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APAC Voice

Advancing together: USP's 2025-2030 vision for APAC

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It is an honor to address you as we embark on our shared journey forward. As a non-profit, independent organization focused on standard-setting and improving global access to quality medicines, USP's priority is ensuring we act inclusively to align with stakeholders worldwide and plan meaningful work together.

These core principles have guided our collaboration with Asia Pacific (APAC) regional stakeholders through our Regional Chapter and other workshops/conferences, gathering needs and priorities across this vital region. I extend my sincere gratitude to all who have contributed to this effort. APAC's remarkable diversity—cultural, economic, social, and pharmaceutical—requires varied strategies to meet different stakeholder needs across markets. By working together and acknowledging this diversity, we can leverage lessons learned and embrace new opportunities that emerging markets offer.

Based on inputs from our APAC Regional Chapter and other Regional Chapters worldwide, along with our functional scientific chapters covering biologics and small molecules, we developed our strategy and resolutions for the 2025-2030 cycle. These were recently approved by our convention members, including many of you, at our May meeting in Rockville, Maryland. This collaborative foundation gives me confidence that you will continue to find USP offerings relevant to your local needs.

The importance of regulatory reliance in the APAC region cannot be overstated. Through harmonized standards and collaborative approaches, we can help accelerate access to quality medicines while maintaining rigorous safety requirements. With USP, you can always count on our local and regional presence—our regional headquarters in Singapore ensures we remain ready to listen to your valuable input and feedback. We are committed to adapting USP products and services to meet your local needs and address any questions about USP implementation.

Thank you for your continued collaboration as we advance this essential mission together.

The Latest

USP Convention Meeting 2025: Launching a new era of global medicine quality standards

5th – 8th May, 2025

The 2025 USP Convention meeting in Rockville, Maryland, marked a historic milestone as over 400 in-person participants from 42 countries gathered to launch the next five-year strategic cycle. Building on more than 200 years of commitment to medicine quality, this gathering of health and science leaders reaffirmed USP's mission to protect patient safety and strengthen the global supply of quality medicines.

See USP's forward looking strategic priorities illustrated above.

Convention Members played a pivotal role in shaping USP's future direction, electing a new Board of Trustees and adopting resolutions that will guide the organization's 2025-2030 strategic priorities. These resolutions embody USP's commitment to building trust in medicines, dietary supplements, and food ingredients worldwide, while championing supply chain resilience in an increasingly complex global environment.

Click here for a summary of the May Convention meeting.
Click here to read USP's Resolutions report

APAC Region Achievements:
The Asia-Pacific region demonstrated exceptional engagement, with 15 Convention member organizations from 10 countries participating. A landmark moment was the signing of a memorandum of understanding (MOU) between USP CEO Ronald Piervincenzi and Taruna Ikrar, Chairperson of Indonesia's National Agency of Drug and Food Control. This five-year collaboration agreement will advance medicine quality for Indonesia's 300 million citizens through enhanced regulatory capabilities and improved market surveillance systems.

On the same week, we held the fifth APAC Regional Convention meeting. Holding this chapter meeting in Rockville provided partners from the region with valuable experience of USP's headquarters and full convention activities. Professor John Lim, Chair of the APAC Regional Chapter and Executive Director of Duke-NUS Centre of Regulatory Excellence (CoRE), received dual honours: election to the USP Board of Trustees for 2025-2030 and the prestigious USP President's Award, recognizing his exceptional leadership in advancing global regulatory science. During the Convention meeting, USP APAC team also had the opportunity to hold a bilateral meeting with the Japanese Pharmaceuticals and Medical Devices Agency (PMDA), furthering the discussion on harmonization and collaboration.

As USP embarks on this new strategic cycle, the organization is positioned to drive meaningful change in global medicine quality standards. The diverse expertise and collaborative spirit demonstrated at the 2025 Convention Meeting provided a strong foundation for addressing emerging challenges and opportunities in advancing pharmaceutical quality assurance worldwide.

USP-NIFDS collaboration achieves major milestone with Korean herbal medicine monographs

USP has reached a significant milestone in its collaboration with Korea's National Institute of Food and Drug Safety (NIFDS), publishing the first new Herbal Medicines Compendium (HMC) monographs since their MOU began in 2012. The newly published monographs feature two Korean traditional medicinal plants: *Angelica gigas Root* and *Forsythia suspensa Fruit.*

These comprehensive standards represent years of collaborative scientific work between USP and NIFDS experts. The associated reference standards are now available on the USP store, including *Angelica gigas Root Powder*, *Decursin*, and *Forsythia suspensa Fruit Powder*.

This achievement marks a pivotal moment for both organizations in fulfilling their joint work plan objectives. The collaboration has recently expanded beyond herbal medicines into the dietary supplements sector, positioning this milestone as a catalyst for deeper collaborative efforts with Korean regulatory authorities and industry stakeholders. The successful publication demonstrates the value of international scientific cooperation in advancing global medicine quality standards.

USP participates in the International Society for Pharmaceutical Engineering Conference & Exhibition in Jakarta, Indonesia

21st - 22nd May, 2025

USP strengthened its presence in Southeast Asia at the ISPE Indonesia Conference & Exhibition 2025, held May 21-22 in Jakarta. Naiffer Romero, MSc, MPH, Principal Scientist, represented USP with a pre-recorded session titled "Nitrosamines Impurities: Past, Present and Future." Naiffer's presentation traced the nitrosamine impurities crisis from its 2018 origins with N-Nitrosodimethylamine (NDMA) detection in valsartan APIs through current regulatory developments. He explored the chemistry of nitrosamines as probable human carcinogens and examined case studies involving sartans, ranitidine, metformin, and pioglitazone.

The session highlighted critical formation factors, including solvent degradation, contaminated excipients like Polyvinylpyrrolidone (PVP) and Hydroxypropyl methylcellulose (HPMC), and packaging materials containing nitrocellulose. USP emphasized the importance of comprehensive risk assessments, supplier qualification, and robust analytical testing throughout manufacturing processes. USP's leadership in addressing nitrosamine challenges was showcased through key contributions, including the development of General Chapter on Nitrosamine Impurities <1469>, eight reference standards, the Nitrosamines Analytical Hub and Exchange Community, and ongoing educational initiatives.

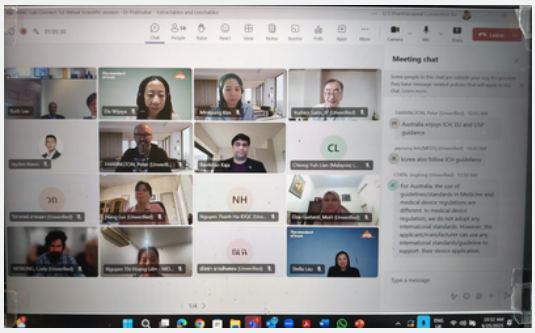
The presentation reinforced USP APAC's commitment to pharmaceutical quality and safety while positioning USP as a trusted partner for industry and regulators navigating evolving nitrosamine challenges.

USP launches APAC Lab Connect for regional technical exchange

25th June, 2025

Following the successful APAC Regional Chapter meeting in May, USP has launched APAC Lab Connect, a new platform for technical information exchange and dialogue among regional stakeholders. Designed primarily for National Regulatory Authorities (NRAs) across APAC, Lab Connect aims to foster active technical discussions while providing capability-building opportunities for regulatory professionals.

The virtual platform will host regular one-hour sessions focusing on specific topics of regional interest. Convention Members can extend invitations to colleagues within their organizations, promoting broader knowledge sharing across the APAC pharmaceutical regulatory community. Sessions will initially occur every two months, with potential monthly frequency based on member engagement. APAC Lab Connect represents USP's commitment to maintaining continuous dialogue between annual chapter meetings, strengthening regional collaboration in pharmaceutical standards and regulatory practices.



Dr Gruddanti brings extractables and leachables expertise to Singapore

25th - 27th June, 2025

Dr Gruddanti Prabhakar Reddy, Director of Pharmaceutical Sciences, General Chapters General Chapters & Complex Generics, at USP, visited Singapore this June. Dr Gruddanti brings over 30 years of pharmaceutical industry and academic research experience, with specialized expertise in analytical method development, regulatory documentation, and complex generics development. His visit was an opportunity for him to lead an in-person roundtable session on extractables and leachables (E&L), organized by USP. The roundtable brought together 30 participant from industry to discuss current best practices and regulatory standards. The session provided comprehensive updates on E&L.

The interactive format encouraged dialogue on industry challenges and regulatory requirements specific to the Singapore market. Participants engaged in Q&A sessions and shared insights on current E&L practices, fostering valuable networking opportunities among pharmaceutical professionals in the region. The roundtable, held at the Devan Nair Institute, exemplifies USP's commitment to supporting local pharmaceutical communities through knowledge sharing and collaborative discussions on critical quality standards.

For more information on E&L, see our USP E&L System Suitability Application Note here.

During his visit, Dr Gruddanti also maximized engagement with the regional pharmaceutical community through multiple USP initiatives. On the morning of June 25th morning, he presented on extractables and leachables via the first session of the APAC Lab Connect platform, facilitating a virtual technical exchange with 62 Regional Chapter convention members. Dr Gruddanti's visit exemplifies USP's commitment to bringing global expertise directly to regional stakeholders.

First external method donation marks milestone for nitrosamines exchange analytical hub

USP's Nitrosamines Exchange Analytical Hub, a central resource designed to unify our collective knowledge and expertise on nitrosamines testing methods, has achieved a significant milestone with its first external analytical method donation, marking one small step for the Hub, but one giant leap for scientific collaboration. This first donation sets an exemplary standard on how a shared information reduces redundant effort, sharpens regulatory readiness, and accelerates safer medicines worldwide.

This milestone demonstrates the Hub's community-curated model for knowledge exchange, with external laboratories willingly sharing expertise for collective benefit. The submission from APAC underscores the Hub's global reach and accessibility, exemplifying USP's commitment to customer-centric solutions that advance pharmaceutical quality worldwide.

USP expands peptide quality arsenal with 22 new analytical reference materials

USP has significantly strengthened its peptide impurity control capabilities by releasing 22 new Analytical Reference Materials (ARMs) for peptide therapeutics, addressing critical quality challenges in this rapidly growing therapeutic class. The new ARMs span multiple established peptide drugs including bivalirudin, calcitonin salmon, cosyntropin, desmopressin, exenatide, glucagon, and vasopressin. These reference materials target specific impurity types that commonly arise during peptide synthesis, including deamidation products, oxidation variants, truncated sequences, and dimer formations.

Why this matters: Peptide impurities pose significant regulatory and safety challenges due to their potential immunogenicity risks and complex analytical detection requirements. Many peptide impurities share similar physicochemical properties with their parent compounds, making separation and quantification extremely difficult without proper reference standards. The new ARMs enable manufacturers to accurately identify and quantify these challenging impurities, supporting robust analytical method development and regulatory compliance. Each ARM is thoroughly characterized using orthogonal techniques including LC-MS, NMR, and HPLC, providing the analytical confidence needed for reliable impurity profiling in peptide drug development and manufacturing.

For more information on USP Peptide Standards and Material, click here.

Coming Soon

Quality Hour

23rd July 2025 (tbc)

Global Bio Conference

3rd – 5th September, Seoul, South Korea

Value of Pharmacopeial Standards workshop series across APAC

8th – 19th September, 2025 in Southeast Asia
28th October, 2025 in Korea

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use guidelines training

23rd - 24th September, Seoul, South Korea

APEC Centre of Excellence Advanced therapy

29th - 30th September, Seoul, South Korea

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