

**Track Title: Risk Management & Quality**

- **Time:** 10:30:00 AM

**Speaker Name:** Chris Dillon

**Professional Title:** Facilities Operations Manager, NBOFacilities Operations Manager, NBO

**Company:** Sanofi Genzyme

**Biography:** Chris Dillon has assumed Facilities Operations Manager responsibilities for the 250,000 sqft Genzyme Northborough Operations Center (gNOC) and the 10,000 sqft Woburn Facility . gNOC Facilities team recognized as "best in class" by Sanofi global Corporate leadership.

Responsible Facilities Management resource for both Facilities ensuring corrective and preventive maintenance compliance/commissioning/qualification/operational readiness/asset activation as well as internal/external audit/inspection readiness. Develops Facilities related input to overall site budget and resource development process. Develops/implements large scale process improvements/process remediation projects and risk based evaluation/decision making scope.

**Session Title:** Predictive Maintenance of Walk-In Chambers compressors

**Session Description:** Presentation will discuss the predictive monitoring technology in use at the Northborough and Masy BioServices facilities to ensure walk-in freezers, stability chambers do not have temperature excursions that risk products. It will cite specific examples of how the technology is being used to change maintenance practices.

1. Improving Reliability of Walk in freezers and stability chambers
2. Reducing risk and cost in maintenance activities
3. Using trend analysis to identify problems in compressors

- **Time:** 12:00:00 PM

**Speaker Name:** Joe Manfredi

**Professional Title:** PresidentPresident

**Company:** GMP Systems, Inc.

**Biography:** Mr. Manfredi has spent more than 35 years specializing in Processing Systems and Process Integration for the Pharmaceutical, Healthcare, and Biotech Industries, including: Design, Integration, Installation, Fabrication, Troubleshooting and Training.

He has been active in numerous industry organizations and has an extensive list of published work including, leading industry magazines, textbooks, and multiple ISPE guides. He has delivered countless lectures and seminars; instructed and certified hundreds of orbital welding technicians and operators; and was the driving force behind the establishment of a Masters Program in Pharmaceutical Engineering at NJIT.

He has been the recipient of many awards throughout his career and continues to serve the industry as a one of the leading experts in Sanitary Design and High Purity Water Systems.

**Session Title:** Sanitary Design: Are we straying from best practices?

**Session Description:** The industry as a whole has become very comfortable with the design and installation of sanitary systems. However many designers use a mechanical approach that fails to properly consider microbial

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unpredictability and the related concerns. This presentation will review many of the key tenets of sanitary design and the practices that evolved over the decades as well as how rules are currently being applied, adjusted and interpreted in the present day cost-constrained environment and how these trends may impact future performance.

- **Time:** 1:30:00 PM

**Speaker Name:** David Macdonald

**Professional Title:** Principal EngineerPrincipal Engineer

**Company:** Hyde Engineering

**Biography:** Dave Macdonald is a Principal Engineer at Hyde Engineering + Consulting, working on front-end engineering, project owners representative and the commissioning and qualification of both small and large molecule capital projects. He has seventeen years of experience in the pharma / biotech industry including leadership roles in process engineering, project engineering, chemical development and commercial launch with operating companies. He has worked at Agilent Technologies, Avecia Biotechnology, Zenenca and Ciba. He is a past member of the ISPE Boston Board of directors and the Education committee.

**Session Title:** Risk Management in Practice: 10 Lessons from the Trenches

**Session Description:** Ten lessons learned while fitting the words of the Risk Management guidances into the real world of pharmaceutical processes and projects. The industry has more than a decade of experience with the Risk Management guidances. They were written with an eye to focusing the limited budget of time, money and attention to the things that are most likely to effect pharmaceutical quality. But there have been many challenges in using the guidances effectively and in keeping the focus on the most risky things that may effect quality. This discussion will cover ten lessons from the trenches of process validation and project execution and qualification, and what we can learn from those lessons, to develop more effective Risk Management approaches.

Three take away points:

- Risk Management requires creative and thoughtful engineering
- Risk Management is a potentially powerful tool to save time, energy and money without sacrificing quality
- Risk Mangement as practiced is filled with potential landmines for the unaware

- **Time:** 3:00:00 PM

**Speaker Name:** Joseph Whyte

**Professional Title:** Director Serialization & Connected Enterprise SolutionsDirector Serialization & Connected Enterprise Solutions

**Company:** Rockwell Automation

**Biography:** Joe Whyte joined Rockwell Automation in 2006 and is currently the company's Director Serialization & Connected Enterprise Solutions. His background at Rockwell Automation includes Life Sciences OEM & Global Strategic Account Management. Since 2009, he has focused on the development, launch and delivery of Rockwell Automation's holistic serialization solution and is currently focused on delivering to global pharmaceutical manufacturers the Connected Enterprise, the Industrial Internet of Things and Industry 4.0.

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Joe has spent 28 years as a sales professional in the Life Sciences & CPG markets. His career highlights include periods in sales and sales management in regional, national and global roles, as well as periods as an entrepreneur, starting and developing new businesses. His technical expertise includes machine and process automation, robotics, packaging, vision systems, IT, data management, analytics, security, mobility and plant floor to supply chain data integration and optimization.

**Session Title:** Leverage Analytics from the Industrial Internet of Things (IIoT) to maximize production and maintain Regulatory Compliance

**Session Description:** Realizing the benefits of a Connected Enterprise is a top priority for most manufacturers. Pharmaceutical companies have been struggling to implement serialization and supply chain traceability solutions to meet regulatory deadlines. However, few realize that the hard lessons being learned to meet regulatory deadlines are the same lessons that must be learned to achieve a Connected Enterprise. This presentation discusses the interoperable challenges that must be solved and the foundational role that serialization & supply chain product traceability plays in achieving the promise of the Connected Enterprise. Learn how Mobile, IIoT, Cloud, Big Data, and Analytics are all related and what problems they are trying to solve. Which is the most important? This talk will break down these topics and discuss an approachable, achievable strategy.

- **Time:** 4:30:00 PM

**Speaker Name:** Michael Bogan

**Professional Title:** PresidentPresident

**Company:** ICQ Consultants

**Biography:** Mr. Bogan has been working in the life science industry for over twenty five (25) years supporting operating companies, facility expansions and green field projects. As a veteran of the armed forces Mr. Bogan understands the importance of discipline and focus that an organization requires to meet their objectives. His leadership and vision have been recognized by many in the industry as being both creative and inspiring. Michael was a co-author for "Risk Management Applications in Pharmaceutical and Bio pharmaceutical Manufacturing:", chapter 7: Points to Consider for Commissioning and Qualification of Manufacturing Facilities and Equipment.

**Session Title:** A proven approach to increasing compliance while increasing efficiency A win/win for everyone.

**Session Description:** This presentation provides a systematic approach and proven strategies for the development and implementation of quality by design programs that employ "right first time" strategies. While focusing on Quality Risk Management systems (QRM) this presentation demonstrates how to align critical processes and programs that meet today's stringent business needs and regulatory expectations. Unlike typical leveraging strategies that ignore the complexities associated with engineering and quality approvals we demonstrate a very simple easy to follow approach with elimination of typical protocols and truly focuses on right first time. The strategy outlined here also aligns facilities, utilities and process equipment design structure with a CQV program that works with existing operations. This strategy has been tested, proven and is a total game changer.

**Track Title: The Future of Biopharma Manufacturing**

- **Time:** 10:30:00 AM

**Speaker Name:** Matthew Kennedy

**Professional Title:** Bioprocess EngineerBioprocess Engineer

**Company:** CRB

**Biography:** Named a 2015 Top 20 Under 40 Award Winner by ENR Mid-Atlantic, Matthew Kennedy is a Bioprocess Engineer whose designs have been on the cutting-edge of technology and have helped to establish him as an industry expert with specialized knowledge in closed processing, single-use technology, flexible manufacturing, and continuous processing. His facility design experience spans the breadth of the biotechnology industry with applications in monoclonal antibodies, vaccine and blood fractionation manufacturing facilities.

Matthew has held a leading role on several ISPE facility of the year award winning projects (Bristol-Myers Squibb's Clinical Manufacturing Facility in 2016 and Shire's HGT facility in 2011). He is an active biotech industry member, regularly participating in groups like the International Society for Pharmaceutical Engineering (ISPE), Biotechnology Industry Organization (BIO) Pennsylvania Chapter. Matthew has been published in Pharmaceutical Engineering Magazine, presented at Interphex, ISPE, Bio-Process Systems Alliance (BPSA) and the ASME Bioprocess Technology Seminar.

**Session Title:** Next Generation Biomanufacturing

**Session Description:** This presentation will discuss next generation biomanufacturing which can significantly reduce a facility's footprint, capital investment, manufacturing cost of goods and improve utilization of assets when compared to conventional batch processing. In response to the uncertainty of ever-changing product pipelines, the biotech industry has recently been evolving to develop flexible manufacturing solutions that can be quickly mobilized to provide a nimble response to changes in production demands. The industry has concurrently improved its ability to assess and control the risk to the manufacturing process by engineering solutions to improve the closure of the process. However, these flexible manufacturing solutions come with capacity limitations that can inhibit their applicability for certain larger scale applications. The advent of continuous processing technologies opens the door to coupling upstream and downstream unit operations to achieve a viable solution for end to end continuous manufacturing of bulk drug substances. Compounding the benefits of other enabling technologies continuous closed processing and implementation of single-use systems, where appropriate " results in a next generation biopharmaceutical manufacturing facility that significantly reduces the facility footprint, capital investment, manufacturing cost of goods, and improves utilization of assets when compared to conventional batch processing.

At the conclusion of this education session, participants will learn how the implementation of continuous closed processing impacts the design of biopharmaceutical manufacturing facilities, be able to analyze the impact to cost of goods for manufacturing therapeutic proteins using a continuous closed process relative to a conventional batch process and understand some of the risks and barriers to entry limiting the implementation of continuous closed processing technology.

- **Time:** 12:00:00 PM

**Speaker Name:** James Levin

**Professional Title:** Sr Strategic GMP Lab PlannerSr Strategic GMP Lab Planner

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**Company:** Perkins + Will

**Biography:** James Levin has been involved with the design and operations of manufacturing facilities for over 30 years. He planned, constructed, and operated GMP facilities at commercial and academic institutions that were essential to investigative clinical trials and subsequent marketing approvals for products and medical devices in the United States and Europe. He has been able to utilize his background in veterinary medicine and pharmacology to develop innovative facilities for commercial product production. More recently he has transitioned into using his experience to help clients design and build GMP manufacturing facilities for a wide array of international products. His experience in managing manufacturing and regulatory operations has allowed him to operate at the intersection of these two skills to help clients understand and develop risk-based approaches to individualized and novel life saving therapies.

**Session Title:** Risk Based Approach to GMP Manufacturing Facility Design

**Session Description:** The recent caution statement issued by the FDA advising companies to establish “a well-controlled manufacturing process” highlights the difficulties to consistently produce high quality therapies that are safe and effective. This challenge is made more difficult by the variability in materials, methods, and controls necessary to perform these processes. While much focus has been on risks associated with manufacturing operations for all forms of cell based therapies, we have found the integration of manufacturing science, facilities operation, and facilities design into a single risk analysis is best suited to identify variables and risks, and then to devise strategies to mitigate these risks while promoting the production of high quality cell based products. This presentation will discuss an integrated approach to the risk analysis process used for individual patient, single product, or multi-product facilities and will highlight how manufacturing science and pharmaceutical operations inform facility design to create an enhanced procedures, improved engineering controls, design upgrades or a combination of all three.

This presentation will discuss the risk assessment process, and how it integrates with the design of manufacturing facilities for FDA-regulated products. It will demonstrate how the process takes a holistic examination of risk, and how the risk assessment generates improvements in operating procedures, manufacturing process flow, engineering infrastructure, and the facility design process. It will highlight both benefits and pitfalls of this exercise and will provide examples of how the risk assessment influences and justifies design changes to protect patient safety. Lastly this presentation will review how the risk assessment procedure can greatly enhance the facility design process resulting in the construction of improved manufacturing environments to consistently produce high quality therapies that are safe and effective.

- **Time:** 1:30:00 PM

**Speaker Name:** Sue Behrens

**Professional Title:** Senior Director, Process DesignSenior Director, Process Design

**Company:** IPS - Integrated Project Services, LLC

**Biography:** Dr. Behrens has more than 20 years of experience in cGMP manufacturing environments. Her global experience encompasses all aspects of scale-up and production of vaccine and biopharmaceutical products and includes an exceptional ability to develop and implement supply chain strategies to fulfill market needs. Sue adeptly conducts root cause analyses to resolve production issues and identify innovative opportunities for improvement.

**Session Title:** Continuous Manufacturing for Biologics & Vaccines

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**Session Description:** Continuous manufacturing operations can provide improved efficiency for biopharmaceutical manufacturing. The consistency of product quality is obtained through extended periods of steady-state operations. Reduced capital expenditure is achieved through process intensification and subsequent reduction in size for equipment as well as the operating facility. The existing “Factory of the Future” process architectural paradigm must be customized to enable continuous raw material feed, operation and final product storage.

Significant advances have been made in the understanding of these opportunities for biologics, many in combination with Single Use technologies. Currently available capabilities for upstream and downstream unit operations and process control strategies will be discussed.

### POINTS TO TAKE AWAY

1. Present the current state of technology for biologic continuous unit operations, including perfusion bioreactors, filtration, chromatography, etc.
2. Define advantages for use of continuous processing, recognizing operational and regulatory factors in the manufacturing environment.
3. Highlight near-term challenges and opportunities in the development of a fully continuous process for the production of biologic and vaccine products.

- **Time:** 3:00:00 PM

**Speaker Name:** Matt Hubbs

**Professional Title:** Senior Project ManagerSenior Project Manager

**Company:** DPS Group

**Biography:** Matt Hubbs is highly skilled in leading cross-functional project teams to administer, manage, and execute engineering, procurement, construction management, commissioning, qualification, and validation (EPCMCQV) projects.

He has over 20 years of experience working for both development and manufacturing facility customers in the pharmaceutical and biotechnology markets. And he has coordinated and managed activities of engineers, constructors, consultants, vendors, and contractors to meet and surpass scope, schedule, budget, safety, and quality requirements.

**Session Title:** Factories of the Future to Factories of the Here and Now

**Session Description:** In response to the advent of innovative and advanced therapy medicinal orphan drug products, pioneering facilities must be designed and constructed to meet the manufacturing needs of these game changing orphan drug therapies. Technologies are evolving with the therapies, requiring flexible and creative thinking design teams to create leading edge facilities to manufacture these new medicines.

We will discuss a new facility design for manufacture of mRNA therapy and personalized vaccines. The presentation considers the changing paradigm from large volume facilities with mature technology to small, flexible multiple processing units, innovative new technologies, clinical and commercial batches in a single facility, flexibility in scale adjustment and miniature drug product batches. We address additional challenges such as the overlap between biologics and small molecule chemistry with some of these ground breaking medicines.

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The changing paradigm from large volume biologics to smaller innovative orphan drugs presents new challenges and opportunities for leading edge facility designs, implementing new and evolving technologies and addresses all the cGMP and regulatory challenges to achieve a “fit for flexible purpose”, “inspection ready” facility. As technologies continue to evolve we have to be creative with our facility design to respond to these changes while addressing the speed to market requirements for these life saving therapies. We have to respond to the problem issue that no existing framework exists in many cases for manufacturing or logistics compared to the frameworks for small molecule therapeutics or standard biologics that have been in place for many years.

The presentation will present a real life project and share the journey undertaken to design and build a facility for ground breaking therapeutics with a process with limited industry benchmark information.

- **Time:** 4:30:00 PM

**Speaker Name:** Morten Munk

**Professional Title:** Global Technology Partner Global Technology Partner

**Company:** NNE

**Biography:** Morten Munk’s career is comprised of 30 years of experience within the global biopharmaceutical industry.

One common denominator for his work has been to ensure a holistic and broad perspective on biomanufacturing challenges from idea to established facilities. His key focus is to ensure compliant and cost-effective production through the optimal use of all relevant and available knowledge and technologies, such as single-use systems and continuous processing.

He combines his technological expertise with a thorough business understanding coupled with a great personal interest in and practical understanding of stakeholder relations and change management.

Morten joined NNE as Global Technology Partner in 2015. In 2001 he co-founded CMC Biologics, after working 14 years at Novo Nordisk.

**Session Title:** Flexibility by Design

**Session Description:** This presentation primary aim is to discuss how a holistic, life cycle management approach should be applied to the design of facilities and product supply models to meet the difficult predictable future demands for pharmaceuticals from the market.

The presentation includes discussion of several new trends in design of Biomanufacturing plants, which include increased focus on the logistics supporting the core production processes. This include the organisation, training and collaboration of the staff, as well as the level of automation and implementation of robotics.

Additionally, the presentation will cover the implication this reality has on manufacturing strategies, cost implications with focus on the development of new technologies.

Key messages

- Options for incorporating flexibility in the conceptual design phase
- Include the future operating model of the final facility in the facility design
- Selection of the “right” technologies balance the use of proven and new technologies

## Product Show 2018 – Final Speakers & Sessions

### Track Title: Biopharma Manufacturing Efficiencies & Improvements

- **Time:** 10:30:00 AM

**Speaker Name:** Jesse Coiro

**Professional Title:** Director of North American SalesDirector of North American Sales

**Company:** Erlab, Inc.

**Biography:** Jesse Coiro is the Director of Captair Sales for Erlab, Inc. His passion to succeed has always been a burning desire. Through his 15-year career in sales he has been dedicated to being a solutions provider for his customers. With 7 years of molecular air filtration experience and energy efficient solutions, Jesse is a trusted resource in the industry with tremendous credibility. You can reach him at [jcoiro@erlab.com](mailto:jcoiro@erlab.com).

**Session Title:** Defining the design of your laboratory - The possibilities with filtration

**Session Description:** Abstract:

Designing a lab to meet the demands of today's world is extremely challenging. With EPA regulations becoming more stringent in regards to adherence of the Clean Air Act (CAA) and Pollution Prevention Act (PAA) not only are there significant design challenges, but also challenges of how your chemistry and fume hood pollution emission will fall into play. To further complicate matters, buildings are also tasked with green initiatives and achieving LEED certifications. All complex and challenging in their own right. Especially in the northeast climate (zone 5). So, what are some of the technological advancements to help assist in providing solutions to these challenges?

With filtration the design of the lab is simplified, reducing not only first cost, but more importantly your annual energy consumption and carbon footprint. Because of filtration, facilities, such as; Bristol Community College, have been able to achieve ZNE (zero net energy). In addition to these benefits, filtration also drastically reduces the load of the buildings HVAC system offering a tremendous value to existing labs and those undergoing renovations.

Filtration has long been thought of as a last-ditch solution, but with significant advancements made over the past 10 years, this should realistically be thought of during the first preliminary design discussions. Not only does filtration drastically reduce the need for complex HVAC designs, but also provides a level of safety that few realize are available. This additional level of safety not only captures emission at the source, eliminating pollutants from being released into the atmosphere, but also works as an ecosystem throughout the lab, capturing emissions throughout the lifecycle of the chemical, wherever and whenever a chemical enters the lab.

Four Learning Outcomes:

- 1) The impact on a facilities infrastructure with and without filtration
- 2) Annual energy savings and carbon footprint reduction
- 3) An ecosystem of safety through filtration and how this can be achieved

- **Time:** 12:00:00 PM

**Speaker Name:** Wayne Bates

**Professional Title:** Principal EngineerPrincipal Engineer

**Company:** Tighe & Bond



## Product Show 2018 – Final Speakers & Sessions

**Biography:** This presentation will be conducted by Wayne Bates of Tighe & Bond and Derek Sykes of Amgen. Wayne is an industrial wastewater treatment expert at Tighe & Bond with 30 years of experience and holds a PhD from Worcester Polytechnic Institute in environmental engineering. Derek is a chemical engineer at Amgen with 20+ years experience and holds a Masters from WPI in environmental engineering.

**Session Title:** Challenges Assessing and Treating Biotechnology Wastewater - Case Study on Phenol Treatment

**Session Description:** Biotechnology plays a critical role in our society. While large scale biotechnology operations are regulated under the federal categorical pretreatment standards, research and development activities are exempt for the categorical standards. Industrial wastewater pretreatment systems (IWPS) from these biotechnology research facilities are typically limited to equalization and neutralization and often oversized to handle future flows. The waste characteristics from biotechnology operations typically include ultrapure water for cleaning and high strength organic wastewater from biological and natural extraction operations. Combining high strength organic wastes with warm water and discharging them to an IWPS with a long residence time and constant agitation can cause excessive biological growth. Amgen Corporation, a major biotechnology manufacturing company in Cambridge Massachusetts found that excessive biological activity in its IWPS was the source of odors and the generation of elevated phenol levels, which is a regulated parameter at 5.0 parts per million by the Massachusetts Water Resources Authority (MWRA).

This paper will discuss methods used to assess the wastewater characteristics and treatability testing conducted to control the generation of phenol and odors from this operation. We will present disinfection and oxidation results obtained through treatability testing using several different oxidizers to control growth including chlorine, peracetic acid, sodium percarbonate, hydrogen peroxide, and hydrogen peroxide with a catalyst. In addition, we will discuss treatability testing conducted to assess the ability of certain oxidizers to chemically oxidize phenol present in the wastewater once generated. The approach taken and data obtained through treatability testing will be of value to other biotechnology companies with similar organic wastes and pretreatment systems.

- **Time:** 1:30:00 PM

**Speaker Name:** John Klostermyer

**Professional Title:** Application Project ManagerApplication Project Manager

**Company:** Steris Corporation

**Biography:** John Klostermyer, PhD an ISPE member since 2004, is an Application Project Manager at Steris Corporation. He supports Steris's sales initiatives globally in developing process solutions that utilize VPHP. Primary markets include pharmaceutical and medical device manufacturing followed by research and food applications. He has worked exclusively in VPHP applications for 14 years. Prior to joining Steris, He worked for AgrEvo GmbH (now part of Bayer) in Berlin and Frankfurt, in the development of agricultural chemicals. His education includes a BA from Drew University and MSc from Rutgers and a PhD from Goettingen, Germany.

**Session Title:** Integrated VPHP Decontamination Systems: The Emerging Utility

**Session Description:** This presentation will review main points and add practical advice and case studies based on the article with the same title recently published in November-December 2017 Issue of Pharmaceutical Engineering, pg 52 - 56.

Content includes concepts and examples of how vapor phase hydrogen peroxide gas can be included into a facility as a utility. How 35% H<sub>2</sub>O<sub>2</sub> can be safely and reproducibly converted to a gas and delivered to

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decontaminate any enclosure via protocols stored in the building automation system. This emerging technology will impact current methods of decontamination that are labor intensive, prone to human error and less efficient in terms of chemical use.

Main points include:

- Clearly defining the your aseptic process capturing it in a URS.
- Pros and cons of manual, integrated and portable systems
- People and skill-sets needed to implement
- Review of common installations with cycle times
- Aseptic and containment environments
- Interfacing with the building automation system
- Best management practices
- Common mistakes
- System validation
- Safety
- Frequently asked questions

- **Time:** 3:00:00 PM

**Speaker Name:** Carl Vose

**Professional Title:** Architectural / Engineering RepresentativeArchitectural / Engineering Representative

**Company:** The Stonhard Group

**Biography:** 25 years experience in construction products related industry.

22 years experience in presenting and providing solutions to the Pharmaceutical/Life Sciences Community

11 years experience as the New England District Manager with The Stonhard Group

8 years experience as a Field Project Manager for The Stonhard Group

**Session Title:** Advancements & Applications in Resinous Floors and Walls

**Session Description:** This presentation reviews polymer flooring and wall systems, and distinguishes the differences between coatings, broadcast, self-leveling and trowel applied flooring systems. Applications and areas of use are reviewed for Pharmaceutical environments. Topics such as chemical resistance, design, performance technology, surface preparation, installation techniques and engineering details, including GMP, are presented.

- **Time:** 4:30:00 PM

**Speaker Name:** Mark McElligott

**Professional Title:** Partner/Principal Process EngineerPartner/Principal Process Engineer

**Company:** Process Design Solutions Sandbox

**Biography:** With over 20 years of SUT experience, Mark McElligott has engineered and deployed SUT solutions accompanied by defendable, integrated SUT programs. Mark is a Partner and Principal Process Engineer with Process Design Solutions and PDS Sandbox.

## Product Show 2018 – Final Speakers & Sessions

The other speakers companies for this event have been outlined in the abstract by company and I will provide names once selected. I will provide the moderator

**Session Title:** Simplifying Single Use Technology (SUT)

**Session Description:** Simplifying Single Use Technology (SUT) implementation is achievable. Using a cross functional panel of SUT end users (Shire, Sanofi, Homology), SUT suppliers (Saint Gobain) and SUT subject matter experts (PDS), this presentation will provide SUT simplification guidance from such perspectives as Process Engineering, Supply Chain/Materials Management, Quality Assurance/Quality Risk Management, Process Development and Validation/Materials Qualification. Attendees will be provided guidance on numerous strategies to simplify SUT implementation for both new and existing facilities.

This presentation will provide attendees valuable guidance and strategies including:

- Simplification of SUT through site specific standardization
- Developing simplified and relevant SUT requirements
- Strategies to simplify Materials Management/Supply Chain for SUT
- Simplifying SUT program deployment using a phased product stage rollout
- Simplifying the impact of SUT Vendor Change Notifications (VCNs)

Every presenter will have 1, or more, case study to support their simplification strategy.

## Track Title: Optimizing Facilities through Innovation & Technologies

- **Time:** 10:30:00 AM

**Speaker Name:** John Hannon

**Professional Title:** Global Business Lead, Automation and IT Services  
Global Business Lead, Automation and IT Services

**Company:** CAI

**Biography:** John Hannon is an Executive Consultant and Business Area Leader for Automation and IT at Commissioning Agents. With over 29 years in the pharmaceutical, IT, and process automation fields, he has been instrumental in starting up cutting-edge biotech facilities for companies such as Baxter, Monsanto, Amgen, Genentech, Pfizer, and Cook.

He has managed multi-million dollar projects and project teams across the US and Europe, and is responsible for delivering hundreds of high-profile, mission-critical projects for biotech, pharmaceutical, and medical device customers. Currently he leads CAI's IT and Automation business area - responsible for the development of automation, MES, and other IT system projects within the international client base.

**Session Title:** Successful project management for software development and validation

**Session Description:** Description

Software projects, be it for automation or data management, can not be effectively managed as traditional projects. This presentation will discuss 21st century deliverables, processes and tools necessary for software project success:

- selection and implementation of the development and testing strategy
- acquisition of commitment and translation to project planning
- project process measures of effectiveness
- development of simplified tools for reporting, management, and traceability
- subcontractor management and contractual deliverables

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- management of issues, problems, and changes
- ongoing software maintenance and life cycle support

Concepts are applicable to software development projects for both automated medical devices themselves and the automated or data-driven processes that manufacture them.

- **Time:** 12:00:00 PM

**Speaker Name:** Mirek Gorski

**Professional Title:** Maintenance ManagerMaintenance Manager

**Company:** DSM

**Biography:** Worked on start up companies in biotech, biopharma, Life Sciences and semi-conductor on both coasts.

**Session Title:** Optimizing Facilities through Innovation & Technologies

**Session Description:**

Apply Data Science & IIoT methods to facilities management.

Data Science approach to make Facilities, science based.

Concept of IIoT (Industrial Internet of Things); having real time data (from Data Science analysis) from the facilities infrastructure equipment to do true predictive maintenance and planning.

Digital solid state electrical breakers with digital controlled electrical panels to reduce Arc-Flash and achieve utilization of electrical needs.

Variable Refrigerant Flow (VRF) for HVAC equipment to drastically cut down on energy use, if properly applied.

LED lighting for mood environment as well as a virus/bacteria disinfectant for office, lab and GMP environments, reduce energy cost.

Better built HVAC equipment to prolong the life cycles of costly to replace HVAC equipment and reduce operating cost.

New techniques in piping construction to reduce construction time and be cost effective.

- **Time:** 1:30:00 PM

**Speaker Name:** John McGrath

**Professional Title:** Project Management Professor & PM ConsultantProject Management Professor & PM Consultant

**Company:** John McGrath is speaking on behalf of Cora Systems

**Biography:** John is a project management professor at the following Dublin, Ireland universities: DIT; Trinity College Dublin (adjunct professor); Smurfit Business School and UCD as well as Brunel University (London, UK). John is also a seasoned keynote speaker and presents at over 20 global conferences each year. His passion and expertise lies in developing project management competency with organisations. John McGrath started his career with Pfizer as a project scheduler. Since then John has gone on to spend over two decades coaching and consulting to over 200 global companies, government agencies, the United Nations and the World Bank.

**Session Title:** The Digital PMO: Getting Fit for the Future

## Product Show 2018 – Final Speakers & Sessions

**Session Description:** We are in the midst of a new industrial revolution that is transforming our private and professional lives. Digital transformation is omnipresent and has become imperative for all organisations. The most challenging aspect of digital transformation isn't the technology: It's effectively managing change and getting people to embrace it. The PMO can be an effective vehicle to deliver change within an organisation but many PMOs remain digitally immature. PMOs must transform if they are to remain relevant in the new era of constant change and disruption.

Using a series of case studies John will present how organisations struggling with traditional silos and a lack of integration have aligned and developed cross-functional collaboration unlocking the value of digital.

The transformational PMO leading digital transformation programmes?

How a project management approach is essential for delivering measurable benefits when managing a digital transformation programme

Case Study 1: Consolidating project pipeline visibility of 35,000 live projects reporting deviation, resource/capacity management and financial control (Allergan)

Case Study 2: Annual Cost Improvement Programme of \$30 million (Teleflex Medical)

- **Time:** 3:00:00 PM

**Speaker Name:** Jan Thriene and Chris Hamilton

**Professional Title:** Business Development Manager and Director of Industrial IT/OT and Cyber Security  
Business Development Manager and Director of Industrial IT/OT and Cyber Security

**Company:** Systec & Solutions and Grantek Systems Integration

**Biography:** Jan Thriene is the Business Development Manager at Systec & Solutions, a Karlsruhe, Germany based manufacture of best in class GMP-IT hardware for clean room production environments. Mr. Thriene has over 7 years' experience providing HMI solutions in the pharmaceutical, food and cosmetics industries. Prior to his work with Systec & Solutions, Mr. Thriene held management roles in China and throughout Europe for various American firms. Chris Hamilton is the Director of Industrial IT/OT and Cyber Security at Grantek Systems Integration, a systems integrator with 17 offices across the globe that delivers solutions to complex problems in Smart Manufacturing, Industrial Networking, Automation and Industrial Safety. Mr. Hamilton started his professional career in web design, databases, and server management with a focus in security at every level, but grew up around process flow and P&IDs in Biochemical Pharmaceuticals, in his roles at Grantek he has worked as a controls engineer, a systems engineer and an IT/OT consultant to bridge the gap between IT and Controls teams in order to help clients realize more efficient operations.

**Session Title:** Pros and Cons of Mobile PCs in a Production Environment

**Session Description:** This presentation will examine the use of Mobile PCs in a production environment.

Decision factors will be discussed when considering the implementation of Mobile PCs in a clean room rated production environment. Issues around 21 CFR Part 11 validation for Mobile PCs will be addressed. Attendees will hear the pros and cons and participate in an interactive presentation focused on 3 perspectives:

Cost Perspective Capital expenditure vs. operational expenditure

Handling Perspective Ergonomic factors to consider

Design/Validation Perspective Validation considerations and hardware designed for a production environment vs. hardware repurposed for a production environment

## Product Show 2018 – Final Speakers & Sessions

- **Time:** 4:30:00 PM

**Speaker Name:** Benjamin Willemstyn

**Professional Title:** Founder, Director of Product Development Founder, Director of Product Development

**Company:** PAW BioScience / VWR BioProcessing

**Biography:** Benjamin (Ben) Willemstyn, B.S. Physics, is the Founder and Director of New Product Development at PAW BioScience Products, an Avantor/VWR BioProcessing Company. A patented inventor and entrepreneur, Ben has designed single-use products and components that are used ubiquitously by the global drug and vaccine manufacturing industry and is lead designer for the Omnitop Fluid Sampling Systems at PAW BioScience.

**Session Title:** Designing Novel Fluid Sampling Systems for GMP Operations

**Session Description:** Obtaining critical fluid samples with single-use products from biologic and vaccine manufacturing processes can be problematic and costly. Although many standard solutions exist, some production processes are limited in what they can use and off the shelf products may not be suitable for all situations. The presentation discusses a novel design and approach for a single-use, multi-tube sampling platform that was implemented to replace and improve traditional methods using glassware. Attendees will learn design considerations, methods used to validate the system, material selection and review an actual pre-use integrity test used to verify the efficacy of each system on a batch-to-batch basis.

## Product Show 2018 – Back-Up Speakers & Sessions

- **Track Title:** Biopharma Manufacturing Efficiencies & Improvements

**Speaker Name:** Philip Crincoli

**Professional Title:** Industrial Segment Sales Manager Industrial Segment Sales Manager

**Company:** Aqseptence Group - Airvac Division

**Biography:** Philip Crincoli has joined Aqseptence Group / Airvac Division for their Vacuum Technology Wastewater Conveyance Systems as Industrial Segment Manager. Phil will be developing the Industrial Sales Market, which is one of the company core initiatives for accelerating a positive organic growth pattern. Phil will be affiliated with the Rochester, Indiana headquarters location and he will be working out of his NJ home office. Phil comes to Aqseptence Group with an impressive sales and technical background in the environmental, pharmaceutical and chemical markets, along with a wide network of contacts and colleagues. He has a BS in Biology from Monmouth University and is both LEAN and OSHA 40-Hour HAZWOPPER certified. Phil is active with the International Society of Pharmaceutical Engineers (ISPE-NJ), and the United States Green Building Council (USGBC-NJ) and is a current member of the Institute of Supply Chain Management (ISM-NJ) board of directors for 2017. He is also past VP of IFMA-NJ and former outreach and plant security committee member at the Chemistry Council of NJ.

Aqseptence Group is a leading global supplier of specialized products, equipment and system solutions for filtration & separation and water technology for various applications and unites some of the most renowned brands of the industry, serving industrial and municipal customers for more than 100 years. Its divisions including Airvac, Diemme Filtration, Johnson Screens, Passavant, Geiger, Roediger and Noggerath comprise over \$300 million in gross revenue.

The Airvac vacuum wastewater conveyance systems are a mechanized method for centrally collecting and separating wastewater. Differential air pressure creates flow in a vacuum system, rather than gravity or pressure. The flexibility of the vacuum system and piping, during design and installation, allows the designer and contractor to easily overcome unforeseen obstacles, whereas traditional gravity systems can require lengthy work stoppages and costly change orders. Historically, the cost of installing vacuum piping closely resembles the cost of installing a water distribution system and is significantly less expensive than a traditional gravity system. For more information visit: <https://www.aqseptence.com/app/en/keybrands/airvac>

**Session Title:** Industrial Vacuum Liquid & Waste Water Conveyance Systems In Cleanroom Syringe Washing Operations & other Applications

**Session Description:** An overview of how indoor & outdoor vacuum wastewater conveyance systems operate in industrial settings including FDA regulated properties.

The greatest benefit of a vacuum system is its ability to protect our most valuable resource, water. Do not be put off by the initial material cost of a vacuum system; the overall project construction and operational costs almost always are significantly lower than a standard gravity system with the added bonus of reduced water consumption. Moreover, the system can be installed just about anywhere; in walls and ceilings, tight and confined spaces like attics and crawl spaces and on top of floors. Infrequent system maintenance can be performed outside of critical plant operational areas including controlled environments and Cleanrooms. The system is also virtually leak proof and doesn't require dual containment of piping upon installation.

## Product Show 2018 – Back-Up Speakers & Sessions

- **Track Title:** Risk Management & Quality

**Speaker Name:** Noel Heary

**Professional Title:** Managing Director/Managing Director

**Company:** Lpp

**Biography:** Noel Heary has over 25 years in the design, manufacture and sale of analytical equipment to the pharmaceutical manufacturing industries and has a wide knowledge of the applications and sensor technologies available. He has previously worked for injection systems and pure steam generators. Currently he is the global manager for Insacal, the world's only accredited master system for conductivity measurements.

**Session Title:** The measurement and calibration of conductivity in pharmaceutical environments

**Session Description:** Low conductivity measurements in ultra pure water for injections has been regulated since USP23 in 1996 in the USA and EP in Europe. The correct measurement and continuous correct calibration is an ongoing topic of concern for calibration, utility and facility engineers. The presentation addresses the reasons manufacturers do not recommend the use of standard solutions and they themselves prefer the use of a master standard reference system, similar to the Insacal reference system. The presentation outlines current regulatory requirements and how they can be addressed correctly.

- **Track Title:** Optimizing Facilities through Innovation & Technologies

**Speaker Name:** Paul Hartigan

**Professional Title:** Global Product Line Manager Systems and Software/Global Product Line Manager Systems and Software

**Company:** Particle Measuring Systems

**Biography:** Paul Hartigan is the Global Product Line Manager for Software and Systems with Particle Measuring Systems. He has held various product management responsibilities over the last 10 years with Particle Measuring Systems including responsibility for Liquids, Aerosol and Microbial based products, with his latest role being involved in the Environmental Monitoring Systems. Responsibilities have included developing the latest technologies into products for use in Life Science cleanroom operations. He has written numerous papers related to the application of products in the Life Sciences industry and presented at organizations throughout the world, including instruction at various trade organizations.

**Session Title:** An Industrial Automation approach to Environmental Monitoring System for viable and nonviable particle monitors.

**Session Description:** This will review the shift towards industrial automation monitoring systems away from PC based software systems for particle counting and microbial monitoring systems. Additionally how the latest systems incorporate the latest regulatory requirements for monitoring as well as meeting the FDA Guidance for Data Integrity.

- 1) How an industrial automation system is different than PC based systems
- 2) How an industrial automation system meets the latest regulatory requirements
- 3) How particle sensors, microbial air samplers and other environmental inputs are incorporated into an Environmental Monitoring System



## Product Show 2018 – Back-Up Speakers & Sessions

- **Track Title:** The Future of Biopharma Manufacturing

**Speaker Name:** Mike Brennan

**Professional Title:** Project Management Director, Industrial - Engineering and Construction  
Project Management Director, Industrial - Engineering and Construction

**Company:** SNC-Lavalin

**Biography:** Mr. Michael Brennan is a Mechanical Engineer with over 28 years of experience as a design and construction Project Manager in the pharmaceutical, biotech, specialty chemical, petrochemical, and food and beverage industries. He has successfully managed engineering, procurement and construction services from scope development through start-up. He is knowledgeable in engineering, construction, estimating, cost control, scheduling, document control and procurement.

**Session Title:** Project Delivery Methods

**Session Description:** In executing a major project, deciding on what delivery method to implement comes to mind: to do a Design Build project, an EPC project, an EPCM project or a Design-Bid-Build?

Every project delivery has its own strengths and challenges which will thereby be influenced by the:

- Project owner organisation,
- Owner's degree of involvement;
- Owner's openness of risk,
- Internal team experiences;
- Project timeline;
- Project budget;
- etcâ€¦

This presentation will brief attendees on:

- The difference between each project delivery method;
- The key factor which ought to be taken into account for in selecting the right delivery methods
- Consequence on the project delivery methods on the risk management and project quality