is heading towards an ambition of US\$130 billion by 2030 and US\$450 billion market by 2047.

Between September and October 2023, OPPI and EY undertook primary research, consulting with around 40 Chief Executive Officers (CXOs) from leading Indian and global multinational pharmaceutical companies and other industry organizations, to gain insights into the strategic priorities that will pave the way forward for the industry. The report outlines following key focus areas that would help the Indian pharma and healthcare



- sector in achieving the ambitious 2047 milestone:
1. Unleashing pharma’s value-driven research and innovation potential
  2. Becoming an integral part of the futuristic global pharma supply chain
  3. Achieving sustainable and equitable healthcare access for all

### 1. Unleashing pharma’s value-driven research and innovation potential

With the evolving global innovation landscape and country’s ambition for 2047, all leaders unanimously agreed that the next frontier for India is to focus on disruptive innovation. Establishing a resilient innovation ecosystem to foster collaborative engagement of various stakeholders, such as major pharmaceutical/biopharmaceutical

entities, startups, biotechs, academia, and clinical researchers, is key to this shift towards value-driven innovation. This ecosystem’s vitality is further contingent on facilitative elements like financing, infrastructure, and supportive policies and regulations.

Large pharmaceutical/ biopharmaceutical companies play a pivotal role, not just in the research and development of drugs, but also in harnessing innovation potential emerging from academia and startups and translating it into tangible market advancements. Global Capability Centers (GCCs) also make substantial contributions to the country’s innovation ecosystem by fostering talent and skill development throughout the value chain, especially in intricate and strategic domains.



In Sep’23, the government launched the National Policy on Research and Development and Innovation in Pharma-MedTech Sector in India and Scheme for promotion of Research and Innovation in Pharma MedTech Sector (PRIP). The policy will help to strengthen the ecosystem of skills and capacities including the academia and the private sectors and give impetus to new talent among the youth through start-ups. It will also build synergies between various government institutions and agencies.

### Navigating the Landscape of R&D with digital and data analytics:

Digital technology, data analytics, and artificial intelligence (AI)/ machine learning (ML) hold the potential to transform the entire R&D value chain, from the intricate stages of drug discovery to the complexities of clinical development.

This transformation can enhance efficiency and productivity, reduce costs and timelines, and improve patient access and diversity. Leveraging its robust IT capabilities, India has the potential to spearhead advancements in this field globally, and also propel the innovation trajectory of the country’s pharmaceutical industry.

### As numerous Indian companies embark on their journeys into the realms of next generation therapeutics, India is poised to undergo a transformative shift, progressing toward its Discovery 1.0 phase.

### 2. Becoming an integral part of the futuristic global pharma supply chain

Manufacturing and end-to-end supply chain management are pivotal components within the

pharmaceutical industry. In today’s competitive landscape, success hinges on the meticulous management of manufacturing operations and supply chain costs to optimize cost-to-serve ratios and minimize inventory levels, all while upholding the highest service standards.

Over the past few years, several emerging trends such as pricing and inflation, technology implementation, focus on sustainability practices, transition toward personalized and next generation therapeutics, and innovative healthcare delivery models, are compounding the complexities within manufacturing and supply chain operations. These trends serve as crucial catalysts, necessitating a shift in priorities and much needed transformation of the manufacturing sector. These evolving industry trends, along with the macroeconomic variables, and

geopolitical changes, position India at the forefront of the “China + 1” opportunity.

The Contract Research Development and Manufacturing Outsourcing (CRDMO) industry is also expected to grow substantially. This is driven by the strategic shift of global large biopharma companies and smaller biotechs towards prioritizing core services and progressively embracing asset-light models to effectively manage their product life cycles.

During the CXO survey, industry leaders highlighted the following three areas of focus for the Indian industry to be able to leverage these opportunities and become an integral part of the global pharma supply chain.

CXO survey - key priorities for manufacturing and supply chain function

1

Advancement of manufacturing technologies, with a specific focus on automation and digitalization

2

Building credibility in the global market with an unwavering commitment to quality

3

Embracing sustainable practices

Several leading Indian pharmaceutical companies have embarked on digital transformation initiatives to enhance their operational efficiency and ensure compliance with quality standards. Notably, India boasts the highest number of USFDA-approved plants outside of the US. Scaling up in terms of quality is a natural progression for the industry.

3. Achieving sustainable and equitable healthcare access for all

Achieving equitable and sustainable healthcare access is a must for a country to achieve economic growth. Being the world’s most populous country, India faces unique opportunities and challenges in the healthcare space.

Government of India has launched several initiatives to provide healthcare access to the population. Ayushman Bharat launched in 2018 is a significant step toward achieving universal healthcare coverage in the country. The Ayushman Bharat Digital Mission (ABDM), launched in 2021, is aimed at laying the essential groundwork for a seamless integrated digital healthcare infrastructure in India. These initiatives are expected to improve access and reduce cost, enabling coverage of a large part of the currently underserved population, and revolutionize access and healthcare delivery in the Amrit Kaal period.

In addition to the potential offered by various government initiatives, primary research underscored the necessity for comprehensive programs aimed at controlling and

managing India’s most prevalent non-communicable diseases (NCDs). Such programs promise a twofold advantage of enhancing healthcare quality and reducing the overall healthcare expenditure. Another critical finding was the necessity for programs aimed at empowering patients and healthcare providers throughout their healthcare and disease journey. Pharma companies, in collaboration with government and other associations, are playing a very active role across the patient journey.

India’s prowess in manufacturing, cost-effectiveness, and a highly skilled workforce has truly made it the powerhouse of global pharmacies. Riding on this wave, the Indian pharmaceutical industry has the potential not just to meet expectations but to exceed them. The key lies in deliberate and strategic investments, coupled with a focus on transformative innovation driven by value.

Inaugural Session Partner Keynote Address

Mr. Marut Setia  
Senior Vice President - Global Growth Markets & Accounts and Medical Devices, Indegene



Visualizing the power and promise of GenAI

GenAI is poised to be the next significant transformation after the internet. With the unprecedented productivity and speed offered by Generative AI (GenAI), it has the potential to transform the way businesses run currently and the way we work, the way we innovate, the way we go to customers, and so on.

**GenAI use cases:** In the drug discovery process, GenAI can potentially help in saving upto 90% cost and time by its potential to discover molecules, process clinical data, analyze drug interactions, etc. Another example is about

stakeholder communication. Consider the example of the brand emails that are sent to the HCPs by pharmaceutical companies. This email can be changed into a live video by using large language models (LLMs) within a few minutes, while traditionally this kind of work through agencies required a few weeks.

**India potential:** Indian companies exhibit a 57% GenAI adoption rate, surpassing rates in the US. Most of the use cases in GenAI in India are horizontal in nature, with high applicability to healthcare. This presents an opportunity for organizations to repurpose resources and set global benchmarks.

Going forward, India can position itself at the forefront of GenAI driven innovation by leveraging its demographic dividend and identifying areas ripe for immediate disruption.

It is important to figure out what are the areas that are ripe for immediate disruption, and what are the areas that will take some little bit more time. For the mature areas, if you have already not started thinking about it and if you already not disrupted that in your organization, you are late to the table. The middle section are the areas where use cases are already developed – people are already implementing them, but they may not be at scale. And the velocity of

change is so high, maybe next time when I speak to you in 6 months, all of this will be changed. Now people are talking about which are the area which have traditionally been very human driven that can now look at disruption. So again, I keep going back to the whole idea of velocity of change because that is what we are dealing with today. This is one tech where we see a higher velocity of change than anything we have seen in the past.

**Way forward for organizations:**  
The key question for organizations

today is not whether change is necessary, but rather, what should be the velocity of change.

It is important to figure out the areas that are ripe for immediate disruption, and what are the areas that will take some little bit more time (where there are use cases, but they may not be at scale). Proactive disruption is essential in the mature areas. The next wave of disruption will be to identify new areas that have traditionally been very human driven where GenAI can be implemented. The high

velocity of change in the GenAI landscape underscored the need for continuous adaptation.

Organizations must recognize that the existing thinking moulds and constructs, developed over the past 40-50 years, are inadequate for accommodating the innovations brought about by GenAI. There is an urgent need for organizations to reassess and re-evaluate the frameworks they use to comprehend new technologies.



Mr. Maruth Setia - Inaugural Session Keynote Address

## Panel Discussions

### Panel 1: Future of Healthcare in India

Fast-forward 2047 - Reimagining Healthcare 25 years into the future

#### Keynote Address 1

#### Prof. Y K Gupta

Principal Advisor India Strategy Development – Global Antibiotics Research and Development Partnership (GARDP) & President of AIIMS Jammu



#### Future of healthcare in India

In today's context digitalization is not only a buzz word – it is need of the day and need of the future. Entire spectrum of healthcare stakeholders, from students to industry, must embrace digitalization for optimal outcomes.

#### Key healthcare issues that need to be addressed

- **Drugs for rare diseases:**  
Digitalization can play an important role in estimating and

managing rare diseases in India. Creating registries through digital means can help in making estimates and understanding disease burden across different states. The disease burden estimates can help pharma industry understand the economic stake and encourage innovation. This can also enable pooled procurement of drugs for rare diseases, enhancing efficiency, reducing wastage, and benefiting both patients

and the industry.

- **Antimicrobial resistance:**  
Antimicrobial resistance has become almost a silent pandemic resulting in a large number of deaths. The key challenge is the lack of availability of new drugs and diagnostics. Another important challenge is misuse of antibiotics. Digital solutions help in monitoring antibiotic usage for specific infections, track resistance patterns, and improve stewardship. Digitalized



Prof. Y K Gupta being felicitated

prescription monitoring can further help in addressing antibiotic misuse and enhance patient outcomes.

- **Medicine procurement:** Procurement systems for medicines in all AIIMS are very different resulting in disparities in availability of medicines. A digital networking system for hospitals can optimize inventory, streamline procurement, and enhance bargaining power. Digitalized procurement systems will also improve efficiency, reduce wastage, and provide cost-effectiveness.
- **Prescription clarity:** Prescriptions are mostly not readable, especially in government hospitals, with limited interaction time. This can result in non-compliance, resulting in complication of disease. Digitalization of prescriptions with detailed guidance on how and when to take medication can reduce errors, improve medication compliance, and empower

patients. Some startups are working on this initiative, for instance IIT-Delhi startup. Patients can upload their prescription on the system, which is then digitalized by the pharmacist, or the doctors and detailed explanation is provided to the patient on telephone. This will also have advantage for the industry as it will be easy to know that which part of the country, which hospital or which segment is prescribing the drug. Government will be benefited as they will be able to track misuse of specific drugs for specific disease, and accordingly they will be able to develop education or awareness programs for the patients and doctors.

- **Patient safety through pharmacovigilance:** Effective reporting of adverse events is extremely important for ensuring patient safety. Appropriate reporting of adverse events can help in understanding causative relation and accordingly decisions can be made about change

in the label of the medicine, need to withdraw the medicine or put a caution. Digitalized pharmacovigilance program can facilitate patient reporting, signal generation, and informed decision-making. Through the digitalized national pharmacovigilance program for safety, we have generated 12 to 13 signals.

- **Medicine quality:** Another issue that concerns general public safety is the quality of medicine. It is important to outline the best mechanism to ensure quality. For example, how can a patient know the quality of the medicine available at the counter? One very effective method that can reduce 50% of this problem is to ensure that the patient collects the receipt for the medicine – this can help with traceability. There are also mechanisms, such as putting QR code or having a mini-ID number, but in parallel it is also important to ensure that it does not result in any increase in the cost of the medicine.
- **Price-Quality Relationship and Drug Selection:** It is not right to make assumptions that drug quality and drug pricing are directly related. There should be mechanisms or potentially digital solution for patients to compare drug prices across available brands and assess quality differentials, empowering them to make informed choices.

**Digitalization and AI integration:**

- **Patient screening:** Use of artificial intelligence is the future of healthcare system. AI can help in screening and diagnosis, especially in remote areas. For instance, through AI based algorithms, we can effectively and rapidly screen an entire

village or an entire city or maybe entire population for tuberculosis (TB) by just using a simple X-ray.

- **Clinical trials:** Digitalization has become very important aspect of clinical trials. Through digital platforms, complete information about clinical trials can be easily given to the individuals who are entering or likely to enter the clinical trial, including subjects, volunteers, or patients. With digital interventions, clinical trials today are becoming more hybrid and shifting from

hospitals to patients' home. Digital platforms are also enabling flexibility in CTs and adaptive trial designs.

- **Drug delivery system:** During COVID we learnt how digitalization can change the entire concept of drug delivery system, right from drug manufacturing, to drug storage, and to delivering to the farthest point of the treatment. With the use of data and digital, India was the first country to document minimum wastage of vaccine.
- **Geriatric care:** Elderly population have multiple

medication requirements. Use of digital prescriptions can predict drug interactions, reduce prescription errors, and improve compliance in geriatric patients.

**Challenges in digitalization:**

Excessive data can create noise or music. Synchronization of data is critical to get meaningful information and achieve desired outcomes, it is critical and emphasizes the need for synchronized analysis. This requires collaborative efforts between technologists, AI experts, and healthcare professionals.

## Keynote Address 2

### Dr. Akshay Jain

Joint Director, National Health Authority, Ministry of Health & Family Welfare, Government of India



#### Digital transformation in healthcare

Ayushman Bharat stands on four pillars:

1. Ayushman Bharat Digital Mission (ABDM): Focused on digital transformation

2. AB-PMJAY: The largest insurance scheme
3. Ayushman Bharat Health Infrastructure Mission: Building infrastructure for digital transformation

4. Ayushman Bharat Health and Wellness Centers: Addressing primary healthcare alongside the insurance scheme's focus on secondary and tertiary care

**Ayushman Bharat Digital Mission:** With the government's priorities and vision for the future, it is inevitable to change the landscape of how healthcare delivery is happening.

**Vision:** Goal of supporting universal health coverage through digital technologies, standards, and secure information exchange with patient's consent.

**Interoperability:** ABDM is positioned as a connector that links various stakeholders in the healthcare system, such as the government hospitals, private hospitals, practitioners, frontline workers, laboratories, etc. The emphasis is on creating an ecosystem rather than softwares or specific solutions. Standards and protocols are rolled, and compliance to these will ensure interoperability among different digital solutions and participation from private players. Because of the interoperability, any individuals' complete disease history, consumption of healthcare services, and all interactions with different healthcare ecosystem stakeholders can be easily secured and accessed through their own mobile application. This will be critical to break all existing silos.

**Unique Identifiers:** Different unique identifiers, such as Ayushman Bharat Health Account (ABHA) for individuals, healthcare professional registry, health facility registry, and drug registry, are introduced to uniquely identify patients, healthcare professionals, facilities, and medications.

ABHA is like an individual's health account where complete digital health records can be

linked. Today over 48 crore Indian citizens already have ABHA. These longitudinal health records can then be used by doctors, frontline workers, wherever the patient goes (in a secure manner with patient's consent).

**Technology stacks:** There are three stacks – these three verticals are exchanges or interfaces where different information or services can be present with interoperability.

- **Unified health interface:** this has an interface centric approach instead of a platform centric approach. With the interface approach, query from a user can be shared with all connected platforms. Hence, the interface can help with the discovery of services, availing of services, and also paying for the services.

- **Health information exchange:** as the databases created by various stakeholders and functions become interoperable, it will be possible to seamlessly and securely access and share health information across entities and locations.

- **National claims exchange:** medical data or discharge summaries can be put on to this single platform allowing various insurance payers to adjudicate claims quickly. It is said that in processing a single claim, we spend around INR500 to INR600, and therefore OPD services are not provided in India in most of the insurance companies. But replacing the manual adjudication by machine learning, or digital claims will enable expansion of insurance coverage.



Dr. Akshay Jain being felicitated

Opening Remarks:

Ms. Meenakshi Nevatia  
Country President & Managing Director, Pfizer India



All leaders in their respective areas lay out a vision for the future, which then guides the strategy to achieve that vision. In today's session, I would like to put forward 'ABCD framework' to envision the future of healthcare for India@2047. The framework includes:

**A - Access and affordability:** How do we make sure that all patients in India have access to necessary healthcare.

We need to improve coverage of products in Ayushman Bharat to the extent possible. This requires responsibility on the pharma industry to come up with ways to launch products at the right price. At the same time there is also need for a lot of partnership with the government to improve affordability, accelerate private insurance, launching an HTA framework for effective pricing.

**B - Breakthrough innovation:** How do we get innovation for patients in our country, incorporating GenAI as a dimension to provide the right products and information to all stakeholders.

Harmonized regulatory framework for faster launch and patent protection as an incentive for innovation can go a long way in bringing global breakthroughs faster to patients in India.

**C - Comprehensive patient care:** How do we create a healthcare system with electronic medical records providing a holistic single view of patients capturing information beyond basic demographics, such as vaccination status, family history, genetic history, etc.

**D - Diagnosis at the right time:** How do we ensure timely diagnosis and save more lives.

**Need to break the silos for improving patient outcomes:** There is a need to break three key silos: between government and private entities, Indian and multinational companies, and industry and academia. For effective collaboration, all stakeholders need to move towards common goals and objectives with same velocities.

It is also important to define accountability and agree on some specific metrics to measure progress. While the ultimate goal for everyone is to improve patient outcomes, metrics can be defined around the path to reach that goal, such as the number of patients enrolled in Ayushman Bharat, dollars spent per patient, speed of product launches in India, and the range of products available.

Session Partner Keynote Address:

Ms. Monica Gangwani

Executive Director India, Advisory Services, EVERSANA APAC



**Imagining future of healthcare in 2047:** There are four key pillars of healthcare.

- 1. Access and affordability for everybody: Vision includes remote monitoring, reimbursement for innovative therapies, and patient access programs.
- 2. Advanced disease management: There will be a significant shift in the way diseases are managed. Certain diseases will be completely eradicated. There will be 3D printing of organs, robotic surgeries, and these will continue to evolve. There will be new vaccines and many diseases will become vaccine preventable
- 3. Empowered patients: Patients will be seamlessly connected to the whole healthcare ecosystem, a lot of data will get through

different sources, such as implants, and will get captured in EMRs.

- 4. New face of Healthcare Professionals (HCPs): Future HCPs will be medical engineers. There will be tech-savvy doctors providing virtual consultations with their digital avatars.

**Enablers for future of healthcare:** Key enablers to realize this vision include affordable innovation, collaboration, technology, and policy intervention.

All industry stakeholders also need to critically think about a few important aspects around the need to balance innovation and cost, bridge the gap between intent and infrastructure, support India’s healthcare workforce, and continue building on the digital disruption.

**“PINK” framework for the future of healthcare:** The framework outlines essential elements for future of healthcare.

- Proactive and Predictive measures: Empowering patients to be able to identify diseases well in advance so that are able to ensure that they get the right treatment.
- Inclusivity: Ensuring a balanced focus on digital transformation, workforce management and community support
- New Frontiers: India being the pharmacy of the world, how can we further expand our global presence and become even more self sufficient
- Kind-heartedness: Helping each other

Panel Discussion

**Amrit Kaal period**

During the Amrit Kaal period, a substantial economic uplift is anticipated for India, which is a nearly US\$4 trillion economy. Both the manufacturing and services sectors are expected to thrive, with a notable rise in affordability and per capita income projected to increase to US\$15,000. This growth bodes well for India’s prominence in the pharmaceutical sector. The pharma industry is undergoing significant digital transformation, with innovations like CAR-T therapy emerging. Alongside this, an evolving digital ecosystem, inclusive of various platforms, is set to revolutionize healthcare delivery. Given existing shortages in medical professionals and resources, the digitalization of the healthcare ecosystem holds promise for addressing these gaps. The upcoming 25 years are deemed pivotal in this transformative journey.

**Future of Indian pharma in Amrit Kaal period**

India possesses a significant advantage in scale within the pharmaceutical sector, boasting

a US\$50 billion industry split evenly between exports and the domestic market. India’s global pharmaceutical footprint is substantial, supplying every third tablet in the U.S. and every fourth tablet in Europe. Projections indicate that by 2047, the industry could grow to US\$450 billion. India should be #1 in terms of volume and among the top five in terms of value globally. To realize these ambitions, collaborative efforts are essential in the following five areas:

- 1. **Quality:** Emphasizing uncompromised quality with initiatives like the immediate implementation of Schedule M and adherence to ICH quality specifications, targeting International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) compliance by 2030.
- 2. **Innovation:** Prioritizing innovation is crucial. There is a need to upgrade sales systems

- and integrate drug, devices, and diagnostics.
- 3. **Reach:** India should aim to be a global health custodian, expanding beyond current major markets like the U.S. and Europe. Opportunities lie in enhancing market penetration in countries such as China and Japan, along with boosting the presence of biosimilars.
- 4. **Resilient supply chain:** Collaborative efforts with countries like the US are underway, emphasizing the importance of diversifying supply chains rather than relying on a single nation.
- 5. **Sustainability:** Adopting green technology and sustainable practices will be pivotal for the future growth and environmental responsibility of the industry.

**Healthcare evolution in India**

In the next 25 years, India is poised for significant transformation, becoming a technology-driven and knowledge-based nation with democratized health awareness and outcomes. This vision includes a focus on data-driven, personalized,





and cost-effective healthcare. Remarkably, India has rapidly expanded its medical infrastructure, exemplified by doubling the medical force in just around six years. Key policy changes like Ayushman Bharat, Health Policy 2017, and progressive pharma policies focussed on technology, AI, blockchain, and patents, all aiming for broader access through tech-driven solutions. A pivotal shift in the pharma industry in moving from volume to value and promoting innovation within India holds the promise to bring innovative products to India swiftly. With India emerging as a technology hub, marked by advancements in AI and ML and supported by a burgeoning startup ecosystem, transformative changes in healthcare are anticipated, driven by both MedTech and Healthtech innovations.

Digital ecosystem is further poised to transform healthcare access and delivery. Any nation without a digital health strategy risk falling behind in the future. India, with its vast population of 1.4 billion,

views digitalization as a significant advantage, ensuring healthcare access for its citizens. Digital initiatives, akin to the successful adoption of UPI for financial transactions, are anticipated to revolutionize the healthcare sector.

#### ***Digital therapeutics and beyond the pill solutions***

Patients, who are at the center of everything, want good health and outcomes. Keeping patients at the core, the primary objective remains achieving optimal health outcomes. Pharma's role needs to evolve from merely supplying medicines to offering holistic therapies and solutions to improve patient outcomes. These could be mobile applications, digital therapeutics, predictive algorithms, non-invasive diagnostic devices, or even disease monitoring devices. Healthtech startups possess innovative solutions but often grapple with market entry and regulations. Pharma companies can bridge this gap by collaborating with startups to integrate and distribute innovative solutions.

Furthermore, transforming patient support programs from auxiliary functions to profit-generating entities could further enhance the industry's growth and effectiveness.

This requires collaboration. An interesting example is collaboration of AstraZeneca with the government of Karnataka and Qure.AI for early diagnosis of 29 lung diseases, including lung cancer. Another instance is Novo Nordisk, which emphasizes delivering comprehensive solutions, such as combinations of drugs and devices.

The current era emphasizes customization and personalization, urging pharma to provide solutions beyond traditional medication for individual patient needs.

#### ***Keeping patient at the center of everything***

The dialogue often emphasizes patient-centeredness, but frequently the patient is absent from crucial discussions. While concepts like co-designing and

co-creating are touted, real patient involvement seems limited to treatment discussions. A WHO framework from May'23 highlights meaningful engagement of individuals with NCDs, positioning patients as experts. However, the language around patients—viewing them as consumers, vendors, or beneficiaries—needs re-evaluation for genuine collaboration. Current collaborations across

medtech, healthtech, pharma, and government are often siloed based on individual objectives rather than holistic health outcomes. A broader perspective should prioritize overall national health rather than individual business goals.

To truly empower patients, they must be recognized as integral parts of the health ecosystem.

Current short-term sponsorships don't ensure sustainability for patient groups, and there's a need for a more significant partnership role with the government. Patients require educational resources to understand topics like drug discovery and health tech, enabling meaningful participation in advisory boards. Lastly, commitments made to patients must be honored consistently without lapses.

#### **Moderator:**

**Mr. Suresh Subramanian**, Partner, National Life Sciences Leader, EY India (standing to the left)

#### **Panelists:**

**Mr. Vikrant Shrotriya**, Managing Director And Corporate Vice President, Novo Nordisk India Pvt. Ltd.

**Dr. Sanjeev Panchal**, Country President & Managing Director, AstraZeneca Pharma India Ltd.

**Mr. Sudarshan Jain**, Secretary General, Indian Pharmaceutical Alliance (IPA), Senior Advisor, APAX Partners

**Dr. Arbinder Singal**, Co-founder & CEO, Fitterfly

**Dr. Ratna Devi**, CEO Dakshama Health Director, Patient Academy for Innovation and Research Founder, Indian Alliance of Patient Groups (IAPG) Chair- ISPOR Patient Council, The Professional Society for Health Economics and Outcomes Research

**Mr. Marut Setia**, Senior Vice President - Global Growth Markets & Accounts and Medical Devices, Indegene

**Ms. Monica Gangwani**, Executive Director India, Advisory Services, EVERSANA APAC

#### **Felicited by:**

**Mr. Manoj Saxena**, President Elect – OPPI and Managing Director, Bayer Zydus, Pharma And Country Division Head, South Asia – Pharmaceuticals, Bayer Pharmaceuticals Pvt Ltd (standing in centre)

## Panel 2: Moving from Volume-Based to Value-Based in Pharmaceuticals



### Success factors to enable volume to value shift

The paradigm shift of moving from volume to value is long overdue. In India we have great scientific talent, fabulous technological innovations, and strong catalysts now in the government encouraging not just make in India, but discovery in India. Key ingredients for value discovery to happen in the country include:

- Patient centricity: drug discovery and development guided by desired outcome for the patient.
- Willingness to pay for the innovation: domestic market for innovative products.
- Definition of innovation: is innovation only about finding a new chemical, or along with that innovation is also about reapplying the chemical to a new indication, to a new patient group

- Data protection: biggest R&D expense is around the phase 3 data collection; hence data protection is a critical requirement.
- Collaboration: various stakeholder groups are involved such as the industry, academia, and several others. It is like playing an orchestra. The government or the policy enablers are like the conductor of the orchestra. It is very important for a conductor to have the right tuning for every player involved in the orchestra. We are moving in the right direction, but the pace needs to be much faster to realize our 2047 vision.

### Strengthening industry-academia collaboration

The current ratio of usage of university-oriented innovation

translating into the market oriented innovation and reaching the patients is dismally low.

Innovation requires purposeful research, and that can only happen with extensive collaboration. Collaboration between the basic biomedical scientist like NIPER, IITs, etc., and medical fraternity. Hospitals are very important for any translational research. Third is industry. Today we are mostly working in isolation. It is critical that we work together, and right from the beginning.

For NIPER, a decision was made this year (2023) that a large portion of grant will go for target-oriented research. Predefined communities were formed, including some industry experts, to decide the

projects for working collaboratively with the industry.

There is also a need to identify what is the need of the country today. NIPERs can contribute significantly to biopharmaceutical, phytopharmaceuticals, natural products. Investments are being made in these areas and faculty is getting hired, there is now need for partnership with industry.

### IP and data protection

The importance of intellectual property (IP) protection is crucial for gaining value from clinical trials, clinical diagnoses, and research endeavours.

The move from volume to value, and the shift in focus from generics to biotech requires huge

R&D investment, infrastructure, scientists, and the whole environment around it. Currently, India's investment in R&D is minimal, only accounting for 0.7% of the GDP. Now supposedly R&D investments increase, there are collaborations, and new innovations come up – then the important question is, are we protecting those innovations?

A significant concern also is the lack of awareness and understanding about patenting among researchers and companies. There's a need to introduce patent education starting from schools to colleges to post-doctoral studies. While strides have been made in speeding up the patent process, there's still a need for improved infrastructure and awareness.

A notable challenge lies in Section 3 of the patent act, which restricts patenting of several improvement patents, limiting innovation potential. As there is shift from being a generic to innovator or a discovery, along the way improvement patents are also required.

### Value addition by global MNCs to the healthcare and pharma ecosystem in India

Immense contribution coming from the MNCs, and it will continue to happen. MNCs have introduced innovative concepts like understanding and supporting the entire patient journey from awareness and diagnosis, to ensuring drug affordability and compliance, and improving patient outcomes.

While globally available innovations are sometimes inaccessible in India, MNCs are working to bridge this gap. Beyond merely providing drugs, there's a focus on comprehensive patient support solutions, addressing issues like affordability, compliance, and awareness.

Quality remains paramount – it is important that the patient benefits from the drug in the desired manner. Strengthening India's supply chain and distribution systems is also a priority, with collaborations and contract manufacturing initiatives aiming to enhance local capacities.

Alongside, patient outcomes and emphasis on data presentation alignment with global standards is also very important.

#### ***Skilling manpower***

The primary factor distinguishing successful organizations is their skilled manpower. To propel India's life sciences sector from US\$50 billion to US\$500 billion over the next 20 to 25 years, a significant emphasis on skilled manpower is crucial.

The Life Sciences Sector Skill Development Council, a body under the Ministry of Skill Development and Entrepreneurship, is

responsible for establishing national occupational standards, conducting training programs for academia and industry, and offering certifications. Organizations can collaborate with the council to assess their workforce's skills and identify gaps and reskilling requirements, for instance in areas such as Good Manufacturing Practices (GMP).

Furthermore, there's a government initiative promoting apprenticeship programs, allowing companies to employ apprentices for up to 15% of their workforce. These apprentices can be trained and later absorbed into the organization or released based on requirements.



#### **Moderator:**

**Ms. Sukanya Choudhury**, Executive Vice President - Regulatory Affairs, GlaxoSmithKline Pharmaceuticals Limited (Standing second from left)

#### **Panelists:**

**Mr. Gagandeep Singh Bedi**, Managing Director And Head Of Human Pharma, Boehringer Ingelheim India

**Mr. Sudheendra Kulkarni**, MD and Chief Executive Officer, South Asia and ASEAN, Ferring Pharmaceuticals Pvt Ltd

**Prof. Dulal Panda**, Director, NIPER Mohali

**Mr. V. Simpson Emmanuel**, Managing Director & CEO, Roche Pharma India

**Mr. Goutam Bhattacharya**, CEO, Life Sciences Sector Skill Development Council (LSSSDC)

**Dr. Malathi Lakshmikumaran**, Executive Director and Practice Head, Lakshmikumaran & Sridharan Attorneys

**Ms. Suneela Thatte**, Vice President and Head – R&D India, Merck KGaA

#### **Felicitated by:**

**Mr. Suresh Pattathil**, President – OPPI & Managing Director and General Manager, AbbVie India (Standing fourth from left)

## Panel 3: Ease of Doing Business

### Keynote Address 1

#### **Ms. Supriya Devasthali,**

*Director, Department for Promotion of Industry and Internal Trade (DPIIT)*



#### ***Ease of doing business***

Ease of doing business initiatives of Government of India have always put a lot of emphasis on digitalization. We are working on a national single window system, which has two aspects – ‘Know Your Approvals (KYA)’ and ‘application and approval process’.

National pharmaceutical policy is in the public domain for stakeholder consultations right now. And one of the policy suggestions in that policy is related to single window system – synchronizing all permissions, all approvals, with all the stakeholders together on a single platform to save time and cost.

We are aware that there are specific challenges for pharmaceutical industry in terms of multiple regulators, lack of coordination among these regulators, time taken for certain permissions like environmental clearance, etc. We are also aware about overlapping and sometimes outdated regulatory requirements. In January 2023, in a conference of Chief Secretaries of all the states that was presided over by honourable Prime Minister, we discussed about ‘cost of regulation’ and ‘regulatory impact assessment’.

Cost of regulation indicates the cost incurred to remain compliant to the regulations. We recently ran a survey throughout the country and

realized that industry has to incur a substantial cost of regulation. In this survey we looked at several types of costs.

- **Time cost:** For instance, a company is supposed to get environmental clearance in say 90 days, but the company gets it in 180 days. The delay of 90 days can impact inventory management, or additional costs incurred due to idle labor. All these are aspects of the time cost we have tried to study.
- **Paperwork cost:** We have also looked at the time that human resources have to spend on filling up certain forms and filing certain returns. For instance, environment related

permissions have very complex and long forms, and require a lot of documentation, even for renewals.

- **Intermediary cost:** Regulatory requirements are sometimes complex and confusing, companies need to hire intermediary, say chartered accountant, company secretary, lawyers, or some agents in common parallels, or some kind of a facilitator. And this is a substantial cost, which affects the competitiveness of the business or competitiveness of the industry.

Coming to the theme of this Summit, India@100, for India to do well requires some hard measures on part of the government, on

part of the industry, on part of all stakeholders. One measure is to make our industry more competitive by simplifying regulatory regime, saving time and cost for the industry so that companies can focus energy and resources on production and on the core business.

We also maybe need a resilient policy because the field of pharmaceutical industry changes very fast. A lot of research is going on globally. There is technology advancement. Hence, it is very important that the regulations are also resilient to meet the requirements of the industry, and not hold up the industry. Pharma industry is about safety and wellbeing, which is very important

and cannot be compromised. But in parallel, the regulatory regime should also facilitate industry's growth.

We had a target of US\$5 trillion economy. We have already reached US\$4 trillion economy, so maybe it's time for us to improve our target now and work towards it. I am confident that pharmaceutical industry will play a pivotal role in India's growth story.

I will close my keynote address with two requests – provide feedback on the National Pharmaceutical Policy and National Single Window System to enhance its effectiveness.



Ms. Supriya Devasthali being felicitated

## Keynote Address 2

### Mr. John Cabeca

United States Intellectual Property Counselor for South Asia, U.S. Patent and Trademark Office (USPTO) American Embassy – New Delhi



#### Strong India and US ties:

India and the US have a lot in common because of their shared vision to achieve success for their communities and for their families. Both countries embrace the possibility of new opportunities, new knowledge, and the chance to make a difference, with the objective of leaving the world better off and more secure.

The strong US and India ties are built on the long history of diplomatic relations and trusted partnership. We are two of the world's leading democracies and the two of the world's largest economies powered by our innovative spirit and people.

The US is India's largest trading partner. We enjoy over US\$190 billion in two-way trade between our

countries. Most major US firms have made significant investments and operations in India, making the United States also India's largest source of foreign direct investment, especially in the pharmaceutical and healthcare sectors. An expanding number of Indian companies have also found the United States to be a welcoming destination for trade and investments.

For decades, US companies have also played a key role in building and advancing India's health care system. The US government and the health agencies, such as the US AIDB (US Agency for International Development), and the Department of Health and Human Services, work closely with their Indian partners to support health needs throughout India and globally. Our US public health experts have been partnering with India to strengthen public health laboratories,

advancing joint research and development, strengthening regulation for life saving drugs and devices, and improving infection prevention and controls at hospitals and public facilities. In the last 20 years, United States has invested over US\$1.4 billion in health care systems in India, and have worked closely to battle life threatening diseases, such as smallpox, polio, HIV, and tuberculosis.

#### Need for robust Intellectual

**Property regime:** One of my key roles is to promote awareness and the importance of mutual respect for intellectual property throughout the region. I work closely with Indian government and with other countries throughout South Asia as they seek to strengthen their economies and their innovation ecosystems through effective regulatory and IP regime enforcement.

From intellectual property perspective, I very much value our work together as we seek to streamline processes, share international best practices, and encourage regulatory and legal systems to support all industries.

According to a recent study, IP intensive industries constitute around 41% of the gross domestic product and contribute ~US\$7.8 trillion to the US economy. Many of the US industries investing into India are IP intensive industries.

Today the US and other global health care companies have partnered to bring critical technologies and know-how, and experience to India on a range of corporate social responsibility programs - from voluntary licenses, to access to innovative technologies during the pandemic, to patient assistance programs. While these programs help ease the burden, the complex and difficult to navigate

healthcare and regulatory landscape in a country can place a strain on patients and their families.

In my years in India, I have seen a tremendous spike in the innovative capacity within the country, including in the life sciences space. And all of this means that IP systems also have to keep pace.

I am pleased to see that, that is has actually been taking place. Recently the India IP office has published draft amendments for streamlining several changes to its current procedures, including foreign application filing disclosures, an annual working statements form 27, etc. The Indian IP Office is also asking stakeholders to share with the government the issues they are facing. All these are steps in the right direction.

**Building resilient supply chain:** During ministerial level meetings over the past two years, through the

Indian United States Trade Policy Forum, the ministers acknowledge the significance of creating resilient and secure supply chains. In this context, they agree that India and the US could continue together with like-minded partners and take a leading role in developing secure supply chains in critical sectors of trade and technology. Acknowledging the strong history of collaboration between India and the US in the field of health, the ministers also identified this sector as being particularly important in the context of work and resilient supply chains. India also noted its interest in partnering with the US and US allies in developing more secure pharmaceutical manufacturing base for augmenting global supply chains.

**Way forward:** From robust economic development, to access to clean energy, from maintaining food security to promoting health, we are stronger when we work together on these issues that matter to our people.

Today, India is improving lives and pulling people out of poverty through its transformative technologies. And the work of OPPI and its members play a very important role in this transformation. The summit provides a great opportunity to discuss ways to achieve the next phase to support India's efforts on a global scale.

So in closing, I'll just say that our futures, our people and our prosperity are linked. And together, we will advance our prosperity, promote shared democratic values, and bring the creativity, innovation, and brilliance of our people together to solve the most pressing problems of today and tomorrow.

## Panel Discussion



India has been a growth engine for the world. We have really galloped on ease of doing business. We have jumped ranking from 140 to 68. In the context of Ayushman Bharat Mission, the commitment that the government is making in terms of healthcare infrastructure is commendable.

### **Ease of doing business: what is working well**

The first draft paper on Ease of Doing Business (EODB) was produced in 2001. We have been talking about EODB for the last so many years, but it is only in the last few years that we have seen very clear changes and improvements. Notably, India's global ranking in the Business Enabling Environment (BEE) report by World Bank has improved from 142nd out of nearly 190 countries to 63rd. Similarly, our position in the Global Innovation Index (GII) by WIPO has enhanced from around 80 to 40 in recent years, signaling a positive shift in our innovation ecosystem. Illustrating

this, there has been a 7x increase in patent grants, rising from 2,000 per year to 30,000.

From an intellectual property (IP) perspective, there's been a notable shift in mindset in India, especially in the way IP is administered. This transformation is attributed partly to digitalization efforts and also allocation of right resources to manage IP effectively. Significant reforms even on the judiciary side of things, establishment of specialized IP courts in India has instilled confidence within the industry, ensuring timely resolution of conflicts through the judiciary.

There is a significant political will, starting with the National IP policy, which was reinforced by the parliamentary committee, and the modernization of the infrastructure at the IP Office. A noteworthy instance was the joint training program with the patent office focusing on innovation with participation from controllers, examiners, and industry.

### **Ease of doing business: areas for improvement**

#### **Policy predictability:**

While having a predictable policy framework is beneficial, also important is its transparent and dependable implementation. For example, this is missing in the clinical trials. A lot of power has devolved to the Subject Expert Committees (SECs). So, the SECs need to make sure that there are standards that the industry should know and play back.

#### **Robust Intellectual property and regulatory data protection:**

To bolster innovation, focusing on patents and regulatory data protection is essential. India has traditionally adopted a defensive approach towards IP. Instead as a country, there is a need to embrace it as a more enabling policy. The time-tested way that other countries have achieved value is by having IP. While recent documents discuss innovation funding, there's a notable gap in detailing the path forward.



Mr. John Cabeca being felicitated



To drive value-based innovation in India, there are several critical areas to address. Firstly, there's a need to focus on how IP quality is measured at the examination level, especially to match global standards. Secondly, while efforts have been made to enforce patents and IP rights through specialized IP courts, there's a need for consistent enforcement nationwide.

**Safeguarding trade secrets:** A significant concern is safeguarding trade secrets, especially in cross-border collaborations and technology transfers within the pharmaceutical sector.

Additionally, as advancements in health technologies and

personalized medicines emerge, regulations related to human genetic resources and biodiversity act need refinement for better protection and sharing protocols. There's a pressing need for a legislative framework in India concerning trade secrets. While our National IPR policy acknowledges this necessity, there remain uncertainties. For instance, if foreign innovators establish R&D facility in India and generate a lot of data or bring new technology to India and partner locally doing technology transfer, the question is if existing legal structures adequately safeguard their trade secrets. There is a need for supplementary support system in terms of law to give confidence to global innovators that will

encourage them to invest even more in India.

Additionally, if clinical trial data is used by other companies to get approval for subsequent molecules, there's a concern about ensuring protection and incentivizing such endeavour.

#### **Driving collaborative efforts:**

There's significant potential for collaboration between the government and other entities, signaling greater openness. However, current initiatives often rely heavily on individual motivation rather than systemic processes. To truly improve the landscape, these efforts must be formalized and standardized. Despite good intentions,

numerous challenges hinder progress, underscoring the need for streamlined processes to enhance the ease of doing business, especially regarding access in India. Addressing these

issues demands a collective effort; no single organization or the government alone can resolve them. A collaborative ecosystem is crucial. Currently, navigating multiple departments and agencies

individually is cumbersome, emphasizing the necessity for a facilitating body within the government to streamline these interactions.

#### **Moderator:**

**Manoj Saxena**, President Elect – OPPI and Managing Director, Bayer Zydus, Pharma And Country Division Head, South Asia – Pharmaceuticals, Bayer Pharmaceuticals Pvt. Ltd. (Standing second from left)

#### **Panelists:**

**Mr. V. Simpson Emmanuel**, Managing Director & CEO, Roche Pharma India

**Mr. Sanjay Sharma**, Managing Director, Bristol Myers Squibb, India

**Dr. Rajeev Ranjan**, Indian Administrative Service, IAS (retd)

**Mr. Ravi Bhola**, Managing Partner, K&S Partners

**Ms. Krishna Sarma**, Founder and Managing Partner, Corporate Law Group (CLG)

**Dr. Vivek Kashyap**, INTERPAT India Champion

#### **Felicitated by:**

**Mr. Anil Matai**, Director General, OPPI (Standing on the left)

# OPPI Awards and Recognition

## OPPI Lifetime Achievement Award 2023

### Mr. Dilip Shanghvi

Founder and Managing Director, Sun Pharmaceutical Industries Ltd.



Award was accepted on behalf of Mr. Dilip Shanghvi by: Dr. Azadar Khan, Senior Vice President, Corporate Relations, Sun Pharma

## OPPI Ratna Award 2023

### Mr. Ranjit Shahani

Former President, OPPI



Award was accepted on behalf of Mr. Ranjit Shahani by his Son: Mr. Siddharth Shahani, Executive Director of ATLAS SkillTech University



## OPPI Scientist Awards 2023

### OPPI Woman Scientist of the Year 2023

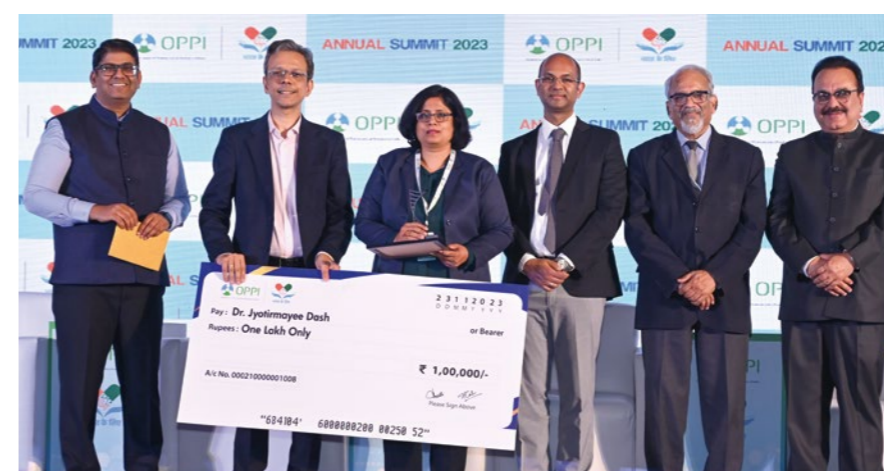


**Dr. Ellora Sen**  
PhD, Scientist VII,  
National Brain Research  
Centre, Haryana

Award Sponsor



### OPPI Scientist of the Year 2023



**Dr. Jyotirmayee Dash**  
Professor, Indian  
Association for The  
Cultivation of Sciences

Award Sponsor



### OPPI Young Scientist of the Year 2023



**Dr. Vinaykumar Kanchupalli**  
DST Inspire Faculty,  
National Institute of  
Pharmaceutical Education  
and Research (NIPER),  
Hyderabad

Award Sponsor



Svrán Group



## OPPI Quality Award for Excellent Facility of the Year 2023

1. MSME (Micro, Small and Medium Enterprises) Pharma Companies
2. Large Pharma Companies

### MSME Pharma category

#### Galentic Pharma (I) Pvt. Ltd.

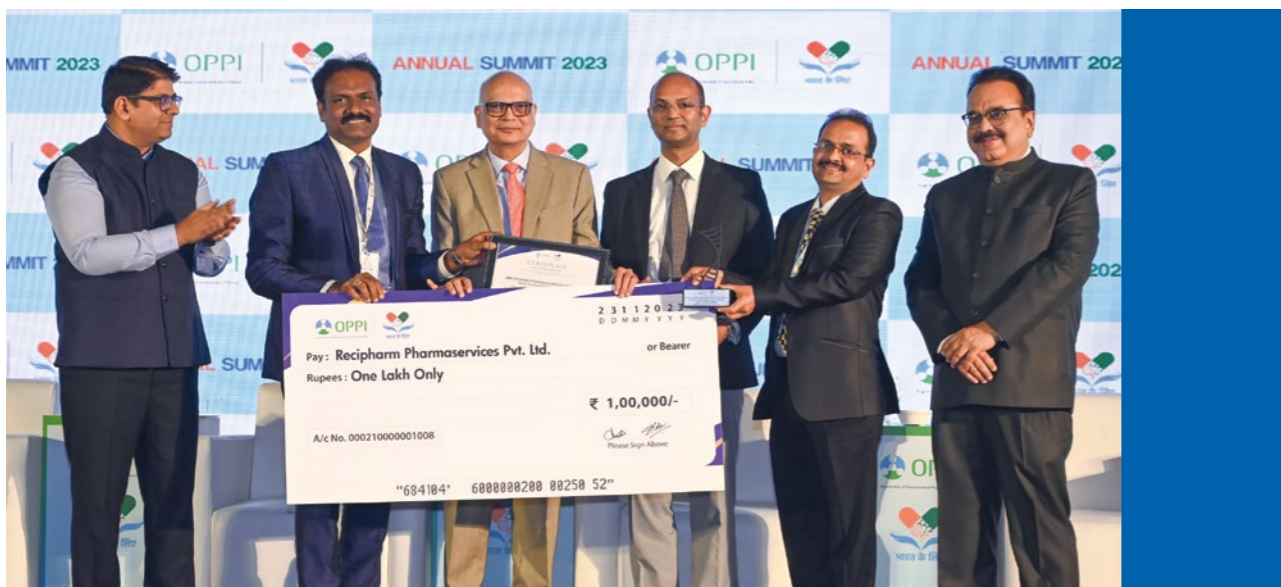
facility located at Gujarat



### Large Pharma category

#### Recipharm Pharmservices Pvt. Ltd.

facility located at Bengaluru



## Appreciation Certificate For OPPI Quality Award for Excellent Facility of the year 2023

1. MSME (Micro, Small and Medium Enterprises) Pharma Companies
2. Large Pharma Companies

### MSME Pharma category

#### Modern Laboratories

facility located at Indore



#### Sovereign Pharma Private Limited

facility located at Daman

### Large Pharma category



#### Encube Ethicals Private Limited

facility located at Goa



#### Pfizer Healthcare India Private Limited

facility located at Visakhapatnam



## OPPI Excellence in Innovation Award for Healthcare Start-up of the Year 2023

HealthPlix Technologies Pvt. Ltd.

Award Sponsor



## Appreciation Certificate OPPI Excellence in Innovation Award for Healthcare Start-up of the Year 2023

Curio Digital Therapeutics Inc



Tech Care for All (TC4A) India Pvt. Ltd.



DeepTek Medical Imaging Private Limited



Backyard Creators Private Limited



TeraLumen Solutions Pvt. Ltd.

## Summary



### Ms. Asawari Sathaye

*Director Communications and Patient Advocacy, OPPI*

The OPPI Annual Summit has consistently united diverse stakeholders who share a common vision—creating innovative healthcare solutions for patients. Our Annual Summit has become a platform where the brightest minds, the most dedicated innovators, and the most passionate advocates of healthcare come together under one roof to engage in transformative conversations.

The discussions that have taken place today have been nothing short of visionary, sparking ideas that stretch the boundaries of what we thought possible in healthcare.

Today, as our great nation races towards India@100, this Summit shines a light on the invaluable roles played by the Government, both at the central and state levels, corporate entities, academia, patient advocacy groups, and all stakeholders in the healthcare ecosystem.

As an association, we have consistently prioritized the well-being of our country, embodying the spirit of “Bharat Ke Liye.” Our members have been fueled by innovation, working tirelessly to find solutions for unmet medical needs, forging partnerships with government stakeholders, and

co-creating with like-minded partners to tackle our nation’s healthcare challenges head-on.

As we navigate this transformative journey, let us carry the spirit of today’s discussions with us—a spirit that embraces innovation, value-driven healthcare, and a collective vision for a healthier and more prosperous future. The road ahead may be challenging, but with each step, we inch closer to a healthcare ecosystem that is not just responsive to the needs of the present but anticipates and shapes the needs of tomorrow.



*Enlight Map depicting Bharat Ke Liye  
Map not to scale*

## Thanking Our Partners

### IN COLLABORATION WITH



Department of Pharmaceuticals  
Ministry of Chemicals & Fertilizers  
Government of India



### SUPPORTED BY



### KNOWLEDGE PARTNER



### GOLD PARTNER



### INAUGURAL SESSION PARTNER



### SESSION PARTNER



### LOGO PARTNERS



### AWARD SPONSORS



# Photo Gallery



Summit Theme #BharatKeLiye



OPPI Annual Summit 2023 - Event Stage



Registration Desk



OPPI Welcome Standee



LED Sponsors Panel



Pfizer Stall



NHA Stall



Eversana Standee



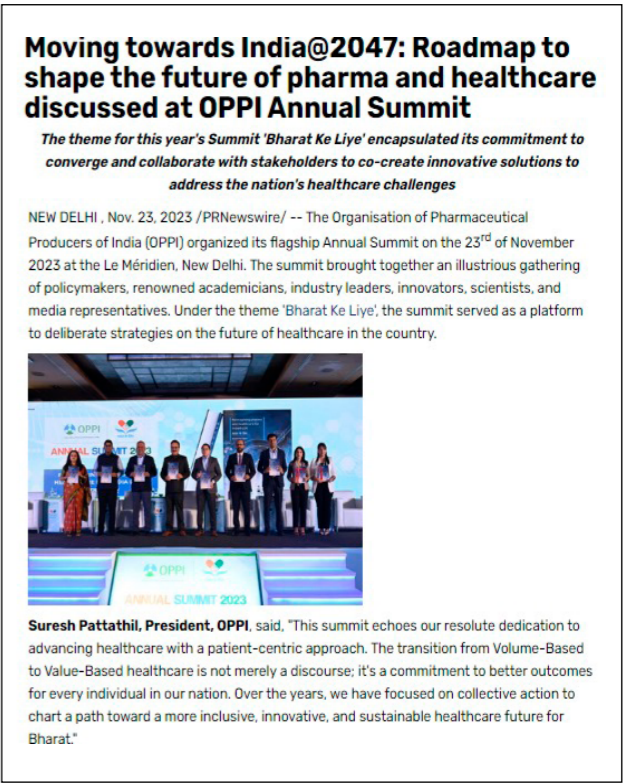
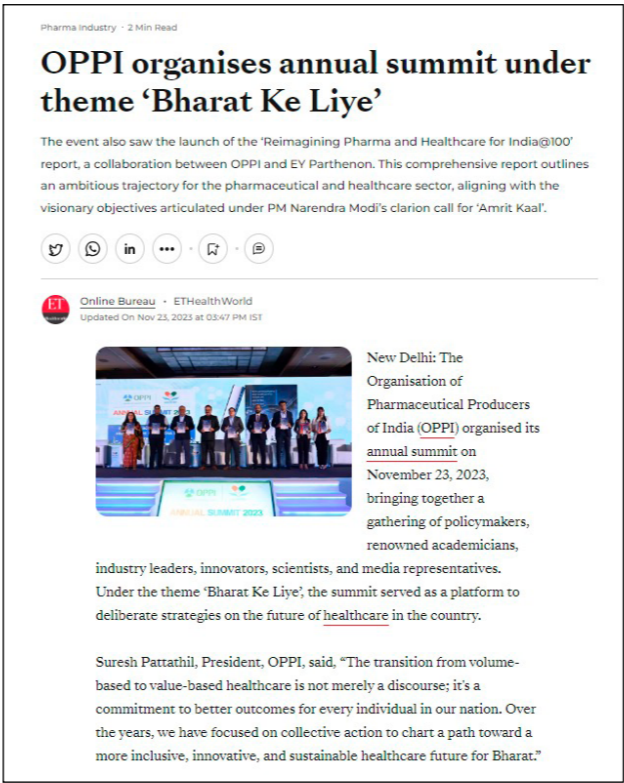
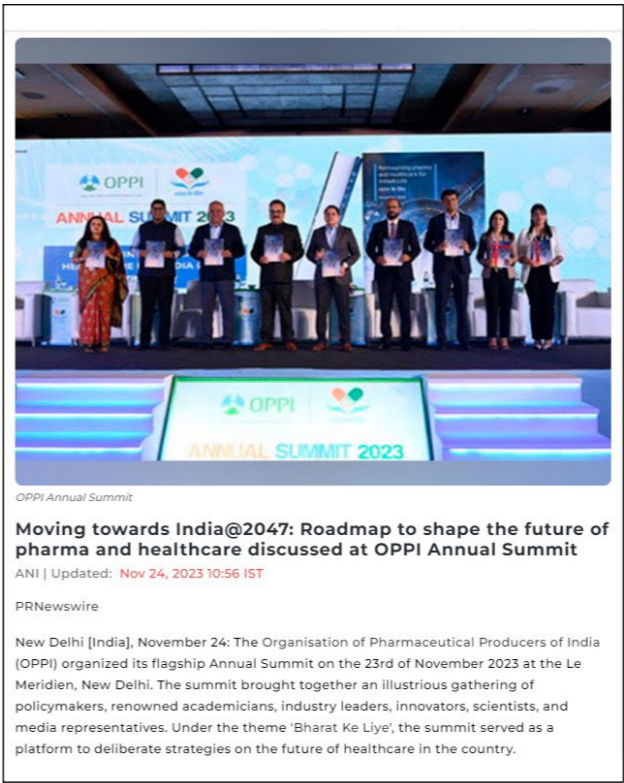
EY Standee



Media Lounge

An engaged Audience






Social Media Gallery

OPPI India @OPPIIndia · Nov 10

India's life sciences sector stands at an inflection point and the vision [#healthforall](#) at 2047 beckons! Witness key stakeholders join hands and minds to steer the journey towards Reimagining the Future of Healthcare भारत के लिए at India's most prestigious healthcare summit.



[#OPPIAnnualSummit](#) [#BharatKeLiye](#)

<https://twitter.com/OPPIIndia/status/1722931194226942083>

OPPI India @OPPIIndia · Nov 13

Scientific breakthroughs are set to scale new heights at the OPPI Annual Summit! We're thrilled to unveil the distinguished validator and stellar line up of jury members for the OPPI Scientist Awards 2023.

Register now by clicking on this link: [forms.gle/A3HSmnQ3poTbPD...](https://forms.gle/A3HSmnQ3poTbPD...)



[#OPPIAnnualSummit](#) [#BharatKeLiye](#)

Validator: Dr. M. H. Welling  
Jury: Dr. Shekhar C. Mande, Prof. Padmanabhan Balaram, Prof. K.G. Akamanchi, Prof. Y. K. Gupta


<https://twitter.com/OPPIIndia/status/1724037369379037509>

OPPI India @OPPIIndia · Nov 22

Envision the future of healthcare with Monica Gangwani, Executive Director, EVERSANA, in her keynote address "The Future of Healthcare in India: Navigating 2047" at the OPPI Annual Summit

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<https://twitter.com/OPPIIndia/status/1727293373919490092>

OPPI India @OPPIIndia · Nov 22

Join Marut Setia, SVP at Indegene, for an insightful keynote on how Pharma can double down on Gen AI and outpace other industries while making Indian healthcare future-ready.

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<https://twitter.com/OPPIIndia/status/1727310965476114686>

OPPI India @OPPIIndia · Nov 14

The OPPI Excellence in Innovation Award for the Healthcare Start-Up of the Year recognises innovations that can revolutionize healthcare in India. Meet our stellar jury panel.

Register for the Summit by clicking on this link: [rb.gy/nudmj](https://rb.gy/nudmj)



[#OPPIAnnualSummit](#) [#BharatKeLiye](#)

<https://twitter.com/OPPIIndia/status/1724335449429184743>

OPPI India @OPPIIndia · Nov 15

We are celebrating the pinnacle of quality at this year's OPPI Quality Award for Excellent Facility! Meet the discerning minds on our esteemed jury, dedicated to recognizing the outstanding facilities that surpass the global benchmarks.

Register here: [rb.gy/nudmj](https://rb.gy/nudmj)



[#OPPIAnnualSummit](#) [#BharatKeLiye](#)

<https://twitter.com/OPPIIndia/status/1724719116739919956>

OPPI India @OPPIIndia · Nov 23

Congratulations to Mr Dilip Shanghvi, Founder and MD, [@SunPharma\\_Live](#), on the well-deserved honor of receiving the prestigious Lifetime Achievement Award at the [#OPPIAnnualSummit](#) 2023. Your unwavering commitment to healthcare inspire us all! [#BharatKeLiye](#)

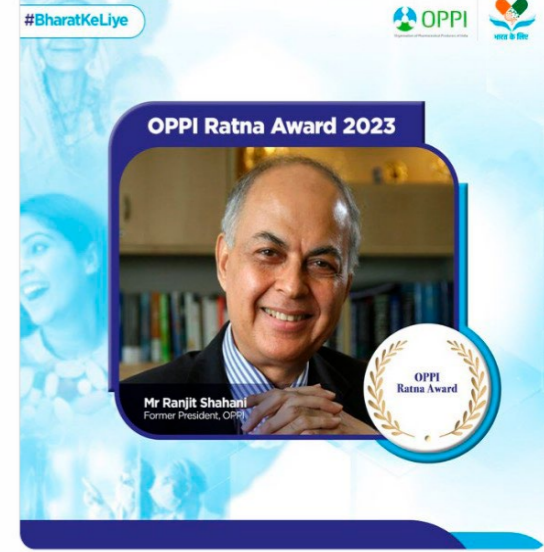


[#BharatKeLiye](#)

<https://twitter.com/OPPIIndia/status/1727631980903403560>

OPPI India @OPPIIndia · Nov 23

Congratulations to Mr [@ShahaniRanjit](#), Former President, OPPI on receiving the prestigious 'OPPI Ratna Award 2023' at the [#OPPIAnnualSummit](#). Your unwavering commitment to advancing healthcare in India continues to be an inspiration for all of us. [#BharatKeLiye](#)



[#BharatKeLiye](#)

<https://twitter.com/OPPIIndia/status/1727635151868534983>

## About Annual Summit 2023



The OPPI Annual Summit brings together diverse stakeholders such as Government officials, renowned academicians, leaders of the pharmaceutical industry, innovators, scientists, and media under one roof and engages in conversations that drive sustainable solutions in bringing value to the patients of the country.

## Theme for the Annual Summit 2023 - भारत के लिए

The theme highlights the importance of health driving outcomes in building a Nation and a World together, carrying forward the discussions on G20 thought of One World One Family. OPPI Annual Summit 2023 will include conversations that are future-focused in terms of reimagining healthcare 25 years into the future, Moving from Make in India to Discover in India; from Volume-Based to Value-Based. As the nation gears up towards India@100, the Summit will focus on highlighting the contribution of Government (Central and States), Corporates, Industry, Academia, Patient Groups, and other relevant stakeholders.

## About OPPI

The Organisation of Pharmaceutical Producers of India (OPPI) established in 1965, represents the research-based global pharmaceutical companies in India. OPPI has been an integral part of the healthcare journey of the country. We remain committed to supporting the nation’s healthcare objectives, putting patients at the core of all decision making and collaborating with all stakeholders to find sustainable solutions to realize the collective vision of Health for All.

Our member companies have been serving the country’s healthcare ecosystem since pre-independence and continue to remain committed to patient safety and providing quality care in the future as well. As an association, our advocacy decisions, patient commitment and work are always keeping the country first and we embody the spirit of working for ‘Bharat Ke Liye’; driven with innovation to find solutions for unmet medical needs, collaboration with government stakeholders, and co-creation with partners coming together to address the nation’s healthcare challenges. We are committed to the Hon’ble Prime Minister Shri Narendra Modi-ji’s clarion call of ‘Jai Vigyan and Jai Anusandhan’.

Connect with us on:



@OPPIIndia



OPPI India



Organisation of Pharmaceutical Producers of India (OPPI)



OPPI



[www.indiaoppi.com](http://www.indiaoppi.com)



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***#OPPIAnnualSummit***

***#BharatKeLiye***



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