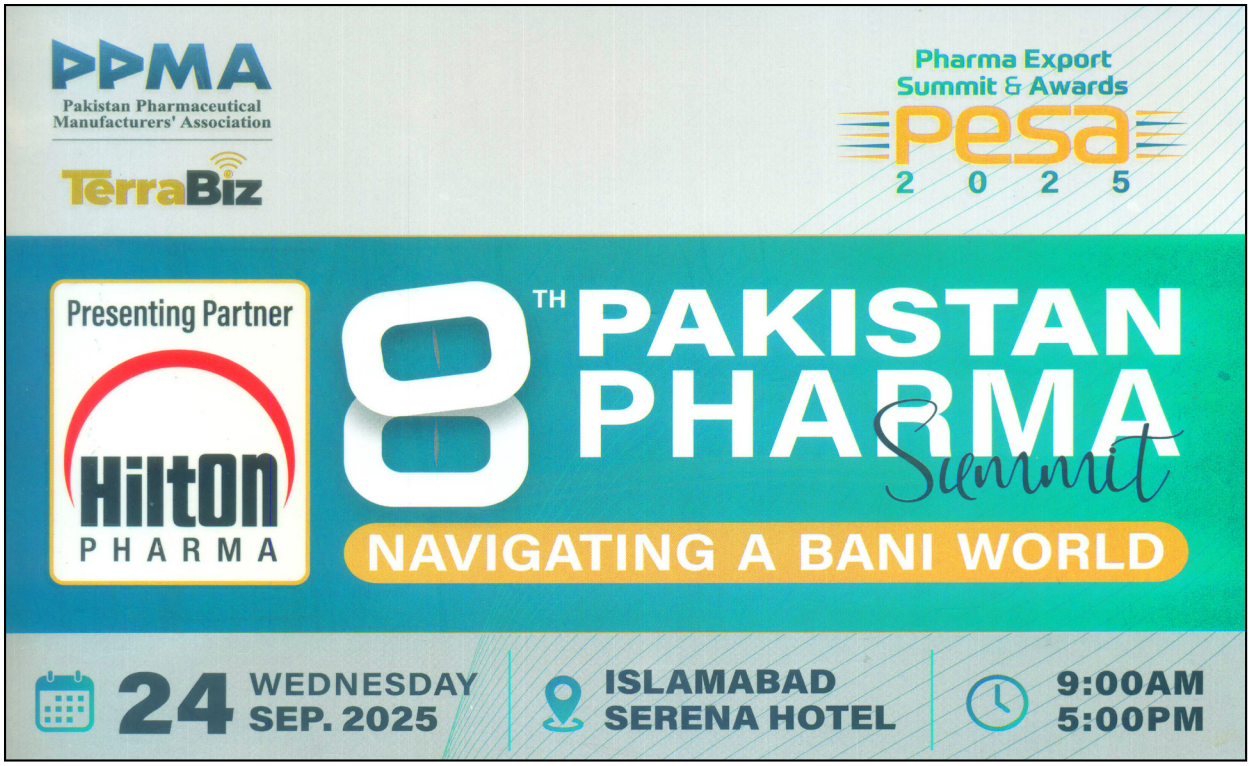

Proceedings of Eighth Pakistan Pharma Summit

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CONTENTS

Pre-Conference Workshop

Conference Proceedings

Post-Pharma Summit Workshop at Karachi

PRE-CONFERENCE WORKSHOP

AI and the Future of Pharma

Facilitator

Mr. Jim Harris

AI, Gen AI & Disruptive Innovation Expert

KARACHI: Mr. Jim Harris, an expert in Artificial Intelligence (AI), Generative AI, and Disruptive Innovations. as well as a bestselling author and one of the top-rated speakers from North America was the guest speaker at a pre-conference workshop titled “AI and the Future of Pharma”, organized during the 8th Pakistan Pharma Summit.

The workshop, organized by the Pakistan Pharmaceutical Manufacturers Association (PPMA), held on September 22nd 2025 was attended by selected participants from the pharmaceutical trade and industry, representing departments such as marketing, sales, manufacturing, and quality control. One of the workshop’s key features was its interactive format, with Mr. Harris actively engaging participants throughout the sessions.

Using AI Chemists are talking about eliminating all major diseases in ten years

During his presentations, Mr. Harris spoke in detail about several critical areas, including:

- AI and Personalized Medicine
- AI in Drug Discovery
- The potential elimination of major diseases within the next ten years
- Improvements in healthcare systems through AI
- Regulatory frameworks in uncertain times

He highlighted that AI is transforming the pharmaceutical industry at an unprecedented pace. “Chemists are now discussing the possibility of eliminating all major diseases within a decade,” he remarked. He noted the introduction of numerous AI tools, emphasizing that they are not expensive, simple to use, and remarkably fast.

AI is not expensive, simple and fast, increasingly being used in Sales, Marketing and Manufacturing in Pharma Industry

AI is rapidly gaining attraction in pharmaceutical sales, marketing, and manufacturing. Tools like the ChatGPT Voice App are revolutionizing how professionals work, enabling real-time translation into multiple languages within seconds.

Mr. Harris shared several groundbreaking developments, including:

- Early cancer detection through a simple blood test

Using AI customized personalized vaccine development has become possible

- Gene sequencing of tumors becoming more accessible and affordable
- The future potential to vaccinate people against certain cancers
- Use of early data and AI to develop cancer vaccines and initiate treatment within just 48 hours

He further explained that AI now makes customized and personalized vaccine development possible. Missed medical appointments can lead to serious consequences and increased costs. AI is helping solve this by enabling flexible scheduling, evening and weekend appointments,which is especially beneficial for working mothers.

Mr. Harris emphasized AI's vast reach, stating that thousands of AI applications are already in use. Its adoption across industries is significant:

Mr. Jim Harris, Mr. Haroon Qassim and Dr. Kaiser Waheed speaking at the Pre-conference Workshop on "AI and the future of Pharma" organized by PPMA at Karachi on September 23rd 2025.

- IT: 73%
- Finance: 70%
- Sales: 67%
- Operations: 65%
- Human Resources: 57%
- Marketing: 56%
- Supply Chain: 43%
- Legal: 46%

Faster drug development has now become possible. However, we need to use AI to educate and train ourselves which should be the top priority

He noted a tenfold increase in coding productivity due to AI. Reflecting on the impact of the COVID-19 pandemic, Mr. Harris pointed out how the drug development timeline was dramatically reduced from 8–10 years to just 11–12 months leading to the swift rollout of COVID-19 vaccines. Regulatory procedures were also fast-tracked globally.

In China, 400,000 patients now use AI to consult with doctors. Telemedicine allows immediate virtual consultations and rapid test result delivery. In Singapore, telemedicine booths operate 24/7, staffed by doctors, where patients can even provide urine samples and receive test results on the spot—for a small additional fee.

AI is a powerful research assistant and the most powerful learning tool

AI also helps detect drug-drug interactions, and has enabled pre-cancerous polyp detection and the advent of personalized precision medicine. The cost of gene sequencing has dropped significantly—to just $100 per human genome, making personalized vaccines more accessible.

Mr. Harris also highlighted the fact that technology has progressed so much that : "In the 1980s, we had to spend thousands of dollars to access services that are now readily available on a smartphone. The medicalization of the smartphone has truly sparked a healthcare revolution."

Mr. Jim Harris posed three thought-provoking questions to the participants, asking them to form small groups, discuss the questions, and present their insights:

- What has been the most surprising aspect so far?
- What will have the greatest impact on your firm and the pharmaceutical industry as a whole?
- What will you do differently going forward?

Quality of prompt is essential hence we need to learn prompt engineering

The feedback from participants was highly encouraging. Representatives from different groups highlighted various perspectives. One group noted that the most surprising developments were the acceleration of genome sequencing, time savings, improved accuracy, and significant cost reductions.

A notable example shared was from a trauma center, where AI could scan a patient while they are still on the stretcher. A provisional diagnosis could then be made even before the patient reaches the emergency department, allowing for immediate treatment and minimizing errors. AI can also be effectively used in forecasting, sales, and supply chain optimization.

Humility is the first virtue of leadership.
Speed is God, Time is Devil

However, the importance of developing local medical data was strongly emphasized. Currently, most patient treatment is based on datasets generated in Europe and the U.S. Participants agreed that data should reflect the diseases prevalent in Pakistan. AI can significantly aid in drug development, changing the entire process and making faster drug discovery a reality.

Another key insight was that patients today are more informed and educated. However, there is a pressing need to use AI for education and training—this must be a top priority.

In our group, after thorough internal discussion, we decided to ask ChatGPT the same three questions. It provided detailed responses instantly, which we shared with the speaker, who appreciated our use of AI during the session.

Technology will have a great impact on the medical profession and how medicine is practiced

Mr. Harris further encouraged participants to explore how AI can be integrated into their workflows. For instance, AI can be used for predictive maintenance—predicting brake failure in vehicles weeks in advance, thereby preventing accidents and reducing the need for maintaining large inventories of spare parts.

He highlighted AI's potential in medical diagnostics, such as identifying drug-drug interactions and offering faster solutions. However, he cautioned that symptoms can overlap across various diseases, so differential diagnosis is crucial. While AI helps accelerate the process, quality local data remains critical. AI should be trained on local datasets, not solely on Western data.

Participants acknowledged that decision-making based solely on U.S. or European data could be misleading. Therefore, prompt engineering—crafting high-quality prompts—is essential. Training in prompt engineering and investment in these tools was strongly recommended.

Some participants expressed concern that AI could encourage self-medication, which might lead to dangerous outcomes. Patients may input symptoms and receive treatment suggestions without understanding the complexities involved—like how a cough could be a symptom of many conditions. Medications also come with side effects.

Mr. Harris shared that during the COVID-19 pandemic, the University of Cambridge developed a Sound App to detect COVID symptoms, enabling faster diagnosis. AI is also being used for retinal examinations. He acknowledged that AI-based diagnoses can sometimes be compromised. However, AI systems are now capable of taking patient histories and gathering information before they even see a doctor—helping to streamline the diagnostic process. This could also introduce a level of accountability among doctors.

AI drones are being used to transport organs to different hospitals within the city

He pointed out that approximately 2.5 million people in the U.S. are hospitalized annually due to adverse drug reactions, and that the use of AI could help reduce such cases. As AI adoption accelerates, it will inevitably transform the pharmaceutical industry. While the generic drug market will remain strong, personalized medicine will gain ground—expected to account for about 20% of all treatments in the future.

One participant shared finding from a survey on how doctors are briefed about new drugs. It was observed that e-detailing using laptops was less impactful than personal interactions where representatives leave product folders behind, which doctors tend to review later. This opens up opportunities to enhance e-detailing methods.

Mr. Harris noted that over 7,000 scientific papers are published daily, making it impossible for doctors to stay updated. With AI, summaries of these papers can be generated in minutes. Doctors are increasingly relying on online resources, including training content on platforms like YouTube. Large Language Models (LLMs) compile this information, making it accessible and efficient.

Technical personnel working in the industry should learn these new skills including AI and use them efficiently to improve quality and accelerate production- Dr. Kaiser Waheed

Participants discussed the potential risks of patients relying too heavily on AI. However, having access to more information generally leads to better health outcomes. AI empowers patients to make better-informed decisions. For example, a patient with bone cancer might question whether surgery is the best treatment option. In such cases, AI offers a second opinion, making patients more confident in their choices. Still, doctors must ensure their role is not diminished.

Mr. Harris stressed that AI is one of the most powerful learning tools available today. It can be personalized for students, and training costs have significantly decreased, making it more affordable. AI saves time, but learning how to use it effectively is essential. Upskilling and reskilling the workforce is vital.

Interestingly, Mr. Harris mentioned that low performers often achieve the best results using AI. However, some countries are now discouraging the use of computers and AI in schools, raising questions about how best to integrate these tools. He also highlighted the potential for reverse mentoring, where younger, tech-savvy employees train senior staff. “Humility is the first virtue of leadership,” he quoted, a popular saying in Silicon Valley. He further added, “Speed is God, Time is the Devil.” He explained that single-gene diseases can now be eliminated by gene replacement, though conditions involving multiple gene defects remain challenging. However, he cautioned that bad actors can misuse AI, and we must stay vigilant. AI should be used responsibly—for staff training, for instance. Families should also adopt safe words to guard against potential AI-related impersonation threats.

He emphasized that technological innovation is driving down costs, especially in healthcare. Crises like COVID-19 accelerated digital transformation. Tools like Otter.ai are now routinely used for transcription, and diagnostic costs have reduced thanks to AI.

AI has significantly impacted automobile manufacturing, where processes like wheel changes now take minutes rather than hours. In healthcare, AI-powered drones are being used to transport organs between hospitals.

The session also touched upon emotional intelligence and different types of innovations that deliver 90% of value:

Mr. Jim Harris an eminent expert on AI, Gen AI and Disruptive Innovation who conducted a workshop on “AI and the future of Pharma” at Karachi on September 23rd 2025 photographed with Dr. Kaiser Waheed, Mr. Haroon Qassim Chairman & Vice Chairman of the Organizing Committee of 8th Pakistan Pharma Summit and Workshop participants.

- Business Model Innovation
- Policy and Societal Innovation
- Business Process Innovation
- Services Innovation
- Product Innovation

Continuing Mr. Harris highlighted the importance of therapy adherence. Tools like pill boxes and WhatsApp reminders are now being used to reduce treatment discontinuation and ensure timely appointments.

During the COVID-19 pandemic, hundreds of thousands of nurses quit their jobs, and many doctors opted for early retirement. This led to a severe shortage of nursing staff. In response, hospital administrations trained some administrative personnel to handle tasks previously performed by nurses, such as data entry and documentation. As a result, many nurses lost their jobs. “You can certainly deliver better healthcare in Pakistan using various AI applications,” he concluded.

Mr. Kaiser Waheed, Chairman of the 8th Pharma Summit Organizing Committee, in his concluding address said that the PPMA is working diligently on human resource development by organizing professional training to help bring Pakistan's pharmaceutical industry up to international standards. Currently, about eight pharmaceutical companies in Pakistan have received international accreditation from both PICS and the WHO.

"For the past four years, we have been discussing AI and robotics in these workshops and conferences. This is the future," he said. He urged participants to begin implementing such technologies in their organizations, stating, "One day, we will reach our destination."

"We, the owners and entrepreneurs, are often unaware of what is happening inside our drug manufacturing plants. It is you—the technical personnel—who understand the processes far better. You should learn these new skills and use them efficiently to improve quality and accelerate production."

Earlier, **Mr. Haroon Qasim**, Co-Chairman of the Organizing Committee, introduced the guest speaker and expressed his gratitude to Dr. Kaiser Waheed, under whose patronage these workshops and conferences continue to be held regularly.

Welcome address by Dr. Kaiser Waheed

ISLAMABAD: Pharmaceutical is the third largest contributor to national GDP. It is a beacon of resilience and growth. Apart from meeting the 95% of the domestic medicine market, it is exporting drugs to sixty countries of the world demonstrating quality recognition globally since many companies have now achieved WHO, PICs and MHRA pre-qualification. This is the legacy built on decades of hard work, ingenuity, and an unwavering commitment to alleviating suffering. However, this pride must fuel progress, not complacency. This was stated by Dr. Kaiser Waheed Chairman of the organizing committee of 8th Pakistan Pharma Summit in his keynote address in the inaugural session of the Summit on September 24th 2025.

Mr. Jim Harris talking to Dr. Kaiser Waheed, Mr. Tauqeer Rul Haq Chairman PPMA and Syed Farooq Bukhari at Dinner on 23rd September 2025 during the 8th Pakistan Pharma Summit organized by PPMA at Islamabad recently.

Continuing Dr. Kaiser Waheed said that the landscape before us is one of both immense opportunity and significant challenge. We stand at a crossroads defined by: The Imperative of Innovation: Beyond generics, the future belongs to biosimilars, novel drug delivery systems, and precision medicine. How do we foster R&D ecosystems within Pakistan? How do we incentivize local innovation and attract investment in cutting-edge research?

Many Pakistani Pharma companies have achieved WHO, PICs and MHRA Pre-qualification

Speaking about the Challenge of Access & Affordability he said that while we supply most local needs, ensuring every Pakistani, in every village and city, has access to essential, affordable

medicines remains a core mission. Balancing cost, quality, and accessibility in a complex economic environment he added.

As regards, Global Competition & Compliance international standards (GMP, GDP, regulatory harmonization) are not static; they evolve rapidly. To compete and expand our export footprint, continuous upgrades and unwavering adherence are non-negotiable. Dependence on imported APIs remains a critical vulnerability we must address.

Currently Pakistan is exporting drugs to 60 countries which demonstrates quality recognition globally

Talking about the Digital Revolution, he pointed out that AI in drug discovery, blockchain for supply chain integrity, telemedicine aren't buzzwords; they are reshaping healthcare. But the question remains are we ready to integrate and lead in this digital transformation? In order to strengthen the regulatory framework, a robust, efficient, predictable, and science-based regulatory authority (DRAP) is the bedrock of a thriving, trusted industry. Streamlining processes, enhancing capacity, and fostering transparent collaboration between industry and regulator are essential for growth and patient safety. As such our collective prescription for the future is invest relentlessly in R&D & Human Capital. We must champion academia-industry linkages. Establish dedicated R&D zones with tax incentives. Invest in upskilling our workforce – scientists, regulators, production specialists – for the challenges of tomorrow. To achieve all this let's make Pakistan a hub for pharmaceutical sciences. We must embrace technological

Within Pakistan Pharma companies, academia, government (Ministries of Health, Science & Technology, Commerce), and DRAP must work as one team while internationally seek technology transfer, joint ventures, and knowledge exchange

transformation: Integrate AI for predictive maintenance, advanced analytics for quality control, and digital platforms for supply chain transparency. Leverage technology not just for efficiency, but for breakthroughs. He suggested forging Strategic Partnerships. Collaboration, he stated was the key. Within Pakistan Pharma companies, academia, government (Ministries of Health, Science & Technology, Commerce), and DRAP must work as one team while internationally seek technology transfer, joint ventures, and knowledge exchange. CPEC offers unique logistics potential – let's harness it for pharma exports, he remarked. We must reduce our dependence on imported APIs. Incentivize local API manufacturing through targeted policies, infrastructure support, and long-term investment security. This is crucial for national health security and economic sovereignty.

Beyond Generics, future belongs to Biosimilars, novel drug delivery systems and precision medicine

Advocating for a Smart Regulation & Policy: Dr. Kaiser Waheed suggested that we must work constructively with DRAP to build a world-class regulator – well-resourced, proactive, and globally aligned. Advocate for policies that encourage investment, innovation, and export

competitiveness while ensuring the highest quality and safety standards. Data protection frameworks are also vital for innovation, he added.

We need to prioritize Patient-Centricity. Every tablet, every vial, every innovation serves a patient. Let's embed patient needs at the heart of everything we do – from affordability programs to developing medicines for neglected tropical diseases prevalent in our region. Remember our success in combating Hepatitis-C and that spirit must continue. The opportunity is vast. The global generics market is expanding. Demand for affordable quality medicines is universal. Pakistan, with its strategic location, demographic dividend, and proven capabilities, is uniquely positioned to become a global pharmaceutical powerhouse. This is not just business; this is nation-building. A thriving pharmaceutical sector means that healthier citizens and stronger communities, High-value jobs and economic prosperity, enhanced scientific prowess and national prestige besides greater health security and resilience. We must make commitments to:

We must embrace technological transformation, Integrate AI for predictive maintenance, advanced analytics for quality control, and digital platforms for supply chain transparency

* Collaborate more deeply than ever before.
* Innovate fearlessly and invest strategically.
* Advocate passionately for the enabling environment we need.
* Uphold the highest standards of quality and ethics.
* Deliver on our promise of health and hope for every Pakistani.

Dr. Kaiser Waheed concluded his address by stating that let's forge a future together where Pakistan Pharma is synonymous globally with quality, innovation, accessibility, and unwavering commitment to human health. The prescription for success, Dr. Kaiser Waheed stated is in our hands which we must write together.

Conference Proceedings

Inaugural Address by Syed Mustafa Kama Federal Health Minister

Federal Health Minister Syed Mustafa Kamal in his welcome address urged the Pakistani pharma industry to aim for Thirty Million US dollars export in the next few years and putting drugs and medical devices together, it is not impossible. We are capable of meeting this target. Ministry of health is acting as a facilitator and we have been achieving many things in bits and pieces. Now decisions are being taken keeping in view our requirements and industry's desires. We do not wish to interfere in your business but facilitate it.

Continuing Syed Mustafa Kamal said, let us all work together and work hard. I am myself available round the clock to listen to you. We are trying to improve our efficiency. DRAP is going

Syed Mustafa Kamal Federal Health Minister, Mr. Jim Harris and Dr. Obaidullah Chief Executive of DRAP speaking at the 8th Pakistan Pharma Summit organized by PPMA at Islamabad on September 24th 2025.

for automation and digitalization. After deregulation let us move forward and come out of comfort zone. Motivation with enabling environment should increase our Export of drugs. I plead your case in the cabinet and some get the impression as if I am your agent. Drug prices is a very sensitive issue with the government. I understand the issue and I will go for it. We are pleading your case the way you cannot plead it. I plead it because I know you are right. We are having headlines blaming the government of the day for price increase. I have prepared a document of thirty-five pages

Pakistan should aim at 30 Million Dollars Export of Drugs and Medical Devices in next few years- Syed Mustafa Kamal

and eight pages. I know the details as I have to speak in many forums. Trust us, we are doing our best. We must use the technology. I am optimistic. We have health sector which is better termed a sick care sector, he opined. Tertiary hospitals are overburdened. By using TeleMedicine, we plan to improve our primary healthcare. With the use of TeleMedicine, it is planned to refer patients to

DRAP is going for Automation; Digitalization & Govt. is sincere to provide enabling environment for Drugs Export

primary healthcare We wish to reform the primary healthcare system in Pakistan. At present we are going nowhere We have started this as a pilot project. Drugs will be delivered at the doorstep. It will reduce rush in tertiary care hospitals. Cervical cancer vaccination has been initiated. We need to start local production of vaccines so that we are not dependent on others. We must

start indigenous production of vaccines. Why cannot we do that, come together and try to find a solution. We can start vaccine production with foreign collaboration. Prevention of diseases should be given preference. Let us stop producing more sick people. Make sure that people do not fall sick as we cannot provide all of them curative services, he remarked.

Mr. Tauqeer Ul Haq Chairman of PPMA in his address highlighted the remarkable growth of the pharma industry. It has not only shown tremendous growth but also provided cost effective drugs to the people of Pakistan. Mr. Haroon Qasim and Dr. Kaiser Waheed,. he said, has organized this

Pakistani drugs are brand leaders in many countries where we export which shows Trust and Confidence of their people - Tauqeer Ul Haq

event and brought all stake holders on one platform. We have got good international speakers. It is a great opportunity for all of us to learn. At present 80% of pharma market is held by national pharma industry and 90% of drugs being used are produced locally. We are moving for self-reliance and innovations. Healthcare industry makes sure that we provide quality drugs to the people of Pakistan. He commended the increase in drug exports by the pharma industry helping the country

Federal Health Minister Syed Mustafa Kamal along with other guests presenting Mementoes to Mr. Tauqeer Ul Haq Chairman PPMA, Mr. Jalal during the 8th Pakistan Pharma Summit organized by PPMA at Islamabad on September 24th 2025.

by bringing in foreign exchange. Pakistani brands are leaders in many countries where we are exporting our drugs. It shows trust and confidence of people of those countries. Continuing, Mr. Tauqeer Ul Haq said that there is great potential and we could achieve all that the government wish. He appreciated the help and assistance being extended by Federal Health Ministry and CEO of DRAP to bring pharma industry in line with the international companies. Two years ago, there was serios shortage of many drugs in the market as we had 25% inflation. We faced lot of agony. Government understood and deregulation of drug prices was undertaken which came as a great help. All drugs are now available. Anti-cancer drugs are also now available. This gave confidence to

Pharma industry is moving towards self-reliance and innovations - Tauqeer Ul Haq

the industry and new investment was witnessed. The result was 34% increase drugs exports, the highest in the last twenty years. Now eight companies have got PICS accreditation and two from WHO. Ten to fifteen companies will get PICS accreditation soon. We could achieve all that with the

support of the government. We hope this policy will continue in the days to come and we aim at Three Billion drugs exports. Due to some of the issues many multinationals left the country and local industry came forward to ensure uninterrupted supply of drugs.

Unfortunately, the pharma industry in the past faced lot of harassment and prosecution of CEOs who were dragged to the drugs courts and treated as criminals. Government gave us facilitation; ministry of law and DRAP came forward and amended the law. New guidelines are now in line with

Ten to Fifteen more companies will get international accreditation in the next few years

international standards. formulated by DRAP which is just like fresh breeze. MNCs have stated they will stay. Ministry of commerce has prepared a position Paper. We will have Pharma Export Council, its importance has been realized and accepted by Government. DRAP also helped us and it is submitted to the health ministry for approval. Private and public sector should work together to achieve the target of Three Billion dollars export in a year. He also highlighted that cases of thirty-

Syed Mustafa Kamal Federal Health Minister presenting Mementoes to Mr. Saeed Ghani, Mr. Nadeem Rahmat, Mr. Jim Harris and other distinguished guests during the 8th Pakistan Pharma Summit organized by PPMA at Islamabad on September 24th 2025.

five essential drugs were approved by the Policy Board but the Prime Minister did not approve it hence this case is pending. Price fixation of these drugs must be decided for which we need your help. Another request he made was related to production of certain combinations which is their requirement but we do not get registration. These combinations should be approved which will also increase our exports.

Future of pharmaceutical industry in Pakistan. Mr. Tauqeer Ul Haq stated was very bright. We have a Vison but need Action. Quality drugs should be made available to the local population. If we

Authorities should consult PPMA while formulating any policy related to Pharma industry

make our drugs available outside Pakistan it will also help improve our image. We ask for vaccines. Through CPEC we can have arrangements for transfer of technology to ensure local production of vaccines through public private partnership. Vaccines production can be started. We should take it seriously. Almost 90% of APIs are currently imported and only 10% we produced locally. With government support we should be able to make investment and produce APIs locally. Anti-cancer drugs are not produced locally. He made a passionate plea that Pharma industry should be consulted whenever any policy is being formulated. Previously decisions used to take years which are now taken in a week. Digitalization has made all the difference. Registration board is doing

things properly. It is a motivation for us we are now being listened to and our problems are also being solved. He concluded is speech by stating: .

پرواز ہے دونوں کی اسی ایک فضا میں
کرگس کا جہاں اور ہے، شاہیں کا جہاں اور

Dr. Kaiser Waheed Chairperson of the Pharma Summit in his speech remarked that since 1967 when PPMA was established, thing have changed a lot. We are now hopeful for the formation of Independent Pharma Export Council which we have been demanding since many years. When drug prices were deregulated, we have shown 34% increase in drug exports and PPMA had a role in it. Currently about ten companies are accredited by WHO and PICS while many other companies have

We hope Independent Pharma Export Council will be constituted soon for which we have been pleading for some years - Dr. Kaiser Waheed

the potential but they are not focusing on exports at present. We have invited foreign speakers to talk about what are the international standards, he added.

Film Show

This was followed by a Film show wherein some Senir Chief Executives of pharma industry including Dr. Kaiser Waheed, Mr. Haroon Qasim and Mr. Tauqeer UL Haque featured. It highlighted the fact that now 90% of drugs used in Pakistan are being produced locally. It also referred to difficulties faced for exports to United States and Europe. It was stated that we need to focus more on Far East market. Government has to take some more decisions to help the industry. Some industries are allowed to retain 35% of their export earnings, the government should allow the pharma industry at least 25% so that it can make further investments to upgrade the facilities and improve quality assurance and go for international accreditation. It is time to think Big and Act Now, he dded.

Mr. Haroon Qasim Deputy Chairman of the Organizing Committee of the Pharma Summit stated that Dr. Kaiser Waheed is the moving spirit behind all these activities. Pakistan pharma industry export lifesaving drugs to sixty countries of the world. We take care of suffering of humanity. Our

AI and Drug Discovery are the buzz word these days but are we ready for this transformation - Haroon Qassim

dependence on imported drugs has reduced. AI and drug discovery are the buzz word these days but are we ready for this transformation, he sdtated. He also commended the help of DRAP to the pharma industry.

Dr. Muhammad Jehanzeb Khan Deputy Chairman of the Planning Commission who is also Secretary of APEX Committee SIFC was also one of the invited guest speakers. In his address he stated that we should try to have Fair and Transparent drug regulatory policies. The Government has tried to resolve certain issues facing the pharma industry, drugs shortage has been eliminated and our initiatives have some impact on drug exports which is heartening.

He congratulated the PPMA leadership for organizing the Pharma Summit 2025 which has brought together academia, researchers and pharma industry. The Pharma Industry, he stated has

made tremendous progress and made us free from imports which is important for the welfare of the people of Pakistan. Pharma industry should be viable, profitable and the general public must get quality drugs at affordable prices. Apart from meeting the local needs, Pakistani Pharma Industry was earning valuable foreign exchange through drugs exports. We need institutions and organizations in Pakistan which can help increase our drugs exports in a big way, he remarked.

Speaking about the formation of Pharma Export Council Dr. Jehanzeb said that we were able to bring all the stakeholders together. Most important aspect is Research and Development which is

We should try to have Fair and Transparent Drug Regulatory Policies - Dr. M. Jehanzeb Khan

taking a new form after the introduction of Artificial Intelligence. We have experts here who will be talking about AI. Pakistan, he said, has a large segment of population who live in poverty. We have to be mindful about availability of cost effective drugs which remains an important concern of the government. Abnormal increase in drug prices should never take place. PPMA has done a great job to keep the industry moving forward. The industry has some issues with Drug Courts. As per new policy formulated by DRAP, it will ensure that no un-necessary harassment takes place and no one is un-necessarily prosecuted. Pharma industry should come up with Internaitonal standards, produce quality drugs and ensure they are also exported, he added.

AI and the Future of Pharma

Mr. Jim Harris AI GeniiAI & Disruptive Innovations Expert in his address talked about AI and the Future of Pharma. He started his presentation by demonstrating the use of Voice APP translating what he said in numerous languages in a minute. This device, he stated, can translate in one hundred and twenty languages and it costs just five hundred US dollars and it is going to change the market. AI tools are becoming quite cheaper with every passing day with new innovations taking place. DEMIS won the Nobel Prize for his innovaitons. AI these days is being used in drug delivery, in cancer diagnosis, in identification of cancer genes and removal of diseased Gene. It has made

After digitalization of DRAP time period for completing various formalities has drastically reduced – Dr. Obaidullah

vaccination of cancer patients within twenty-four hours and start treatment with early diagnosis. AI, Mr. Jim Harris opined, is going to have an impact on every industry. Covid Pandemic changed the whole word. In China now people can take appointments on smart phone, see doctors, get laboratory reports and then go back to the doctor.

Continuing Mr. Jim Harris said that almost seven thousand scientific papers are published daily and it is not possible for a practicing healthcare professional to read all of them. However, AI will give you summary of all these within a minute. Today any doctor in USA who uses AI is sued but by 2030 hospitals who will not use AI will have face litigations. That time is coming very soon. Use of AI is very helpful in triage of patients and those who are serious and need immediate attention can be seen early and immediate treatment can be initiated. In Singapore Doctors Booths are available round the clock to get consultation. Use of ring and other wearable devices gives you all the data. A tiny camera used in a Pill is being successfully used for colonoscopy which is now a routine. There are single use devices which identify tissues which looks like cancers.

Gene sequencing, thirteen years ago, Jim Harris said used to cost 2.7 Billion US dollars which is now available in just ten dollars. It is going to be a great revolution. Smart phone in 1980 used to cost thousands of dollars and now it costs just one hundred dollars. Medicalization of smalt phone, Jim Harris opined, will increase in the days to come. Now risk of stroke and heart attack can be predicted. Cambridge University is using App to identify people at risk of Covid. Apps like Otter. ai are used for transcription. AI can be effectively used for preventive maintenance. Many people die due to Adverse Drug Reactions but now AI can be used to find ADRs and it is going to minimize these ADRs. He concluded his presentation by stating that AI works must faster.

DRAP Initiatives and the Way Forward

Dr. Obaidullah Chief Executive Officer of Drugs Regulatory Authority of Pakistan in his presentation talked about the Sustainable Development Goals. He pointed out that Good Health and Wellbeing is our responsibility to the people. Government cannot provide it alone. DRAP has taken many decisions in the last two years for the resolution of our problems. We are going for digitalization and facilitation. Time period for completing various formalities has been

In China now people can take appointments on smart phone, see doctors, get laboratory reports using AI - Jim Harris

drastically reduced. We are moving forward. Without enabling environment, regulators cannot work. We work for implementation of regulations. DRAP is helping industry get Internaitonal certification which cannot be done by the DRAP and industry alone. We all need to work together. Compliance with regulations is essential. Most regulation compliance pharma company has bright chances for export in regulated markets. Personalized medicine is the future. Pharma industry should go into manufacturing of APIs. DRAP is going for Internaitonal certification. We wish to become PICS accredited. Once that is accomplished, there will be no need for audit by FDA and Bioequivalence. DRAP has taken many initiatives which include Regulatory Reforms, WHO GBT, PICS, CTD, CRP SRA, PV, ICH, WHO PQ laboratories, Collaboration with NRAs, IHPs, Digitalization and Export facilitation

Speaking about the Way Forward, Dr. Obaidullah said DRAP should go for Regulatory reforms – Ease of doing business, Facilitation for local production of Vaccines, APIs, Complex dosage forms, Enhanced Regulatory Capacity –BABE, Risk based Approach, International alignment with WHO,

Gene sequencing, thirteen years ago, used to cost 2.7 Billion US dollars which is now available in just ten dollars - Jim Harris

PICs, ICH and IMDRF, For the pharma industry, it is essential to Improve compliance as regulation is the guardian and not Burden. Indigenous manufacture of APIs and Biologicals, Introduction of Novelty treatments like Chemotherapeutics, Biosimilar, Internaitonal partnerships for technology transfer besides export orientation exploring high return markets.

DRAP Dr. Obaidullah said is trying for WHO Level-3 accreditation to strengthen reliance, PICS legislation phase wise implementation. Risk based inspections and regulatory decision making, CTD Bioequivalence, Quality by Design through scientific evaluation and Internaitonal standard compliance, Vigilance Active Surveillance through Pharmacovigilance and post

marketing surveillance,2D Bar Code ensuring Track and Trace stemming, ensuring end to end digitalization. He concluded his presentation by stating that if you want to go fast, go alone. However, if you want to go far, go together.

USP Standards to enable quality, innovations and Resilience in a BAMI World

Mr. Geoff Tsen Global Vice President and General Manager of Greater China US Pharmacopeia was another invited speakers at the 8th Pakistan Pharma Summit 2025. US Pharmacopeia, he said, is used in one hundred forty countries of the world. We have legal representation in fifty countries. We help regulators and manufacturers. We have over one thousand employees who work in many countries. In Pakistan we are working in close collaboration with Dr. Obaidullah in DRAP. We work with global and regional platforms like WHO with whom we have official relations framework for

Most regulation compliance pharma company has bright chances for export in regulated markets - Dr. Obaidullah

Engagement of Non-State Actors, we have NGO consultative status with United Nations Economic and Social Council, we have official observer status with Pan American Health Organization and World Health Organization. In addition, we have official observer status with ICH, have Life Sciences Innovation Forum Board regulatory center of Excellence.

USP, he said, work as partners in science with academic practitioners, Partners with industry Research & Development companies and Generic manufacturers. We work as partners with Governments with Regulatory and Health Authorities.

Talking about USP's ongoing plans to enrich their standard portfolio to support quality of medicines and innovation Mr. Geoff Tsen said they were accelerating the creation of new general chapters, offering new analytical methods which are recognized by FDA of United States besides

Regulation is guardian and not Burden - Dr. Obaidullah

major regulatory agencies. Technical notes are not public standards but timely collection of industry best practices to reduce regulatory burden of proof in methodological development. We are also planning cross cutting physical reference standards to achieve 80/20 goal. A new approach is also being worked out for developing and sharing information with stakeholders. Through emerging standard programmed USP posts early concepts for potential standards allowing members of the scientific community to view the related documents, ask questions and post comments engage in fruitful discussions and share the emerging standards with other colleagues. The paper edition was renewed once a year but now it is fully digitalized since 2023 and renewal is possible three to six times in a year.

USP standards cover the whole value chain across all drug classes Geoff Tsen maintained. It coves from discovery to characterization, method development, quality control besides lot release and stability. In all there are four hundred chapters, with over one thousand overviews, they are ready to use analytical methods validated by Experts Committee of USP and recognized FDA of United States.

He also talked about a data driven approach to strengthening the resiliency of the global medicine supply chain. Some of the important messages regarding supply chain which he mentioned included identifying and addressing the supply vulnerabilities to prevent drug shortages and ensuring patient access. USP's data driven approach highlights risk factors, geographic concentration, quality, price and manufacturing complexity to ensure resilient medicine supply chain policies. Quality is crucial and must be incentivized.

Continuing he highlighted the four key risk factors to guide public policy. He disclosed that USP supply chain Map uses machine learning and predictive analytics to provide end-to-end visibility into the upstream supply chain by helping to predict and present drug shortages, by assessing optimization of manufacturing capacity and by providing support in strengthening regulatory frameworks. These

Syed Mustafa Kamal Federal Health Minister and Dr. Jehan Zeb Khan Deputy Chairman of Planning Commission photographed during the Pakistan Pharma Summit 2025.

analytics identified four key risk factors that drive supply chain disruption which include Geographic concentration, Quality, Price and Manufacturing capacity. USP, he further stated, urges collaborative efforts from policy makers, regulators, and industry stakeholders to identify and respond to risks in the pharmaceutical supply chain with the objective to reduce disruptions in drugs supply.

The policy recommendations call for collaborating in supply chain resilience and reliability, efforts, increase in supply chain visibility, establishing a vulnerable medicines list, aligning the market to incentivize a quality and resilient supply chain, research for better understand market interactions besides bolstering manufacturing capacity.

US Pharmacopeia works with numerous Global & Regional Platforms like WHO, UN, ICH, ECOSEC & APEC - Geoff Tsen

Strategy papers, Geoff Tsen said, are crucial to build resiliency for the supply of quality drugs. Early warning system are the availability of more data to drive better insights, creating a vulnerable medicines list to plan mitigation strategies. He also talked about Geographic diversity, payment reforms including prioritizing essential medicines and incentives to resilient supply chain.

Consideration for dynamic stockpiling of essential medicines, investment in advanced manufacturing technologies to expand production capacity besides coordination among government and non-government stakeholders is also essential. Pharmacopeial standards grounded in rigorous science are recognized and endorsed by regulatory authorities all over the world. They can help streamline

MHRA's GMP Inspectors major observations was lack of senior management involvement in Quality Control - Khalid Ahmed Sheikh

review and approval to speed drug development and save resources, allow focus on discovery while assuring quality medicines, ensure that the medicines meet the quality standards besides enhancing manufacturing control for safety and quality, Geoff Tsen concluded.

Beyond Compliance Building a Culture of Quality for Global Competitiveness

Prof. Khalid Ahmad Sheikh from UCL School of Pharmacy was another invited Guest speaker at the Summit who made a presentation on" Beyond Compliance Building a Culture of Quality for Global Competitiveness" . He discussed in detail the Threats and Opportunities for the Pharma Manufacturers. He asked the participants whether they were worried about their business? Speaking about regulatory inspections Prof. Khalid Sheikh discussed failure of compliance to legislations, critical major and minor observations and why we need GMP

Chairman PPMA Mr. Tauqeer Ul Haq along with Dr. Kaiser Waheed presenting Mementoes to Geoff Tsen and Prof. Khalid Sheikh during the Pakistan Pharma Summit held on October 24th 2025 at Islamabad.

compliance companies. Are the drug manufacturers from Pakistan ready to export their products to international developed markets. If the answer is NO, then what are the potential Threats and Barriers. Are the regulatory guidance national and international clear enough to them. Are they aware of PICS, PakEUGMP and ICH Guidelines? We wish to see Pakistan Flag in the international market for which we all look towards DRAP, he remarked.

He put a few questions to the participants i.e., Do they think that non-compliance to legislation has anything to do with Quality? How many of you are involved in routine manufacture of products and in which capacity? Do they have any involvement in quality meetings and if so in which capacity? The next question he posed to the participants was "Do they think that a Good Quality System/culture is the answer to all the above questions? He then disclosed that

MHRA's GMP Inspectors major observations was lack of senior management involvement. It is time to explore it, he asked.

Pakistan Pharma Statistics

Speaking about the Pakistan Pharmaceutical industry Prof. Khalid Sheikh said that there are over fifteen hundred pharmaceutical, nutraceutical and consumer products companies. The number

Quality is crucial and must be incentivized - Geoff Tsen

of active manufactures is over six hundred. The total pharma market is approximately 1.3 trillion. Surprisingly about fifty pharma companies has 90% of the share and one hundred companies have 97% share of the market. What about the remaining over five hundred drug manufacturers, he asked?

Four key risk factors that drive supply chain disruption include Geographic concentration, Quality, Price and Manufacturing capacity - Geoff Tsen

The total number of products registered by DRAP, he said are about eighty-five thousand. The number of WHO Prequalified products was just Five. Pak Regulatory Agency's WHO maturity level was Level-2. As regards BANI there is lack of resources. There are some issues of communication between the manufacturers and regulators which are potent threats. The opportunities include

Fifty pharma companies have 90% share of drugs market in Pakistan, hundred companies account for 97% share. One wonders what the rest over five hundred companies are doing

initiative by DRAP, Policy implementation, Invest in People and Training for QMS and QBD. India has about one hundred twenty-five pharma companies who are involved in drugs exports while Pakistan has just about twenty-five or so. There are a few API manufactures in Pakistan. Almost 60% of APIs going to EU is form China and India because of government support and regulator's initiative. With DRAP's support by Government of Pakistan, Government support to the pharma industry is some of the opportunities which we must avail for API manufacturing.

Almost 60% of APIs going to EU is form China and India because of government support and regulator's initiative

Continuing Prof. Khalid Sheikh said that supporting the Chief Executive Officer of DRAP, Investments and Innovations, training of regulator and industry, constant dialogue between regulator, academia and industry is essential. We must set realistic goals, achieve WHO maturity-3 by 2026, share good practices and comply with recently adopted international standards which will go a long way in achieving our objectives, aspirations Prof. Khalid Sheikh remarked.

“Regulations, Policy and Trust Advancing Access to Quality Medicines”

Dr. Zakieh Al Kurdi Regional and Operations Director MEA US Pharmacopeia discussed “Regulations, Policy and Trust Advancing Access to Quality Medicines”. The Misson of USP, it was stated was to improve global health through public standards and related programme that help ensure the quality, safety, benefit of medicines and foods. With USP partnerships are at the heart of quality. It partners with academic practitioners, with industry in Research & Development and Generic manufacturers. It also partners with government with regulatory and health authorities. Past is used to shape the future.

USP assesses the quality of drugs besides monitoring counterfeit and substandard products - Zakiya Alkurdi

USP continues to build upon its expertise and scale through conventions meetings to meet the worlds challenges. It has a deep scientific bench with a diverse and committed base of experts who volunteer for USP. We have forward looking global relationship and global collaborations. We have four hundred ninety members and over forty countries are represented. We deal with biologicals, healthcare practice, Generic manufacturers, Dietary supplements, and innovations sector. USP has chapters in South Asia, Latin America, Asia Pacific, Greater China, Middle East and North Africa, Europe and Africa. We had our last meeting in North Bethesda Maryland in

Syed Yousuf Raza Gilani Chairman Senate (third from left) chairing one of the sessions during 8th Pakistan Pharma Sumit held on October 24th 2025 at Islamabad.

May 2025. Strategic priorities from 2025-2030 were also shared. Our work, Dr. Zakieh said, is strengthened by our collaboration with regulators globally. We are increasing access to quality medical products. Lifecycle approach to Pharma manufacturing were also discussed in detail. USP has scientific basis for decision making in regulatory review, manufacturing besides enforcement. It contributes to research and development fostering innovations. It also ensures a consistent approach to quality for innovator and generic products. It assesses the quality of products besides monitoring counterfeit and substandard products. Its impact is global

and our work is broader and deeper. USP standards are used in one hundred fifty countries around the world. Every year billions of people rely on medicines based USP standards and our scientists' volunteer dedicate their valuable time every year to achieve USP mission. The presentation concluded with a message that USP will expand and make consistently available standards which are needed to address highest quality issues and create awareness on supply chain topics. It will develop standards, publications, expand partnerships and collaborations to provide these tools besides facilitating global access to quality medicines. It will also

Artificial Intelligence, Genomics and Preventive Health are redefining the value of medicines - Philippe Gerwill

support analytical and regulatory capabilities of our partners. It will endeavor to build thought leadership, utilize innovative approaches to collect feedback.

Future of Pharma in a Digital World

Philippe Gerwill Digital Healthcare Futurist & Humanist talked about the Future of Pharma in a Digital World: Human Centric Innovations and Global Regulatory Shifts." He pointed out that the future of pharma is not about selling more pills but ensuring fewer people need them. Artificial Intelligence, Genomics and Preventive Health, he said, are redefining the value of medicines.

PICS compliance was a challenge and opportunity for Pakistan - Rafael Beaus

Speaking about the old paradigm he mentioned Blockbusters, One- Size Fits-All, Reactive, Costly and Fragile. This he said, was the challenge but it also offers opportunity. The new Parading, he mentioned consisted of Predictive, Preventive, Personalized and Resilient. It spreads form Sick Care to Health Assurance.

Artificial Intelligence, he further stated, was the Brain of Next Generation Pharma. It is faster for Research & Development, is helpful in Smarter Clinical Trials, offers personalized medicine, is helpful in predictive supply chain. However, there are ethical issues. Genomics is unlocking the code of life. Cost of sequencing is decreasing. One can now aim at targeted therapies, predict genetic risk but there remains the privacy issues. In future health assurance will replace Sick care. He also mentioned about predictive, preventive, personalized and participatory approach. Regulatory approval of Apps, biomarkers and digital endpoints. Tomorrow's future business models will include Platforms drugs and digital monitoring, preventive health markets, value-based contracts, data monetization and longevity solutions. The risks involved in standing Still include disruption by technology, loss of patient struts, policy pressure besides drying cashflow. Global Regulatory will shift to fragmented AI/Digital health rules, there will be push for harmonization, adaptive push offers regional opportunity for Pakistan. Future strategies will consist of adaptability, ethics, capacity and collaboration between pharma, technology and policy makers including patients. He concluded his presentation by stating that the future of pharma will not be defined by selling more pills but by healthier lives. Henc, let us share the future together for our industry, our societies and above all the people we serve.

PICS Compliance

Rafael Beaus Global Consultancy Manager at Syntegon Telstar Technologies talked about PICS compliance, which he said, was a challenge and opportunity for Pakistan. The presentation also referred to regulations of FDA, MHRA, Korea, Australia, South Africa which are different in different countries. PICS compliance covers premises assessment, facility evaluation besides evaluation of quality assurance systems. Pakistani Pharma industry has great potential for growth. PICS are increasing standards. If Pakistan joins PICS, the whole country will have to move ahead and comply with standards.

Mr. Nadeem Rahmat spoke about ISPE Membership Drive in Pakistan. This, he said, was founded in 1980 and it has forty regional chapters. We need one hundred members to get Pakistan Affiliate status. He shared the list of different categories of members and also gave an overview of benefits for the members. By joining ISPE one can expand the global network.

Address by Senate Chairman Yousuf Raza Gilani

Syed Yousuf Raza Gilani Chairman Senate was the Chief Guest in the afternoon session. Speaking on the occasion he said that Pakistan Pharma industry was fast evolving improving healthcare and earning foreign exchange through export of drugs. The related ministries and regulators

Mr. Tauqeer Ul Haque Chairman PPMA, Dr. Kaiser Waheed, Syed Yousuf Raza Gilani Chairman Senate Chairman, Kh. Shahzeb Akram, and Mr. Asad Shuja photographed during the Pakistan Pharma Summit.

need to work together for healthier nation. There has been tremendous increase in our drugs exports. Meeting the national requirements and then exporting drugs overseas are some great achievements. Many Pakistani companies are expanding their business into international markets which shows the trust in quality of their products. Artificial Intelligence, Digitalization and advances in technology offer great help. Government needs to provide incentives like reduction in duties on

APIs which will be a great help. I will be glad to help the industry in whatever way I can because healthcare is a vital sector which requires collective efforts. He also referred to empowerment of various committees in Senate and the industry will get our all-out support, he assured. We should help create an enabling environment for industry to develop and grow. He emphasized the importance of working together to unlock opportunities to increase exports. We need progressive approach and sustainable collaboration, he added.

We should help create an enabling environment for industry to develop and grow - Yousuf Raza Gilani

Earlier in his welcome address **Mr. Haroon Qassim** Vice Chairman of the organizing committee remarked that our drug exports in 2018 was just two hundred million US dollars which has increased to four hundred seventy-five million dollars in 2025. We are opening our doors to WHO, USP for

Mr. Tauqeer Ul Haq Chairman PPMA, Dr. Kaiser Waheed and Mr. Haroon Qassim Chairman & Vice Chairman of Organizing Committee of Pakistan Pharma Summit presenting a Mementoes to Mr. Haroon Akhtar Advisor to the PM.

compliance. We have earned the trust of doctors and public. He also talked about PESA Awards which are presented to various companies who are exporting drugs to different countries.

Panel Discussion

This was followed by a Panel Discussion. **Syed Farooq Bokhari** talked about Export Regulations and highlighted the challenges in African market. We hired a French speaking person in the company which was very helpful. **Dr. Faisal** stated that because of WHO and PICS Accreditation they have some advantages in access to new markets. There are certain challenges but global export is very big market. Companies need to set up their offices in London and they should move to Europe and

United States markets. Because of acceptance in Spain, we had acceptance in Europe. There is a big medical devices market and Pakistan should focus on that. Previously there was no problem but now though it has a potential but it is challenging. It is an opportunity in Europe but not so easy these days**. Mr. Zahid Saeed** said that they were exporting to twenty-two countries but if the government can sanction some revolving credit for Central Asian and African States, it will work much better. If you have all documentation, the products are good, there are good prices. There are different requirements for local and export market. The situation is now different even the least regulated people come with WHO regulations. **Dr. Obaidullah** remarked that Afghanistan is another big market for us and if the situation improves, we can export drugs for which we have started documentation. In DRAP we are moving in the right direction. **Dr. Asad Zaheer** remarked that we need to overcome barriers to improve our drugs export. At present thirty to forty companies are active in exports. One of the participants remarked that technology is there, we need funding and opt for cost effective initiatives. It was also suggested to accelerate efforts for Banding Pakistan to enhance the image of Pakistan in these countries.

Mr. Haroon Qassim remarked that WHO Accreditation makes a big difference and we noted it when we participated in Arab Health at Abu Dhabi in 2022. When people know that you have WHO accreditation, they are keen to talk to you and know more about the company. It also helped us to export our products to thirty-five countries.

Post-Pharma Summit Workshop at Karachi

“Pathway to Regulated Markets: A Practical Guide for Pakistani Pharma Manufacturers”

Dr. Khalid Ahmad Sheikh, Professor of Pharmaceutical Quality and Regulations at the UCL School of Pharmacy, UK, who has over two decades of experience in academia, industry, and regulatory affairs, conducted a post-conference workshop on “Pathway to Regulated Markets: A Practical Guide for Pakistani Pharma Manufacturers”. It was organized in Karachi on September 26, 2025.

Marketing authorizations for Europe are typically valid for five years, with unlimited renewals upon reassessment - Khalid Ahmad Sheikh

The event drew large participation from the pharmaceutical industry, including representatives from Marketing, Quality Assurance, Manufacturing, and Regulatory Affairs departments.

In addition to Prof. Khalid Ahmad Sheikh, other facilitators included Dr. Nadeem Irfan Bukhari from Qarshi University, Lahore. Several experts also delivered virtual presentations on various regulatory and quality-related topics.

PPMA organized a Post-Pharma Summit Workshop on “Pathway to Regulated Markets: A Practical Guide for Pakistani Pharma Manufacturers” at Karachi on September 26th 2025. Sitting on the dais from (L to R) are Prof. Khalid Ahmad Sheikh Main facilitator and moderator of the workshop, Syed Farooq Bukhari, Dr. Kaiser Waheed, Mr. Tauqeer Ul Haq Chairman PPMA and MS Sadia Special Secretary Health, Government of Sindh.

Ms. Sadia, Special Secretary of Health, Government of Sindh, was the chief guest at the inaugural session. Addressing the workshop participants, she emphasized that Pakistan’s entry into regulated international markets is a matter of national interest. “We must pursue this goal with confidence”.

Environment, Materials, Processes and systems all effect quality - Nadeem Irfan Bukhari

She highlighted two key benefits: the availability of high-quality drugs within Pakistan and the potential for pharmaceutical exports to drive economic growth. “We must move quickly, or risk being left behind. The government will create an enabling environment to help the industry achieve its goals. Workshops like these should become regular, meaningful, and results-oriented events,” she added.

Dr. Nadeem Irfan Bukhari, Dean of Pharmaceutical Sciences at Qarshi University, emphasized that patients have a right to safe, effective, and innovative medicines. He presented in-depth discussions on Quality by Design (QbD), drug development, and the various factors affecting quality—ranging from environment and materials to processes and systems.

This was followed by a joint online presentation from **Dr. Fatemah Al-Salm (**Kuwait) and **Hissah Al-Suwaid** (Saudi Arabia), who shared insights on regulatory pharmacy practices across the GCC countries. They discussed centralized registration systems for six GCC member states and highlighted their strategic goals, including price control, chronic disease management, and public safety.

Prof. Khalid Ahmad Sheikh, Prof. Irfan Nadeem, Mr. Haroon Qassim, Dr. Kaiser Waheed, Mr. Tauqeer Ul Haq Chairman PPMA and Ms. Sadia speaking at the Post Pharma Summit workshop organized by PPMA at Karachi on September 26th 2025.

They stressed that dossiers are evaluated jointly by representatives from all six GCC countries, and inspections—particularly from Saudi Arabia—can be stricter due to high accountability. The presentation also covered the classification of herbal, nutraceutical, and pharmaceutical products and emphasized that although Kuwait cannot manufacture drugs locally, it is open to international cooperation.

WHO accreditation adds credibility to the pharmaceutical companies - Haroon Qassim

Prof. Taylor Keui from the UK discussed the British Pharmacopeia, MHRA registration processes, and the role of expert committees. “The quality of the dossier is crucial for successful regulatory submissions,” he emphasized.

He highlighted that expert groups, working independently of the pharmaceutical industry, ensure that medicinal products meet stringent standards. These groups collaborate with

Quality of Dossier is the Key to the Success of Regulatory Submissions – Prof. Taylor

MHRA and other European agencies, contributing to international harmonization of standards. Key areas discussed included particle size, polymorphism, dissolution profiles, sterilization methods, packaging, and dosing devices. “Dissolution must be a routine quality control measure,

and the development process must follow pharmaceutical guidelines unless a valid justification is provided," he said. He also reviewed EMA's decision tree for sterilization and emphasized the importance of clear, justified documentation to avoid regulatory setbacks.

GMP and Regulatory Framework

Dr. Attia Hasnain delivered a comprehensive presentation on Good Manufacturing Practice (GMP) inspections based on international guidelines, particularly those by PICS. She explained the mission of PICS to harmonize GMP standards and ensure consistency in inspections.

AI should be seen as a co-pilot, not a replacement - Paul Palmer

She outlined how inspections cover Quality Control (QC) labs, document compliance, equipment validation, microbiological standards, stability testing, warehousing, and vendor qualifications. Inspections typically last two days and involve a thorough review of workflows, contamination risks, and documentation. "All aspects—from particle size to analyst qualifications—are critically evaluated," she noted.

AI can optimize yield, detect mechanical issues, and support predictive maintenance - Paul Palmer

Market Authorization in Europe

In the afternoon session, **Dr. Khalid Ahmad Sheikh** discussed regulatory procedures for obtaining market authorization in Europe. He elaborated on centralized, decentralized, mutual recognition, and national procedures, explaining their scope and legal frameworks. "Even after MHRA approval, individual countries can raise questions. Therefore, it's often advisable to get approval from a single country first," he advised. He also detailed how centralized procedures apply to drugs for conditions like AIDS, cancer, and diabetes. Marketing authorizations are typically valid for five years, with unlimited renewals upon reassessment. Dr. Sheikh noted that many Indian companies operate through Malta or the UK to gain access to the EU market, leveraging regulatory flexibility in those countries.

We wish to see Pakistan Flag in the international market for which we all look towards - Khalid Sheikh

He further explained that countries under the Mutual Recognition Agreement (MRA)—such as Switzerland, Canada, USA, New Zealand, Japan, Finland, and the UK (post-Brexit)—share inspection reports and waive batch testing on imports. He also stressed the importance of European GMP certification and compliance with local legislation.

Artificial Intelligence in Pharma

In a video presentation, **Mr. Paul Palmer**, an expert in AI in manufacturing, highlighted the growing role of artificial intelligence in pharmaceutical processes. He compared AI with traditional automation and explained how AI can optimize yield, detect mechanical issues, and support predictive maintenance. It can be used in visual inspection of vials and tablets, detection of pattern anomalies in drying processes, and document consistency checks. He concluded by saying, "AI should be seen as a co-pilot, not a replacement, and it can be an affordable solution even for small companies."

Earlier in his welcome address, **Mr. Taqueer Ul Haq**, Chairman of the Pakistan Pharmaceutical Manufacturers' Association (PPMA), stated that the association has 285 member companies, which collectively hold an 80% market share. "Ninety percent of the medicines used in Pakistan are produced by the national pharmaceutical industry. We manufacture quality medicines at affordable

Participants of the Post Pharma Summit Workshop held at Karachi on September 26th 2025 photographed with Prof. Khalid Ahmed Sheikh, Prof. Nadeem Irfan, Dr. Kaiser Waheed, Mr. Haroon Qassim Chairman and Vice Chairman of the organizing committee respectively.

prices and have continuously raised our quality standards," he noted. He also mentioned that Pakistan currently exports pharmaceutical products worth approximately USD 500 million annually, and top exporters are recognized at the PESA Awards Summit regularly.

Dr. Kaiser Waheed, Chairman of the Organizing Committee of the Pakistan Pharma Summit, emphasized the need to meet international standards. "No institution in Pakistan is currently providing up-to-date knowledge and information on pharmaceutical developments. There are well-established guidelines from authorities like the FDA and the European Union. The question remains—why isn't Pakistan exporting to markets like the USA and Europe, while countries like India and Bangladesh are doing so?" He stressed that Pakistan does not have a single FDA-approved plant, whereas India has many. "We at PPMA have been conducting workshops for the past five years to find answers. Some local units are now accredited by PICS, WHO, and MHRA—but much more needs to be done." He encouraged professionals to take the lead in this transformation. "The industry can achieve FDA, MHRA, and WHO accreditations if professionals guide the process based on what's best for public health."

Mr. Haroon Qassim, Co-Chairman of the Organizing Committee, remarked that WHO accreditation adds credibility. He appreciated DRAP and government regulators for being on the right path and expressed hope that more companies would achieve international certifications soon.

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