ISPE Connecting a World of Pharmaceutical Knowledge | New Jersey Chapter

Professional Development Day

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Biopharmaceutical Manufacturing Facilities Baseline Guide Review

Norman Goldschmidt

Vice President – Genesis Engineers Inc.

Norman Goldschmidt is Vice President and Principal at Genesis Engineers Inc. He has nearly 30 years of experience in engineering management, planning, design and construction in the pharmaceutical and biotech industry. Prior to joining Genesis, Norman served in numerous capacities during 20 years with Bristol-Myers Squibb (BMS). Starting as a Mechanical Engineer / Project Manager and serving in both technical operations and R&D, culminating as Executive Director, Global Engineering for Strategy and Design. His industry experience spans the many facilities and processes necessary to bring a drug to market - from R&D through Manufacturing.

Mr. Goldschmidt holds 4 patents for innovations in HVAC and Pharmaceutical Processing, is an International Standards Organization (ISO) TC209 delegate, and international lecturer on design and management of clean/controlled environments. He also serves as an Adjunct Professor at the New Jersey Institute of Technology, is Lead Author of the ISPE Good Practice Guide for HVAC and author on multiple other ISPE Baseline Guides, including Biopharmaceutical Facilities, Sterile Manufacturing and Oral Products. Norman is a risk management trainer, contributing author and instructor for NIH, NSF, ASHRAE, ISPE and others.

Marc Pelletier, Ph.D.

Lead Process Engineer – CRB

Marc is Director of Process Technology at CRB Consulting Engineers. His roles include strategic planning, conceptual design, process engineering, risk assessment, compliance and validation for the Life Technologies sector. He has been with CRB for 7 years. Prior to joining CRB, Marc was President of MPP BioDesigns, a consulting group also specializing in Bioprocessing.

Although Marc is formally educated as a biochemist, he has worked as a process engineer the majority of his 25+ year career. His contribution to the life sciences sector has been focused on the food and biopharmaceutical industries. Prior to consulting, Marc spent the majority of his career as an end user developing bioprocesses and in technology transfer. His role on various projects have included that of project manager, fermentation / cell culture and downstream process design lead, equipment designer, facility designer, risk assessment moderator and validation manager. He is currently the vice-chair of the ASME BPE. He is a contributing advisor to the BPOG Room Classification Team and was a co-author of the recently revised ISPE Biopharmaceutical Manufacturing Facilities Baseline Guide. His chapters focused on closed processing and the potential risks and impact on biopharmaceutical facility design. Marc has served as adjunct professor at the University of Manitoba, Canada and Bemidji State University, MN. He is a frequent lecturer for the AAPS, ASME, IBC and ISPE.

Serialization Solution Design and Deployment

Hardware and Software Strategies at the Packaging Line

David DeJean

Vice President - Systech

David DeJean, Vice President, is responsible for Systech's Center of Excellence, which supports and educates customers and stakeholders on best practices for implementing Enterprise Serialization, Track & Trace and Authentication solutions. DeJean brings a wealth of market knowledge, hands-on experience in serialization solution development and project methodology. His role includes staying abreast of international regulations, business and industry drivers, and supporting customers and stakeholders, defining high performance, cost-effective solutions that are integrated and expandable to meet future needs. DeJean is a serialization subject matter expert, previously holding various roles within Systech including, Engineering Management, Product Marketing, Professional Services and Sales Management.

Serialization Project Management Considerations

Mike Salinas

Director of Manufacturing Technology – M+W Group

Mike Salinas has 30 years of Life Science facilities planning, design, construction, and technical project management experience for both Owner-operating companies (brand and generic) and global engineering and construction service providers. Mike has been with the M+W Group since 2011 as Director of Manufacturing Technology where he plays a key role in expanding their EPCM service offerings within the Life Sciences division, and supporting key business development opportunities; including Serialization solutions. Mike holds a BS in Industrial Engineering from Columbia University, and an MS in Engineering Management from Drexel University. He can be reached at 610 427-3310 or mike.salinas@mwgroup.net.

Abstract:

Success in both planning and implementing a Serialization project or program can only be assured with an organized approach where all stakeholders are on board from the start—not just during execution. This case study will walk you through a Serialization project for a grass roots facility from an EPCM perspective. It will provide insights on the importance of:

- building up a cross-functional team,
- clearly defining user requirements and expectations up front,
- vendor evaluations
- market relationships,
- training,
- design and layout,
- facility ramifications and
- Lessons learned from managing the project and vendors alike

Traceability through the Supply Chain

Brian Daleiden
Vice President of Marketing – TraceLink

Brian leads marketing and global regulatory analysis at TraceLink. Brian also guides the company's market education programs that help industry stakeholders understand current and emerging regulatory, business and technical issues. In addition, Brian leads the TraceLink Cloud Community of customer thought leaders from across the global pharmaceutical supply network. Prior to co-founding TraceLink, Brian led product and corporate marketing at SupplyScape. In addition, Brian has held numerous marketing, business unit management and software development leadership roles focused on the global manufacturing and supply chain space at Catalyst International, Rockwell Automation and several startup companies.

Lucy Deus
Vice President of Product Management - TraceLink

Lucy leads product design and market requirements development at TraceLink where she focuses on the vision and capabilities for TraceLink's Life Science Cloud platform. A noted industry thought leader, Lucy is also deeply involved in multiple GS1 standards workgroups and has won several awards for her contributions to Life Sciences, including the 2009 PharmaVOICE 100 Most Inspiring People award and the 2008 EPCglobal Person of the Year award for technical editorship of the Drug Pedigree Messaging Standard. Prior to co-founding TraceLink, Lucy led product management at SupplyScape where she was instrumental in creating the industry's first electronic pedigree system. In addition, Lucy has held product design and development leadership roles at the Mitre Corporation, iWant.com and Performaworks.

Title: Preparing Your IT Infrastructure, Internal Operations and External Network to Meet Diverse Global Track and Trace Regulations
Content: Today's diverse global serialization, traceability and reporting regulations from the US to China and beyond impact IT, the enterprise and the supply network. Drawing learnings from dozens of commercialized projects, this session will look at the required solution capabilities that pharmaceutical companies need to put into place and the key IT infrastructure, business process and external supply network considerations to prepare for.

Key areas of the discussion include:

- Key similarities and differences across serialization, traceability and reporting requirements
- Understanding the scope of your business requirements for global compliance
- Defining the required capabilities for a global IT and compliance solution
- Analyzing the impacts of serialization and track and trace on your Master Data
- Layering serialization over logistics processes
- Defining the integration touch points between IT architecture and business processes
- Integrating your network and data exchange considerations
- Network partner on-boarding both upstream and downstream
- Building Your Readiness Checklist: Preparing your enterprise and your network for global compliance

Regulatory Environment

Rick Mitzner

Senior Director, Engineering Technology - Pfizer Global Engineering

Rick Mitzner has been with Pfizer for 28 years and currently leads an Engineering Technology team comprised of process engineering, equipment engineering, process automation and Serialization program management. His background at Pfizer includes packaging network strategies, new technology initiatives and implementation of business technology core solutions. Prior to joining Pfizer, Rick worked for Nabisco Brands and Union Carbide in consumer products and food processing plants in the US and Puerto Rico. He holds a B.S. in Industrial Engineering from Lehigh University and an MBA from New York University.

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Operating Company Experience

Mark Wessel

Pfizer Inc.

Bio:

Mark is a Global Serialization Program (PMO) Leader at Pfizer Inc. responsible for enabling serialization across the global internal/external supply network to achieve the program compliance strategy. He has over 27 years of experience in Engineering, Maintenance & Operations in the Pharmaceutical, Agricultural & Chemicals Industry. Mark served as a member of the ISPE Maintenance Guide Core Team and contributing authoring of the published ISPE Facilities & Maintenance Baseline Guide. Prior to joining Pfizer, he worked 15 years in the Chemical & Agricultural Industry holding assignments in areas including: Engineering, Maintenance & Facilities, Reliability Engineering and Production Operations. Mark holds a Bachelor of Science in Mechanical Engineering from the University of Tennessee.