Beyond Compliance

2018 Annual Conference

Protecting Patients – Support Innovation

May 8th - 9th, 2018

Holiday Inn Hotel, Kemayoran, Jakarta

ISPE Indonesia Affiliate

Conference Highlight

The main responsibility of pharmaceutical industry, including all professionals involved, is to develop and produce safe and effective medicines to fulfill patients' needs in all health matters, from saving life, curing, enhancing quality of life and maintaining health throughout their life span.

All operations must strive for obtaining sustainable production of the highest possible quality. To achieve this, a policy must be in place to continually improve the system, processes, and skills needed. The goal is to enhance the stability and predictability of operations and to ensure product quality, safety and efficacy at all stages at a competitive cost. Compliance to all regulations when manufacture medicines is no longer the question of today nor future, industry should address to a "Beyond Compliance" level to stay competitive in the wave of never ending progress of knowledge, science and technology.

This 2-days conference will highlight aspects which are already embarked and/or approaching the pharmaceutical development (QbD), manufacturing (processes, control, resources) , supply chain and patients protection from illegal and counterfeit medicines through serialization initiatives. Innovation in all aspects to ensure patient safety and protection should be the policy for the pharmaceutical industry alongside with building a culture of Quality Beyond Compliance to all personnel involved.

Meet world class speakers to understand the future of medicines.

Presenting International Speaker such as:



Norikazu Eiki
In 1979 he joined to Ciba-Geigy Japan Co., Ltd. Since joining Bayer Japan in 1994, he took over as Bayer Pharmaceutical Director and Shiga Plant Manager since 1997. From 2002 to 2006, he was the President and Representative Director of the company, from 2007 until 2014 Representative Director and Chairman of the company. Meanwhile, he served as a member of the Japan Pharmaceutical Manufacturers Association Association, the Japan Heart Foundation Board Member, the Osaka Pharmaceutical Association Board Member, the Japan PDA Board Member, and the ISPE International Member. After retiring from Bayer in 2014, he moved to NJ USA and belongs to the New York Consulting ABPS Group.



Vee (Vasiliki) REVITHI studied Chemistry and holds a PhD in Biochemistry (with distinction). She has worked for 36 years in EOF (1976 to 2012), the Medicines Authority of Greece, in various positions (laboratories, regulatory departments and mainly GMP & GDP inspections). She has been Head of Division for more than 14 years of her career, 10 of them as Head of the GMDP Inspectorate of the Agency. She joined Roche in Basel, Switzerland in June 2013 in the unit of External Relations Europe in PTQG.

She has led the implementation of a Quality System according to EU, Pharmaceutical Inspectorates Cooperation Scheme (PIC/S) and ISO 17020 requirements in the Greek GMDP Inspectorate, the implementation of EU and PIC/S Inspections methodology and the accession of EOF/Greece to PIC/S in 2002.



Mr Vimal Sachdeva had been working as an inspector with the WHO PQT (for medicines, vaccines, IVDs and diagnostics) since year 2010, based in Geneva, Switzerland.

Mr Sachdeva has had more than 26 years of pharmaceutical industry experience including 15 years as a regulator. Before joining WHO, Mr Sachdeva worked with the Singapore Health Sciences Authority a Senior GMP Auditor and Senior Regulatory Specialist.

Since he joined WHO PQT, Mr Sachdeva has led inspections of facilities manufacturing Active Pharmaceutical Ingredients (APIs) and Finished Pharmaceutical Products (FPPs), Contract Research Organizations (CROs) and National Pharmaceutical Quality Control Laboratories. To-date, he has performed more than 200 inspections in Asia, Africa, Latin America and North America.

- **Who Should Attend**
  Decision makers at top and middle management levels, technical leaders and professionals responsible for drugs development in R&D, Regulatory Affairs, Process Development, Production, QA&QC, Engineering and Human Resource Development from manufacturers and distributors, Consultants, Regulators and Academia.

- **Sponsor/ Exhibitors**
  - Brand your company to industry decision makers through table-top and booth exhibition
  - Share knowledge to participants from various industry decision makers, regulators and academia through presentation opportunity
  - Business opportunity by direct interact with client.

TENTATIVE SCHEDULE

The schedule & topic can be changed whitout notice

Day 1 - Tuesday, May 8, 2018

Plenary

- Future Policy of Indonesian NADFC
- Future Milestone of PIC/S
- Sustainability of Pharmaceutical Industry in Indonesia
- Disruptive Innovative in Pharma Industry - Beyond Medicine

Track 1
CULTURE AND BEHAVIOUR

- Redefining the "C" in CGMP - Creating, Implementing and Sustaining Culture of Compliance
- How to build and Foster a Quality Culture
- Working as A Team

Track 2
SUPPLY CHAIN

- Enterprise to Line: IT Solutions for Serialization
- Third Party Logistic and Transport
- Transportation Verificatin

Day 2- Wednesday, May 9 ,2018

Track 3
REGULATORY

- Harmonization
- Industry Maturity
- Life After PIC'S Membership: Challenges for Authority and Industry
- Important Consideration to WHO PQ; Critical and Major Observation during PQ Audits
- Panel Discussion

Track 4
MANUFACTURING

- Factory of The Future
- Building Management System and Environmental Monitoring Systems in Regulated Environment
- Risk based Qualification
- The Biosimilar Journey
- Automation in Packaging System to Support Serialization

Track 5
QUALITY BEYOND COMPLIANCE

- EDQM Certificate of Suitability
- New Standards Define Single-Use Materials Qualification
- Process Analytical Technology
- Lean Laboratory

Track 6
PRODUCT AND PROCESS DEVELOPMENT

- The importance of QbD in designing Process Performance Monitoring System during Comercial Manufacturing
- Bioassay Design, Development and Validation
- Exipient-Evolutions of Exipients GMP and Vendor's Audit
- Packaging - Extractable and leachable

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Registration Form

Seminar Fee

- ☐ ISPE Member* : **USD 250**
- ☐ Non Member : **USD 350**
- ☐ Regulator : **USD 150**
- ☐ Academia : **USD 150**

Cancelation after April 15th, 2018, 50% refundable
Cancelation after May 2nd, 2018, not refundable

Day 1 : Please choice ☐ Track 1 or ☐ Track 2
Day 2 : Please choice ☐ Track 3 or ☐ Track 4 and ☐ Track 5 or ☐ Track 6

Please fill in with capital letters:

Complete Name: .....

- ☐ ISPE member, No. .....
- ☐ Non Member ISPE

Main Business*

- ☐ Pharmaceutical Industry
- ☐ Distributor
- ☐ Consultant
- ☐ Academia
- ☐ Government Institution
- ☐ Suppliers and other pharmaceutical industry service
- ☐ Other (please specify)
- ☐ Company* .....
- ☐ Address .....
- ☐ Department* .....
- ☐ Job Position* .....
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- ☐ Mobile Phone* .....
- ☐ Phone No. .....
- ☐ Fax No. .....

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Secretariat 2018 ISPE Indonesia Annual Conference

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transfer receipt at the latest by April 25th, 2018