

Coming Soon: ISPE Eurasian Economic Union Affiliate

People and Events



The team took time out of the meeting to commemorate the visit

A delegation of pharmaceutical industry professionals and regulators from Russia met with ISPE leadership and staff on 20 July. The visit was arranged by the International Visitor Leadership Program (IVLP), a professional exchange program run by the Bureau of Educational and Cultural Affairs at the US Department of State. The IVLP's website states that its goal is "to provide firsthand knowledge about American society, culture, and politics, while cultivating lasting relationships."

Since 1940, more than 200,000 people have taken part in the IVLP. Participants are nominated by the staff at US embassies, and thematic topics are based on key foreign policy objectives.

Of the 12 attendees, seven were from the Russian Ministry of Industry and Trade, two from Unica Engineering Ltd., and three were translators. Representing ISPE were Board Chair Michael A. Arnold, RPh, Investigational Product Business Process Owner, Pfizer Global Clinical Supplies; ISPE CEO and President John E. Bournas; ISPE Director of Regulatory Operations Carol Winfield; ISPE Senior Director of Membership and Component Relations Ciara Durkan; Joseph C. Famulare, Vice President, Global Compliance, Genentech, and immediate past chair of ISPE's Board; George P. Millili, PhD, Senior Principal Technical Advisor, Genentech, and Co-Chair, ISPE Regulatory Quality Harmonization Committee; Roger Nosal, PhD, Vice President and Head of Global Chemistry, Manufacturing and Controls, Pfizer Inc., and Chair of the ISPE Regulatory Steering Committee and ISPE Pharmaceutical Engineering Committee.

GOOD NEWS FOR EAEU

The delegates requested a meeting with ISPE to learn about its role in building effective partnerships with regulators and agencies around the world, the Quality Metrics initiative, and to discuss the launch of a new ISPE affiliate. Delegates also want to foster cooperation with ISPE's Board of Directors and communities of practice, organize an annual conference, hold professional and technical seminars, and translate select guidance documents into Russian.

"We had a very productive meeting with the delegation from Russia," said John Bournas. "We have been working with them since April on the establishment of the ISPE Eurasian Economic Union (EAEU) Affiliate, and our goal is to have an official launch in Moscow this October. "The affiliate goal is well underway, with some 100 members already enlisted. Among the EAEU Affiliate's top priorities will be the harmonization of industry standards that promote the circulation of quality products throughout its territory.

The EAEU is an international organization for regional economic integration whose member states are the Republic of Armenia, the Republic of Belarus, the Republic of Kazakhstan, the Kyrgyz Republic, and the Russian Federation.

"This is an amazing opportunity that will allow us to bring all of ISPE's member benefits to professionals in the EAEU region," said Ciara Durkan, Senior Director, Membership and Component Relations. "Now companies can learn best practices to produce generic and innovative drugs, create new medical products, and train their staffs.

"Industry professionals will not only be able to access *Pharmaceutical Engineering* magazine, join compelling conversations via the CoPs, attend our conferences, and more, but they will also have an organized local network," she continued. "Personal connections are essential in an industry as important and complex as ours, and we're so excited for the people of the EAEU to have that."

THE DELEGATION

Ministry of Industry and Trade

Russian State Institute of Medicines and Good Practices

- Nadezhda Valentinovna Arkhipova, Lead Specialist, Production Inspection, Department of Medicines
- Vyacheslav Viktorovich Goryachkin, Lead Researcher, Department of Inspection
- Mikhail Dmitrievich Morozov, Head, International Cooperation Department
- Vladimir Aleksandrovich Orlov, Deputy Chief, Department of Pharmaceutical Production Inspections
- Vladislav Nikolaevich Shestakov, Director
- Elena Sergeevna Zelenova, Administrative Assistant to the Director

Russian State Research Institute of Pharmaceuticals

Igor Vsevolodovich Falkovsky, Department Head, Proper Engineering Practices

Unica Engineering Ltd., Moscow

- Alla Anatolyevna Iurtaeva, Unit Leader, Unica Engineering Ltd.

Translators

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