



APAC Voice

Associate Professor Son Doan Cao, PhD.
Director of the National Institute of Drug
Quality Control and Chairman of the
Vietnam Pharmacopoeia Council

For our second APAC Voice feature, USP invites Professor Son Doan Cao to share his views on the collaboration between the National Institute of Drug Quality Control (NIDQC) and USP APAC.

"The National Institute of Drug Quality Control (NIDQC) is a service unit established in 1957 under the direct supervision of the Ministry of Health Vietnam; being the highest drug quality control unit at the central level in Vietnam. NIDQC's collaboration with USP started in 2009 through training on quality control methods, analytical development, and establishing reference standards. Since then our collaboration has expanded through several initiatives as illustrated below.

Establishing, maintaining and expanding NIDQC's cooperation in scientific research with international organizations, in compliance with the Vietnam laws, has always been one of our highest priorities. We are honoured to have been a reliable partner of USP for many years. NIDQC strongly believes in a successful and ongoing collaboration with USP."



The Latest

Philippines Food & Drug Administration (PFDA) Conference

5-7 Dec 2022

USP's Ruth Lee presented at a conference held in Baguio City, from 5-7th Dec 2022, on the theme of "Empowered Regulators Gearing Up for Global Recognition". Close to 500 inspectorate staff of the PFDA participated, including the Director-General of PFDA, Dr Samuel Zacate.





The conference focused on compliance and international commitments including the Global Benchmarking tool, the Pharmaceutical Inspection Co-Operation Scheme (PIC/S), the ISO/IEC 17020:2012 Inspection Body Accreditation as well as the ASEAN Mutual Recognition Arrangements. The purpose was to raise awareness of international regulatory commitments among the PFDA inspectorate staff and to identify where inspection skills needed improvement to meet globally-recognized standards. USP shared knowledge and insights on preparing for global recognition with PFDA inspectors.

USP participates in the Regulatory Strengthening Program (RSP) workshop at the Therapeutics Goods of Australia (TGA)

20-23 Feb 2023

USP has been a partner of the RSP program since its inception in 2018. During the workshop, Gary Dahl from USP Global Health Programs, presented our laboratory-strengthening initiatives in Cambodia and Lao PDR under the RSP. USP has been supporting the national labs in Cambodia and Lao PDR work towards international accreditation (ISO or WHO). The workshop was a welcome opportunity for USP to connect with APAC stakeholders and to better understand new developments in respective National Regulatory Authorities (NRAs). During the workshop, the 60 attending participants from across eight different drug regulatory agencies in Asia Pacific openly shared their challenges in terms of strengthening regulatory frameworks. USP is pleased to be a RSP partner, an important platform for improved collaboration between NRAs in the region.



Quality Hour on Dissolution Performance Verification Standard

7 Feb 2023

Agenda

- › Performance Verification Testing
- › USP DPVS – Prednisone
- › Benefits of USP DPVS – Prednisone
- › Notice of Intent to Revise (NITR) GC <711> Dissolution
- › Features and Benefits of DPVS - Prednisone (Product #1222818)
- › Transition Plan
- › Resources

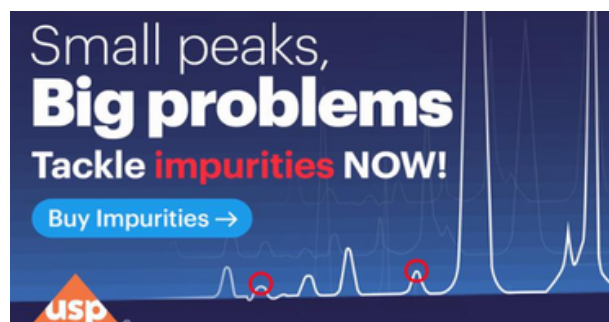
More than 250 participants virtually attended our 22nd edition of Quality Hour. Our USP-certified instructor, Mr Joe Eaton presented on the USP Dissolution Performance Verification Standards and the advantages of using them in the quality assurance of medical products. Participants were actively engaged with up to 30 questions raised during the session. In response to the overwhelming interest in this topic, USP APAC will be organising an on-site course titled: Fundamentals of Dissolution - See more on p 5.



New listing of Pharmaceutical Analytical Impurities

Pharmaceutical Analytical Impurities (PAI) help companies understand their Active Pharmaceutical Ingredient (API) and product impurity profiles, identifying and correcting issues before they become bigger problems and accelerating getting products to market. USP is now offering a PAI product line, with more than 200 impurities in our growing portfolio. Using PAIs, together with official USP Pharmacopeial Reference Standards, can help manufacturers build confidence in analytical methods for Research & Development, process development and for quality control.

Learn more [here](#)



USP APAC mAbs Workshop in Korea, Japan and Thailand

27 Mar - 3 Apr 2023

Interactive mAbs guide available [here](#):



The workshop on monoclonal antibodies (mAbs) held between 27th of March and 3rd of April, catered to regulators and contract development and manufacturing organizations (CDMO) including academia. The workshop covered the characterization of mAbs including a live demonstration of the USP interactive mAbs Analytical Guide.

Tech Talk

DEG Toolkit

Recent deaths of children around the world are suspected to have been the result of substandard ingredients after laboratory analysis found that samples of these products contain unacceptable amounts of diethylene glycol (DEG) and other contaminants (see [here](#) and [here](#)). DEG can find its way into the supply chain in several ways, through mislabeled products, human error, or through intentional adulteration by manufacturers or suppliers to achieve higher profits. Testing of the ingredients by manufacturers can be used to successfully detect the presence of DEG and other poisons along the supply chain.

To prevent deaths due to DEG contamination, USP has made available a free [virtual toolkit](#) for measuring and controlling levels of DEG. The toolkit includes relevant General Chapters, monographs, and other resources that can help ensure the quality and safety of excipients, identify and mitigate risks associated with DEG and other contaminants, and develop best practices for drug manufacturing.



USP resources can help **identify diethylene glycol in cough syrup**

Learn more →



US Pharmacopeia on LinkedIn: #pharmaceuticals

Substandard cough medicine has been linked to the death of children in at least two countries in recent months. Check the complete pharmaceutical...

USP's Director for International Government and Regulatory Engagement, Dr Chaitanya Koduri, is featured in a Reuters [article](#) which reinforces the importance of global guidelines for quality control.

Closing quality gaps for pharmaceutical ingredients will help protect patients and prevent tragedies like childhood deaths. We invite you to join us in our global efforts to advocate for quality throughout the medicines supply chain. Read more about our [USP Regional Chapters](#).

April

Coming Soon

APEC Medical Product Supply Chain Dialogue

Date: 25-26 April 2023

As part of the APEC USA 2023 Host Year, and in support of the Regulatory Harmonization Steering Committee (RHSC) Global Supply Chain Integrity Priority Work Area, USP and co-sponsors are delighted to announce the APEC Medical Product Supply Chain Dialogue which will be held on 25-26 April 2023 in-person at USP's Headquarters in Rockville, Maryland (USA) and virtually. This program will convene APEC regulators, academia, and industry partners with the aim of accelerating domestic and regional efforts to strengthen the resilience of the medical product supply chains in Asia Pacific and beyond.

Agenda and registration available [here](#).

USP Asia Pacific Regional Chapter Meeting

Date: 27 April 2023

This year's USP Asia Pacific (APAC) Regional Chapter Meeting will take place in conjunction with the APEC Meeting, in Maryland and virtually, on Thursday, 27 April 2023.

Register [here](#).

APEC Center of Excellence Advanced Therapy virtual workshop

Date: 9th and 11th May 2023 (8am-11am SGT)

The workshop will offer training on cell and gene therapy (CGT) products, selecting and building tests to ensure quality. The workshop will share Chemistry Manufacturing and Controls (CMC) and CGT best practices, an overview of best practices by CGT experts, and insights from CGT experts on CART-T products.

May

June

Course on Fundamentals of Dissolution

Date: 5th-23rd June 2023

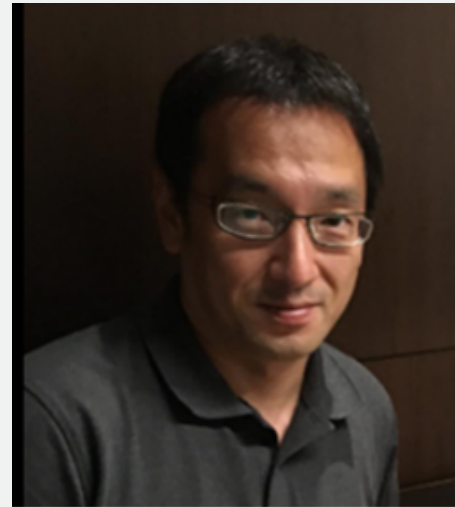
Guidance for Verification and Qualification of a Dissolution Apparatus (CM-711-08).

The course will be led by USP Certified Instructor, Mr Joe Eaton, Director, Global Standards Distribution. This 1-day course will emphasize the fundamentals of dissolution testing of solid oral dosage forms and address specifics related to the qualification of USP dissolution apparatus 1 and 2. Specifically, this course is dedicated to dissolution theory and the guidance presented in USP-NF General Chapter <711>, the handling of dissolution data and the qualification of an apparatus to prove its suitability for use. The course is open to dissolution and analytical chemists, regulatory professionals, laboratory technicians and others interested in a refresher.

Introducing

New Team Member

We are pleased to welcome Mr Masahide Tamura san (Masa) to our team as Strategic Customer Development Manager for Japan. Masa will lead all customer engagement activities in Japan, and work closely with USP distributors in Japan. Masa has 27 years of experience working and servicing the pharmaceutical and biopharmaceutical market in Japan. His experience includes sales and business development of analytical and precision equipment in the laboratory divisions for the pharmaceutical and life sciences industry in Hamilton, Spectris KK and Mettler Toledo KK. He specializes in professional business development, including new projects, regulations, and educational training. Prior to joining USP, Masa worked in Business Development in the Pharma and Biotechnology industry with Kerry Group. Masa received his BSC in Biotechnology from Kanagawa Institute of Technology.



Contact Us

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