ISPE Boston Area Chapter Presents: Pharma 4.0: the Next Industrial Revolution in Manufacturing for Automation, Controls and Decision Making

Thursday, May 16, 2019

5:30 pm to 8:30 pm

PTC Global Headquarters

121 Seaport Blvd. Boston, MA 02210

EVENT INFORMATION:

Register today for an evening focused on Industry 4.0 and its impact on the pharmaceutical industry. Learn from three speakers from different perspectives – process automation vendor, user, and academia – who will convene on a panel joined by an industry consultant. Reception will precede the seminars.

PRESENTATION ABSTRACTS:

Paul Juras, PhD., CMA, CPA, Vander Wolk Professor of Managerial Accounting and Operational Performance, Babson College

Agility, market access, cost savings, What organization would not want these? The question is, how do you get them? Pharma 4.0, the pharmaceutical version of Industry 4.0 might hold the answers. Up to this point, many companies initiate on Pharma 4.0 transformation with a 'technology-first' approach and work backwards to determine a source of value. It is like having a hammer and searching for a nail.

The process needs to be reversed and, in this presentation, Paul will start with some of the value opportunities in the pharma space. Then elaborate on some of the Pharma/Industry 4.0 concepts and tools that can be used to create a competitive advantage and help drive value.

Vikas Dua, Sr. Director, Head of Manufacturing Automation Solution Center, Sanofi

Sanofi Digital Factory 4.0: This presentation is to share one of Sanofi's Pharma 4.0 initiatives named, Digital Factory 4.0. This includes Sanofi's vision of the Factory of the Future, drivers for this strategy and a few examples of digital projects and their current status. The applications of new technologies based on cyber-physical systems can lead to significant improvements in our manufacturing factories. These technologies are now readily available and cost effective to enable digitalization. In addition to these new technologies, a new way of working and mindset is required to develop software solutions in an agile manner, delivering solutions an iterative manner and focusing on the user and user experience.

Joel Nichols, Managing Partner, BIoT Solutions:

How will the Industry 4.0 or "Digital" revolution impact Bio/Pharma? Is this a true revolution or only a minor evolution to the way things have been happening the past several decades with the advances in automation and manufacturing systems? Is this just hype? Are there any practical examples out there that show changes will happen? Will this become a reality or only a "virtual reality?"

Predicting the future isn't easy, but by looking at some examples of how the convergence of the key emerging digital technologies are being used in BioPharma along with some practical ways in which they could be used we will see how much of a reality this could all become. There are some business cases which makes these technologies the right solutions that could be very transformative to the industry.

Continued on the next page ...



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WHO SHOULD ATTEND:

This program will appeal to a wide variety of industry personas including Process & Automation Engineers, Quality Assurance, and Operations Professionals. Individuals or organizations involved in life sciences should attend as it shall provide insights into new ways of thinking about existing challenges in life science manufacturing. The expert assembly of speakers shall provide new approaches to streamlining manufacturing processes and cost savings.

SPEAKERS:

Paul Juras, PhD., CMA, CPA, Vander Wolk Professor of Managerial Accounting and Operational Performance,



Babson College - Paul Juras is the Vander Wolk Professor of Managerial Accounting and Operational Performance and past chairman of the Accountancy and Law Division at Babson College. Previously he was a professor of accountancy at Wake Forest University. He earned both his BBA and MBA at Pace University and his Ph.D. from Syracuse University. He is a certified management accountant (CMA) and has a certified public accountant (CPA) license from New York. Professor Juras has experience in strategic management accounting. Professor Juras teaches managerial accounting and strategic cost management courses and has taught in undergraduate program, Masters of Science in Accountancy, full-time MBA, evening MBA, and blended-learning MBA programs. Paul dedicates most of his efforts outside the classroom to the IMA. He is currently chair of the Institute of Certified Management Accountants (ICMA) Board of Regents and in the in-coming chair-elect of the IMA Global Board of Directors. In addition, Professor Juras served a three-year

term as the chair of the IMA Research Foundation and served ten years as an associate editor of the IMA Educational Case Journal.

Vikas Dua, Sr. Director, Head of Manufacturing Automation Solution Center, Sanofi - Vikas Dua currently



heads global solution center for Shopfloor Automation and Execution systems at Sanofi. In this role, he is responsible for defining global automation strategy to support new capital investment projects in order to secure product launches and expansion of capacity to meet market demand. His area of responsibility also includes managing global rollout of serialization systems (track & trace), defining global strategy for MES (Core model design & build) and Asset Management Systems. More recently, Vikas has been engaged in helping shape up Digital/Smart Manufacturing strategy for Sanofi and lead factory of the future architecture discussions with

focus on process intensification, flexible factories and next generation automation strategies. His past experience includes working in various roles which touched upon wide technical/fuctional aspects including leading the CoE for Integration, managing ERP rollouts, working with regulatory teams on clinical trial systems implementation, quality tools rollouts and technical architecture teams.

Joel Nichols, Managing Partner. BIoT Solutions - After spending 17 years in software development and process



automation, Joel realized his passion for true innovation in the industry. He started up and led the software and automation program for Merck KGaA / MilliporeSigma in its efforts to bring digital solutions to their customers in the Bioprocessing space. Joel now helps BioPharma customers with Digital assessments and connecting them to the right solutions and partners for them. More than just technologies alone, Joel promotes agile transformations to adopt the new ways of working that are benefiting companies around the world. Joel resides in Boston and is always an advocate for the right people, processes and technologies for the right problems.

ADDITIONAL PANELISTS:

Yvonne Duckworth, Lead Automation Engineer, CRB - Yvonne Duckworth, PE is a registered automation engineer



with more than 25 years of experience working in the pharmaceutical, biotech and chemical industries. With a strong background in both technical design and project management, her areas of expertise include instrumentation design, process control system design, control system programming, commissioning, validation and construction and start-up support activities. Ms. Duckworth has been actively involved in projects that incorporate many of the automation trends which are part of Industry 4.0, the current trend of automation and data exchange in manufacturing technologies. Ms. Duckworth wrote an article focused on Industry 4.0 for The Medicine Maker. The topic was the cover feature of the magazine. Ms. Duckworth has a Bachelor of Science in Electrical

Engineering from Widener University and a Master of Business Administration from Rider University. She is an active member of the International Society of Automation and International Society for Pharmaceutical Engineering, recently speaking at an ISPE event in San Francisco on Facilities of the Future.

MEETING MANAGERS:

Jack Nedelman. AutomaTech. Inc. Christopher Ciampa, Commissioning Agents, Inc.

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PROGRAM SCHEDULE:

- 5:30 6:30 PM Registration and Networking Reception
- 6:30 7:30 PM Individual Presentations
- 7:30 7:45 PM Networking Break

8:30 – 9:00 PM Q&A

REGISTRATION FEES: Registration After Registration by 05/09/2019 05/09/2019 Members \$50 \$60 Young Professional Members \$20 \$30 Nonmembers \$95 \$115 Student Members FREE FREE

REGISTRATION IS NOW OPEN ONLINE!

Don't waste time filling in the form! Register online at <u>www.ISPEBoston.org/Events</u>. Pay by credit card OR check.

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Payment may be mailed to: ISPE, Boston Area Chapter, 465 Waverley Oaks Road, Suite 421, Waltham, MA 02452 Telephone: 781-647-ISPE (4773) 凝 Fax: 781-647-7222 ♀ Email: office@ispeboston.org **PLEASE NOTE: CANCELLATIONS RECEIVED AFTER MAY 9TH ARE SUBJECT TO BILLING**



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DIRECTIONS AND PARKING:

<u>Click here</u> for door to door directions.



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