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ISPE Members Making an Impact on Industry Issues Worldwide

ISPE President and CEO Nancy Berg discusses the impact that ISPE's new direction is making on individual Members, the companies they work for and regulatory and industry relationships around the world.

After attending an ISPE reception in Philadelphia last month, a Member from the ISPE Delaware Valley Chapter wrote to tell me that ISPE's new direction and vision are "coming to light." Alan told me that the reception was "a perfect example of how ISPE can offer a platform that not only brings together Members and their companies, but also connects them with regulators and regulatory issues." He recognizes that part of ISPE's role as the "industry-regulator connection" is to help ensure consistencies in the understanding of whatever technical or regulatory changes are moving forward.

Members like Alan understand how as a neutral association of *individuals*, ISPE is well positioned to be a leader and a facilitator because it is unencumbered by the politics associated with lobbying. Our new direction is indeed taking shape and today I would like to share examples of how ISPE Members are making an impact on the right issues worldwide.

ISPE's first Executive Forum (2-3 April, Philadelphia, PA-USA) brought together 75 senior leaders from major companies, contract manufacturers and suppliers who heard presentations by peers from the aerospace, defense, automotive and packaging industries on quality management, innovation and leadership. Other speakers included experts and renowned authors who shared views on continuous process improvement and lean leadership and discussed how other industries drive change and respond to government regulations. FDA's CDER Director, Dr. Janet Woodcock opened the meeting by challenging industry to (quantitatively) define *quality* and explained that FDA's new Office of Pharmaceutical Quality will be tasked with identifying new ways of measuring quality. As you may know, FDA has been soliciting industry views on whether common standards and metrics could enhance quality and ISPE has been involved in these discussions. Further dialog is planned during a Quality Metrics session at the ISPE-FDA Joint Conference (11-13 June, Baltimore, MD-USA).

Quality was clearly the theme of our first Executive Forum. Discussions comparing quality management, compliance and leadership in aerospace, automotive, beverage and other industries to the pharmaceutical industry drew candid questions and comments. While there are certainly differences in these industries, the role of leaders is the same whether the company manufacturers automobiles, jets or sterile injectables. Presenters described how great leadership can motivate employees toward a personal commitment to quality in *everything* they do and they emphasized the importance of leadership visibility, thoughtful questioning techniques, understanding processes and the importance of defining expectations for both quality and compliance. At the end of the day, delegates were in resounding agreement: *Quality cannot be a function or an initiative or even a competitive advantage; quality must be the imperative.*

At ISPE's Intensive Workshop on Aseptic Technology (5-6 March, Baltimore, MD-USA), participants heard case studies and discussed approaches to utilizing available technology and regulatory issues. Keynote presenter Rick Friedman, Associate Director, OMPQ, FDA/CDER, declared that "quality rests squarely with industry" and that "ISPE is the most prominent organization encouraging the move to more advanced technology in sterile operations." Friedman also shared his views on the importance of industry carefully monitoring complex and

diverse supply chains and influencing a shift in employee skill sets to reap the benefits of modern technology." Friedman also mentioned that ISPE guidance documents are frequently cited in FDA inspector training. I think Members should interpret that statement as a very positive result of their work. Members who share their experiences by writing documents and articles make an impact well beyond ISPE and their companies—ISPE publications also support regulators who are equally challenged to remain current in a dynamic industry. I am proud to witness the increasing number of positive statements supporting the impact ISPE is making worldwide.

Active Members around the world are making an impact on key issues

Senior ISPE leaders are meeting to discuss progress on ISPE's drug shortages initiative, are engaged in dialog around quality metrics and reviewing the impact of new legislation such as the European Falsified Medicines Directive, the Food and Drug Administration Safety and Innovation Act (FDASIA) and other government directives. The increasing involvement of leaders throughout ISPE is an indication that your Society is addressing the right issues. Here are other great examples of Member projects underway.

Members involved in the GAMP Community of Practice (COP) are actively exploring how the GAMP methodology can be applied advantageously in other stages of the product lifecycle, and our Investigational Products (IP) COP and local ISPE European Affiliate Members are teaming on a new event entitled *Effective Approaches to Optimising Drug Supply and Ensuring Security: Best Practices in Both Investigational Products and Commercial Supply Chains* (13-14 June, Prague, Czech Republic). ISPE Members in China are also developing outstanding conferences and enhancing ISPE's relationship with the China Food and Drug Administration (CFDA), formerly SFDA, a newly constituted drug agency, and our Affiliate in Thailand is at work planning for its 10th anniversary celebration later this year.

Last but not least, Members and regulators are organizing the second ISPE-FDA joint conference entitled *CGMP: Assuring Reliable Supply of Quality Medicines* (11-14 June, Baltimore, MD-USA). Sessions at this meeting include PAI Readiness, Breakthrough Therapies, Quality Leadership of CMOs, CAPA, Flexible Manufacturing, PPPQMS, Quality Metrics and more. Delegates attending will hear from European regulators, co-sponsor FDA and during this meeting, ISPE will present results of the ISPE Drug Shortages Survey. The work done by ISPE Members such as gathering technical and trend intelligence and transforming that information into presentations and publications is part of what positions ISPE as the globally recognized leader in technical and regulatory advancement, education and the source of the most valuable networking throughout the pharmaceutical industry.