Education

12:30 PM – 1:30 PM

East Clubhouse | Red Level | Room R10

Biotechnology: The Challenge for Tomorrow

This seminar introduces the principles and techniques of biomanufacturing and how human therapeutic products are made from living cells and their components such as bacteria and enzymes.

Biotechnology is the technology of the 21st century and one of the fastest growing industries worldwide. It is an interdisciplinary field that incorporates the expertise of life sciences and various engineering disciplines to produce unique biological products. It requires robust implementation of cell culture and purification processes and the optimization of a number of key variables. Successful operations require achieving high productivity at low operating cost, and meeting the requisite quality specifications set by the Food and Drug Administration (FDA). This presentation will examine what biologics are and how they are processed from a seed stock to a final product, including an overview of the various manufacturing unit operations and critical parameters for each, as well as guidance and requirements for operating in a regulatory environment.

Understanding how the various pieces of the biomanufacturing puzzle fit together is the first step in assuring that researchers, scientists and technicians are capable and confident in their handling of these processes. Join us for this overview presentation and be ready for an interesting journey!

Speaker
Kamal Rashid Ph.D. | Director | Biomanufacturing Education & Training Center at WPI

Dr. Kamal A. Rashid has over thirty years of academic experience in both research and biotechnology educational program development. During his career he has developed, directed and implemented biotechnology and biomanufacturing training courses at Worcester Polytechnic Institute, Utah State University, Penn State University and internationally. He joined Worcester Polytechnic Institute in 2013 to direct the newly established state-of-the-art Biomanufacturing Education and Training Center (BETC).

Dr. Rashid has delivered numerous lectures and training programs in the U.S. and world-wide. Dr. Rashid is well recognized for his continuing education, teaching and international programs. He received a national Faculty Service Award in 1997 from US University Continuing Education Association for his meritorious service to Penn State University. He was also honored in 2011 as the international professor of the year in College of Agriculture at Utah State University. Dr. Rashid received his MSc and PhD degrees from Penn State University.

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"Harder Than It Looks" – Projects Executed Concurrently with Manufacturing Operations

From simple tasks like adding a WFI drop to major process change or expansion, performing project work in an operating GMP facility presents significant challenges. Under the best conditions proper execution of engineering projects for GMP use is complex, but retrofit projects in an operating plant engender additional layers of complexity such as the needs for: extreme preparation and planning, maintaining a production schedule and for choreographing every activity to limit risk to product-in-process. This session will first examine some of the not-so-obvious ways that facility design can impact project design and planning, and then focus on operational considerations that constrain project execution and planning techniques to offset those constraints.

Speaker
Rick Kotosky, P.E., CPIP

Rick has over 20 years' experience in the biotech industry in positions ranging from Process Engineer to Senior Director of Facilities Operations. His engineering design work has included renovation of both cell culture and purification suites from single to multi-product use and expansion of WFI distribution systems. In his Facilities Operations roles he has been responsible for planning and executing numerous full plant shutdowns for retrofit work in facilities ranging from 5 to over 100 years of age, and he has managed start-up of a new facility without impact to adjacent GMP manufacturing operations that shared utilities with the new building. He has recently completed a significant upgrade of bioreactor SIP operations, expanding scope to include renovation of clean steam distribution piping while maintaining project schedule for return to manufacturing operations. Rick holds a BS degree in Chemical Engineering from MIT, an MBA from Boston University and received his CPIP credential in 2013..

Speaker
John Spohn, CPIP, Senior Project Manager, Hargrove Life Sciences New England Operations

John Spohn, CPIP, is a Senior Project Manager with Hargrove Life Sciences New England Operations. John has provided owner's representative services and managed mission-critical projects in biotechnology, pharmaceutical and other industries. He has over thirty years' experience in the design and implementation of automated processes, systems and equipment. John is an active member of the ISPE and earned its Certified Pharmaceutical Industry Professional™ credential in 2011. He serves on the Boston Area Chapter Board of Directors and Educational Program Committee, managing educational presentations and authoring articles and presentations on topics of interest to the Pharmaceutical Engineering community. John is co-author of the Pharmaceutical Engineering 2013 Article of the Year: "Automating a Manual Cleaning Program in a Multi-Product Biopharmaceutical Manufacturing Operation". He holds a BS in Mechanical Engineering from Rensselaer Polytechnic Institute.

Education

1:45 PM – 2:45 PM

East Clubhouse | Red Level | Room R10

Water Based Critical Utilities – RO, WFI, Steam: The bottom of the iceberg that makes a plant actually run!

Regardless of whether water is used to product RO grade, USP Purified, Water For Injection (WFI) or as a source for plant or clean steam, water is the most widely used material in the manufacture and purification of many biotech or pharmaceutical products. Used as an ingredient, a solvent, a diluent, a cleaner, a sterilant, and for other purposes, it is important to understand why water needs to be purified and how municipal water supplies are treated to yield the grades of water and steam required for various uses. This presentation starts with water sources, reviews contaminants and their removal, and discusses various grades of water (lab, ASTM, pharmaceutical grades, etc.) and steam based on the ultimate use. Attendees will come away with an understanding of why different grades of purity exist and why a drug's place in its product life cycle may dictate different purity requirements.

Speaker
Brian Hagopian, CPIP | Chemist | Clear Water Consulting, Inc.

Brian is a degreed chemist from Colgate University. He began his life sciences career in 1977, founded and grew Fluid Solutions from 1989-2006, served as Vice President of R&D for Mar Cor Purification from 2006-2011, and is currently a subject matter expert, consultant, and trainer in the field of high purity water and waste water treatment with Clear Water Consulting, Inc. Brian is a charter member of the Boston Area Chapter of ISPE. He has served two separate stints as Chair of the ISPE Product Show Committee, most recently from 2006-2010 and was instrumental in relocating the Product Show to Gillette Stadium, where it has had unrivaled success. Brian served as Vice President of the Chapter for the 2010-2011 year and President of the Chapter for the 2011-2012 year, when the chapter won an unprecedented fourth consecutive "Chapter of the Year Award".

Education

1:45 PM- 2:45 PM

East Clubhouse | Blue Level | Room B10

Successful Project and Organizational Change through Effective Stakeholder Management

The success of a project or any change initiative is not only limited to a strong business case or delivering a quality product or service. It is critically important to manage your stakeholder expectations so that they stay supportive throughout the lifecycle of the project and look forward to adopting the outcome of the project.

While stakeholders often resist change, the project manager must walk a tight rope in balancing diverse and conflicting stakeholder expectations by negotiating tradeoffs and keeping stakeholders satisfied. New and seasoned project managers must know how to embrace, engage, influence and successfully manage stakeholders.

This interactive seminar will dispel the myth that stakeholder management is limited to identifying who they are, understanding their interests, and keeping them informed of project progress.

You will learn about a highly effective yet a simple stakeholder management framework and valuable tools that will help you proactively identify your stakeholder ecosystem, analyze them and develop a strategy tailored to your project to optimally engage your stakeholders throughout the project lifecycle. Applying these strategies will improve your stakeholder's participation, enhance their support for the project and increase the probability of your project's success.

Speaker
Neeraj Shah, MBA, PMP, SCPM

Neeraj Shah is Associate Director of Global Supply Chain IT, Shire Pharmaceuticals, and is the lead for Shire's Global Supply Chain initiatives as the IT Business Partner.

He has demonstrated a track record of consistently delivering projects that convert strategic business initiatives into operations for over 20 years. He has successfully orchestrated and delivered business solutions, led several strategic projects involving global cross functional teams leading to implementation of ERP systems, regulatory compliance solutions, process improvement and market expansion initiative at Shire Pharmaceuticals, Biogen Idec, Welch's, several GE companies and Applied Materials.

His core competencies lie in:

- Strategic Planning
- Business Process Transformations & Solution Design
- Project Management (Strategic Projects and Portfolio)
- Vendor and Business Relationship Management
- Consultative Leadership, Change Management and Coaching

Neeraj is a regular speaker at various professional and educational bodies like ISPE, APICS, Mass Bio and Middlesex Community College.