DRUG REGULATORY AUTHORITY OF PAKISTAN
MINISTRY OF NATIONAL HEALTH SERVICES, REGULATIONS & COORDINATION

DRAP's NewsLetter

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REFORM CHAMPION

The Drug Regulatory Authority of Pakistan (DRAP) is honored to receive the prestigious "Reform Champion" Award from the Prime Minister of Pakistan, Mr. Muhammad Shehbaz Sharif. The award was presented to Dr. Obaidullah, CEO DRAP, in recognition of DRAP's continued commitment to regulatory modernization.

Expressing his gratitude, CEO DRAP thanked the Government of Pakistan and emphasized that this achievement reflects the collective efforts, dedication, and hard work of the entire DRAP team.

Chief Editor :
Dr. Obaidullah
Chief Executive Officer DRAP

Editor:
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Director Pharmacy Services

STRENGTHENING THE PHARMACOVIGILANCE SYSTEM IN PAKISTAN: A COLLABORATIVE MILESTONE FOR PATIENT SAFETY

In a significant stride toward enhancing medication safety and regulatory excellence, the Drug Regulatory Authority of Pakistan (DRAP), in collaboration with the World Health Organisation (WHO), successfully conducted a four-day multi-stakeholder technical workshop from 3rd to 6th of November 2025 in Islamabad. The workshop bonded key national and provincial stakeholders to build a more integrated, and an effective pharmacovigilance framework for the country.

The event brought together representatives from National Pharmacovigilance Centre (NPC), DRAP, the Federal Directorate of Immunisation (FDI), Common Management Unit (CMU) including National TB, Malaria, and HIV Control Programmes—along with Provincial Health Departments, Healthcare Commissions, and VigiFlow focal persons from Hospitals. This diverse participation underscored a shared commitment to improve medicine and vaccine safety across Pakistan.

The workshop was launched with a strong focus on actively engaging the public from the very beginning. Federal Minister for Health, Syed Mustafa Kamal launched the #MedSafetyWeek social media campaign through an informative video demonstrating how healthcare professionals and the public can report Adverse Drug Reactions (ADRs) in Pakistan.

The Federal Minister emphasised the importance of proactive vigilance and disease prevention, urging a unified action plan between provincial and Federal authorities to strengthen coordination and public health response. He reaffirmed the Ministry's full support for DRAP in achieving the WHO Global Benchmarking Tool (GBT) Maturity Level 3—a key indicator of a mature and functional regulatory system.

Dr Obaidullah, CEO-DRAP, highlighted the need to foster a no-blame culture in ADR reporting, encouraging all stakeholders to actively contribute to strengthening pharmacovigilance. He outlined the pivotal role of pharmacovigilance in Pakistan's pursuit of World Listed Authority (WLA) status, noting that this milestone depends on the collective efforts of National and provincial stakeholders. Facilitated by Dr Jean-Christophe Delumeau, a member of the International Society of Pharmacovigilance (ISoP) Scientific Board, and moderated by Dr Akhtar Abbas Khan, Head of the National Pharmacovigilance Centre, the workshop blended strategic mapping with hands-on training.

The first two days focused on mapping pharmacovigilance stakeholders at both national and provincial levels, identifying key players as the National Pharmacovigilance Centre, DRAP, Public Health Programmes (TB, Malaria, HIV, Immunisation and Polio), Provincial Health Departments, Provincial PV Centres, Healthcare Commissions and public and private hospitals. This was followed by two days of in-depth training on following topics:

- Evolution of Pharmacovigilance concepts and landscape
- The Uppsala Monitoring Centre (UMC) Systems
- Benefit-risk assessment
- Risk Management Planning
- Hands-on training on the VigiFlow database
- Risk minimisation and Safety communication

On the last day, an interactive workshop allowed participants to discuss their challenges, share insights, and develop actionable strategies to optimise pharmacovigilance operations.

"Pharmacovigilance is more than a regulatory obligation—it is a public health priority and the frontline defense that ensures every medicine and every vaccine given to people is truly safe."

Dr Dapeg Luo, WHO Representative in Pakistan

Through collaborative dialogue and intensive capacity-building sessions, participants worked together to design a roadmap for a harmonised, integrated, and functional National Pharmacovigilance System. This system aims to enable early detection and mitigation of medicine and vaccine related risks, ensuring the highest standards of patient safety.

This workshop marks a significant milestone in Pakistan's healthcare journey, reflecting a strengthened commitment to pharmacovigilance as a cornerstone of public health. By fostering greater collaboration, technical expertise, and stakeholder engagement, Pakistan is paving the way toward a safer, more responsive, and globally

STRENGTHENING MARKET SURVEILLANCE AND CONTROL TO COMBAT SUBSTANDARD AND FALSIFIED MEDICAL PRODUCTS

The Drug Regulatory Authority of Pakistan (DRAP), in collaboration with the World Health Organization (WHO), organized a three day capacity building workshop in Islamabad from 2-4 December 2025 to strengthen Market Surveillance and Control and address the risks of substandard and falsified medical products—an important step in Pakistan's progression toward WHO Global Benchmarking Tool (GBT) Maturity Level 3. Bringing together leadership and technical team from DRAP, Provincial Drug Control Units, Quality Control Laboratories, and stakeholders, the workshop combined practical sessions on risk based post marketing surveillance, complaint handling, investigation, laboratory workflows, and recall coordination, with hands on group simulations that led participants through the full incident cycle from risk scoring and sampling to recall decision making and communication.

Serving as the WHO consultant, Ms. Pantelia Gkoura, former Head of the Production & Distribution Control Division, Organization for Medicines, Greece conducted an in country mission that included consultations with DRAP and provincial officers, and produced a set of key recommendations and a six-month accelerated implementation roadmap to fast-track reforms in market control and surveillance in Pakistan in line with the WHO recommendations. This roadmap is focused on strengthening collaboration between federal and provincial authorities to enhance harmonized implementation, adopting WHO terminology for substandard and falsified medical products, introducing risk based post marketing surveillance, improving laboratory capacity and accreditation, integrating data systems for real time information sharing, and adopting SMART performance indicators to monitor progress.

Speaking at the workshop, CEO DRAP Dr. Obaidullah said: "it is a national commitment to protect public health. This requires a coordinated approach between DRAP and all provincial drug control authorities to ensure that every medicine reaching patients is safe, effective, and of assured quality." Ms Ellen Mpangananji Thom, Deputy WR, also reaffirmed ongoing technical assistance, global linkages and continuous collaboration. Mr. Rutendo Kawana, Team Lead, Market Surveillance and Control Team, Prequalification and Regulation Department (RPQ), WHO Geneva, presented his insights regarding the National Action Plan against Substandard and Falsified Medical Products. He emphasized the lessons that can be drawn from the successful experiences of South Africa. The workshop closed with a shared commitment to sustained, routine implementation—linking federal and provincial actions to quality, safety, and efficacy across the supply chain, and building the sharepoint for the online system required to deliver measurable progress toward ML3.


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Pakistan
Capacity Building Workshop
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Capacity Building Worksh

NATIONAL CONSULTATIVE WORKSHOP ON STRENGTHENING QUALITY MANAGEMENT SYSTEM AND REGULATORY STRATEGIC PLANNING 2026-30

The Drug Regulatory Authority of Pakistan (DRAP), in partnership with the World Health Organization (WHO), hosted a landmark two-day consultative workshop on 25–26 November 2025 in Islamabad to shape the future of Pakistan's regulatory system for medicines and health products. This high-level event brought together federal and provincial regulators, public health programs, industry leaders, and international partners to design a forward-looking Regulatory Strategic Plan for 2026–2030.

Opening the workshop, the Mr Hamed Yaqoob Sheikh Federal Secretary for Health / Chairman Policy Board declared, "Strategic planning is a public health imperative. The choices we make today will define Pakistan's regulatory resilience for decades to come." DRAP's Chief Executive Officer echoed this vision, stating, "Our mission is clear: Trusted Regulation, Safer Medicines, Stronger Pakistan. We are committed to building a science-based, digitally empowered regulatory system that inspires confidence at home and abroad."

Industry representatives from PPMA, Pharma Bureau, HDAP, Homeopathic Pharmaceutical and Chemist Association, Pakistan Alternative Medicine Manufacturers Association welcomed the initiative, emphasizing the need for a predictable and transparent regulatory environment to foster innovation and local manufacturing.

The workshop featured dynamic group exercises and interactive sessions where participants outlined the mission, vision, strategic objectives, key goals and SMART targets for the next five years. Discussions spanned governance, regulatory services, optimization of public-private partnerships, and strengthening research and advocacy. A major focus was on institutionalizing Quality Management Systems across DRAP and provincial authorities, aligned with ISO 9001:2015 and WHO TRS 1025 Annex 13, to meet WHO Global Benchmarking Tool Maturity Level 3.

Participants also developed an implementation roadmap, including milestones, resource needs, risk analysis, and performance indicators. The introduction of a structured regulatory communication framework promises real-time information exchange and harmonized application of guidelines across all levels.

This consultative process marks a turning point for Pakistan's health regulatory ecosystem. By uniting vision with action, DRAP and its partners have set the stage for a resilient, transparent, and globally trusted regulatory system—one that guarantees the quality, safety, and efficacy of medicines and health


World Health Organization
Pakistan
National Consultative Workshop
on
Strengthening Quality Management Sy
and Regulatory Strategic
Planning 2026-30 Islamabad | Pakistan
25 - 26 November 2025
Margalla Hotel, Islamabad
THE MARGALLA

STRENGTHENING REGISTRATION AND MA FUNCTION: DR. EDWIN NKANSAH, WHO CONSULTANT, VISITS DRAP

Dr. Obaidulalh, CEO DRAP welcomed Dr. Edwin Nkansah, Consultant with the World Health Organization who visited during 15-17 December 2025, the Drug Regulatory Authority of Pakistan (DRAP) to enhance registration and marketing authorization capabilities. WHO representative and Head of Mission Pakistan Dr. Dapeng Luo also graced the occasion.

Dr. Edwin also shared his expertise in regulation of vaccines and biotherapeutics.

During his three day engagement Dr. Nkansah, alongside Dr. Eric Osuwu, delivered an intensive training of DRAP officers/evaluators on the assessment of bioequivalence reports.

Key highlights of the visit include:

- Review of WHO Global Benchmarking Tool (GBT) for Marketing Authorization with DRAP's technical team.
- Virtual interaction with over 38 participants from the Pakistan Pharmaceutical Manufacturers Association and Pharma Bureau, focusing on the implementation of bioequivalence studies, Summary of Product Characteristics (SmPC), and Patient Information Leaflets (PIL).
- Discussions on best practices to streamline the Pharmaceutical and vaccine registration processes.

DRAP thank Dr. Nkanash and Dr. Osuwu for their valuable expertise and look forward to continued collaboration toward safer and more effective medicines for all.

Picture **Gallary**

Syed Mustafa Kamal addressed at the
Health Asia International Exhibition & Conference 2025.

Dr Obaidullah delivered a presentation at the
Health Asia International Exhibition & Conference 2025.

The Drug Regulatory Authority of Pakistan (DRAP) successfully conducted a Seminar on the Implementation of International Quality Standards in the Assessment of Pharmaceutical Products on 22nd September 2025.

H.E. Faisal Niaz Tirmizi, Pakistan's Ambassador to the Russian Federation, visited the Drug Regulatory Authority of Pakistan (DRAP) to formalize a strategic roadmap for bilateral healthcare cooperation.

The Drug Regulatory Authority of Pakistan (DRAP) and the Competition Commission of Pakistan (CCP) have entered into a Memorandum of Understanding (MoU) to strengthen institutional cooperation. The MoU was signed by Dr Obaidullah, Chief Executive Officer, DRAP, and Mr. Salman Amin, Member of CCP, representing their respective organizations.

PROFESSOR DR. SALEH ABDULLAH BAWAZIR, FORMER VICE PRESIDENT OF THE SAUDI FOOD AND DRUG AUTHORITY (SFDA) VISITED DRAP

DRAP had the privilege of welcoming Professor Dr. Saleh Abdullah Bawazir, former Vice President of the Saudi Food and Drug Authority (SFDA), on 21 Nov 2025. During his visit, Prof. Bawazir held productive discussions with Federal Minister for NHSR&C, Syed Mustafa Kamal, Dr Obaidullah, CEO DRAP, and senior officers of DRAP

The meeting was also attended by Syed Anees Ahmad, Managing Director of Abbott Laboratories, Executive Director Pharma Bureau, along with other industry representatives.

Prof. Bawazir generously shared his valuable experiences and reaffirmed his willingness to support DRAP in its journey toward achieving WHO Maturity Level 3.

Dr. Obaidullah, CEO DRAP, highlighted that the Authority has already adopted the reliance mechanism and is making its best efforts to complete all Institutional Development Plans (IDPs) ahead of the upcoming WHO audit.

The Federal Minister emphasized the critical need to harmonize Pakistan's pharmaceutical quality standards with international benchmarks, enabling the local industry to strengthen its position in the global market.

Representatives of the Pharma Bureau presented key challenges and recommendations related to meeting WHO standards. The Minister assured the stakeholders that the Ministry remains committed to providing all possible support to accelerate Pakistan's progress toward achieving WHO Maturity Level 3.

ڈرگ ریگولیٹری اتھارٹی آف پاکستان
منسٹری آف نیشنل ہیلتھ سروسز ریگولیشنز اینڈ کوآرڈینیشن

ڈریپ نیوز لیٹر

فروری: ۲۰۲۶
والیم: ۵
شمارہ: ۱

"ڈریگ سے ڈریپ اور ریفارم چیمپین تک"

گزشتہ برس اگست میں ڈریپ کے میڈیکل ڈیوائسز ڈیجیٹل لائسنسنگ اور رجسٹریشن سسٹم کی افتتاحی تقریب کے موقع پر وزیرِ اعظم پاکستان نے اسلام آباد میں خطاب کرتے ہوئے ڈریپ کے ماضی کا ایک دلچسپ مگر تلخ پہلو بیان کیا۔ انہوں نے کہا کہ بطور وزیرِ اعلیٰ پنجاب ان کے لیے یہ ادارہ "ڈریگ" تھا، جہاں ہر معاملہ تاخیر اور الجھن کا شکار رہتا تھا، مسائل کا حل نہیں نکلتا تھا۔

وزیرِ اعظم نے اس بات پر اطمینان کا اظہار کیا کہ آج ڈریپ میں ایک قابل قیادت موجود ہے اور وفاقی وزیرِ صحت سید مصطفیٰ کمال کی کارکردگی دنیا کے سامنے ہے۔ سی ای او ڈریپ نے اپنے انتخاب کو اپنی کارکردگی سے درست ثابت کیا۔ یہی وہ پس منظر تھا جس کے چند ہی ماہ بعد، 9 دسمبر 2025 کو وزیرِ اعظم پاکستان نے ڈرگ ریگولیٹری اتھارٹی آف پاکستان (DRAP) کو نمایاں اصلاحات کے اعتراف میں "ریفارم چیمپئن" ایوارڈ سے نوازا۔

حکومتِ پاکستان کے سرکاری جائزہ پلیٹ فارم business.gov.pk کے مطابق ڈریپ ان اداروں میں شامل ہے جنہوں نے سرکاری شعبے میں سب سے زیادہ اصلاحات مکمل کیں۔ مؤثر نظام کے ذریعے اربوں روپے کی بچت ممکن بنائی اور ادویات اور صحت کے شعبے میں ایسی اصلاحات متعارف کرائیں جن کا براہِ راست فائدہ عوام کو پہنچا۔ یہ اعزاز دراصل اس امر کا اعتراف ہے کہ ڈریپ اب ایک جدید، شفاف اور ڈیجیٹل ریگولیٹری ادارے کے طور پر ابھر رہا ہے۔

ڈریپ اپنے ریگولیٹری امور کا تقریباً 70 فیصد ڈیجیٹل کر چکا ہے، جبکہ جون 2026 تک سو فیصد ڈیجیٹلائزیشن کا ہدف مقرر ہے۔ آن لائن میڈیکل ڈیوائسز رجسٹریشن سسٹم اور ای۔ آفس جیسے اقدامات نے نہ صرف انسانی غلطیوں اور کاغذی تاخیر کو کم کیا بلکہ درخواست گزاروں کے لیے شفاف اور تیز تر نظام فراہم کیا۔

برآمدات کے فروغ کے لیے سرٹیفکیشن کے اوقات میں نمایاں کمی کی گئی۔ ادویات کی برآمدی رجسٹریشن 60 دن سے کم ہو کر 10 دن رہ گئی، جبکہ FSC اور CoPP جیسے سرٹیفکیٹس 30 دن کے بجائے 5 دن میں جاری ہونے لگے۔ ان اصلاحات کے نتیجے میں دواسازی کی برآمدات میں 34 فیصد اضافہ ریکارڈ کیا گیا، جو ملکی معیشت کے لیے خوش آئند ہے۔

میڈیکل ڈیوائسز کی رجسٹریشن کا دورانیہ کم ہو کر تقریباً 20 دن رہ گیا ہے، جبکہ نئی تھراپیز اور کینسر کے علاج کے لیے تیز رفتار منظوری کا نظام متعارف کرایا گیا ہے، جس سے منظوری کا وقت تقریباً تین ماہ رہ گیا۔ اس کا سب سے بڑا فائدہ یہ ہے کہ جدید اور جان بچانے والی ٹیکنالوجیز مریضوں تک بروقت پہنچ رہی ہیں۔

ڈریپ نے قومی سطح پر کوالٹی کنٹرول لیبارٹری نیٹ ورک قائم کیا ہے اور صوبائی ڈرگ ٹیسٹنگ لیبارٹریز کو ISO 17025 اور WHO معیار کے مطابق لانے کے لیے اقدامات شروع کیے ہیں، تاکہ ملک بھر میں ادویات کا معیار یکساں اور محفوظ ہو۔

قومی ویکسین پالیسی کا مسودہ تیار ہو چکا ہے اور مقامی سطح پر API کی تیاری کے لیے روڈمیپ بنایا جا رہا ہے۔ ون ونڈو سہولت اور سرمایہ کاری کی حوصلہ افزائی کے ذریعے پاکستان کو دواسازی میں خود کفالت کی طرف لے جانے کی کوششیں جاری ہیں۔

مختصراً، جو ادارہ کبھی "ڈریگ" سمجھا جاتا تھا، آج وہ اصلاحات، شفافیت اور عوامی خدمت کی ایک مثال بنتا جا رہا ہے۔ یہی سفر ہے، ڈریگ سے ڈریپ اور ریفارم چیمپین تک کا۔

مدیر اعلیٰ: ڈاکٹر عبیداللہ
چیف ایگزیکٹو آفیسر ڈریپ

مدیر: ڈاکٹر اختر عباس خاں
ڈائریکٹر فارمیسی سروسز

کسی بھی سوال، تبصرے یا اپنی قیمتی رائے سے نوازنے کے لیے رابطہ کریں۔
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