Full Agenda
10th Annual NBC2 BIOMAN Conference
July 13 -16, 2015
Ivy Tech Community College, Bloomington, Indiana

Sunday, July 12, 2015

6:00 – 8:00 PM *Welcome Reception*

SpringHill Suites Bloomington
501 N College Avenue
Bloomington, IN 47404

Introductions, brief overview of conference and guide to local area. Hors d'oeuvres will be served.

Monday, July 12, 2015

8:30 – 9:00 AM *Continental Breakfast and Networking*
Training Suite, ICLS

9:00 – 10:00 AM *Keynote Speaker*
Training Suite, ICLS

"*My journey from clinical lab scientist to corporate R&D to entrepreneur: perspectives and lessons learned*"
Robert C. McCarthy, Ph.D., President, VitaCyte LLC

My journey as an applied life scientist spans a time frame where enormous changes occurred in the life sciences-healthcare industry. It started with the shift in clinical laboratory medicine from fee for service to Medicare's diagnostic related groups. The reason for this change was to control healthcare costs. This was followed by the biotech revolution, driven by two technologies: genetic engineering and monoclonal antibodies. These new technologies stimulated the explosive commercial growth of biotech with very few firms being successful and even fewer remaining as independent entities. My role in commercial R&D shifted from the lab to business strategy with the key question faced by many in the mid 1990's: how would the genomics-proteomics revolution impact my business, my way of life? A few questions have been answered, but many more remain. The key lesson from this period is that technology is accelerating at a pace never seen before in this industry. It is insufficient for new entrants with a promising technology to create a successful business. Those companies that will succeed will have deep insights into the dynamics of the industry, create a sustainable business model, and will benefit from a good bit of luck! Presently, the challenge I face is to decide how to position VitaCyte to maximize its value in the emergence of the cellular therapy-regenerative medicine revolution. This decision, although challenging, will be guided by my personal experience and lessons learned, some of which will be shared during this presentation.

10:00 – 10:15 AM *Break*

10:15 AM – Noon *Interactive Sessions or Hands-On Workshop*

Interactive Session: Funding Your Project

S102

V. Celeste Carter, Ph.D., DUE Lead Program Director, NSF
Sonia Wallman, Ph.D., NBC2 Principal Investigator and Executive Director

Led by Celeste Carter, this interactive session will provide insights into grant writing and tips for developing a good proposal.

OR

Interactive Session: Tools to Enhance Your Program: SBIR/STTR Grant Partnerships and Digital World Biology

S101

Sandra Porter, Ph.D., President, Digital World Biology LLC and Co-PI, Bio-Link

Businesses that are funded by the Small Business Innovation Research (SBIR) Program at the National Science Foundation are eligible for supplemental funding that can benefit community colleges, instructors and students. These businesses are natural allies and partners for members of the ATE community. In this session, we will describe the SBIR program and its goals, describe the supplements, and describe how to find and contact the companies that have been funded in your area and field. We will discuss ways to connect with these companies before they apply for SBIR funding and how you can help them with SBIR grants.

OR

Hands-On Workshop: Confidence in Data Integrity through Pipetting Technique Training and Pipette Repair and Maintenance

S108

Candie Gilman, Training Product Manager, Artel

Did you know that common pipetting technique errors can contribute to volume discrepancies that can lead to false assay results? Experts agree: pipetting performance is critical to obtaining accurate test results. Attending this seminar will arm you with the tools to implement best practices in pipetting within your own laboratory. During this seminar, you will learn how to standardize proper technique, identify causes of pipette failure, and recognize ergonomic risk factors and sources of stress.

The Pipette Repair and Maintenance module will help you become familiar with basic pipette anatomy and procedures for maintenance and repair of air displacement piston pipettes. Sample pipettes will be provided for conducting hands-on pipette maintenance.

Noon – 1:00 PM	*LUNCH* *S102*
1:30 – 4:30 PM	*Hands-On Workshops*

Hands-On Workshop A, Beginner Track
Expression & Purification of Thermophilic DNA Polymerases: Educational resources for teaching biomanufacturing
S107
Tom Burkett, Chesapeake Bioworks, LLC and NBC2
Tim Kull, Biotechnology Lab Assistant, Montgomery County Community College, Blue Bell, PA

Biomanufacturing is used to produce products ranging from high-value protein pharmaceuticals to commodity chemicals. In this workshop you'll learn how production of thermophilic polymerases can be used as a model system to teach the fundamentals of biomanufacturing and can be adapted to be part of a broader course in biotechnology or expanded to a comprehensive course in biomanufacturing. Participants will be provided with protocols covering the cloning, expression, purification, and quality assays used in the production of thermophilic polymerases and will become familiar with kits available through NBC2 that provide all of the materials necessary for expression, purification and quality control of the enzyme product. Laboratory activities will focus on the expression, purification, and quality assays used in producing Taq DNA polymerase at small and large scale.

OR

Hands-On Workshop B, Intermediate Track
Drug Product Manufacturing: Formulation, Fill and Finish — *Parenteral Drug Formulation*
S104
Jeff Schwegman, AB-Biotech

OR

Hands-On Workshop C, Advanced Track
Myoblasts to Osteocytes: Multipotent Stem Cells for Regenerative Medicine
S108
Bill Woodruff, Dept. Head, Biotechnology, Co-Principal Investigator NBC2, Alamance Community College, Graham, NC
Maggie Bryans, Ph.D., Assistant Professor of Biotechnology, Co-Principal Investigator NBC2, Montgomery County Community College, Blue Bell, PA

Introduction to stem cells and subculturing. Presentation of stem cell basics regenerative medicine and the increasing need for cGMP protocols in the real world use and applications of these technologies. The hands-on lab will be spent subculturing mouse myoblast (cell line C2C12) for use on Tuesday.

Tuesday, July 14, 2015

8:30 – 9:00 AM *Continental Breakfast and Networking*
Training Suite, ICLS

9:00 – 10:00 AM *Keynote Speaker*
Training Suite, ICLS

"The Legacy of Cook Medical Bloomington, Indiana"
Rick Mellinger, VP of Global Marketing, Cook Medical

10:00 AM – 1:00 PM ***VENDOR SHOW****-Biomanufacturing Equipment and Supplies Vendors*

12:30 – 1:00 PM *Vendor Show Drawing*

1:30 – 4:30 PM *Hands-On Workshops*

Hands-On Workshop A, Beginner Track
Expression & Purification of Thermophilic DNA Polymerases: Educational resources for teaching biomanufacturing
S107
Tom Burkett, Chesapeake Bioworks, LLC and NBC2
Tim Kull, Biotechnology Lab Assistant, Montgomery County Community College, Blue Bell, PA

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OR

Hands-On Workshop B, Intermediate Track
Drug Product Manufacturing: Formulation, Fill and Finish — *Parenteral Drug Product Filtration and Filling*
S104
Mark Kruszynski, Cook Pharmica, LLC
Cindy Webster, Cook Pharmica, LLC

OR

Hands-On Workshop C, Advanced Track
Myoblasts to Osteocytes: Multipotent Stem Cells for Regenerative Medicine
S108
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Presentation about directed differentiation of stem cells and the process of sterile gowning. Hands-on will include actually gowning and entering the cell culture suite to treat the C2C12 cultures from the previous day with Bone Morphogenic Protein 2 (BMP2) to direct differentiation from myoblast (muscle) to osteobalst (bone).

6:00 PM ***Event Reception and Dinner***
Oliver Winery

Wednesday, July 15, 2015

8:30 – 9:00 AM *Continental Breakfast and Networking*
Training Suite, ICLS

9:00 AM – Noon *Hands-On Workshops*

Hands-On Workshop: QC Microbiology

S108

Maggie Bryans, Ph.D., Assistant Professor of Biotechnology, Co-Principal Investigator NBC2, Montgomery County Community College, Blue Bell, PA
Linda Rehfuss Ph.D., Assistant Professor of Biotechnology and Biology, Co-Principal Investigator of NBC2, Bucks County Community College, Newtown, PA
Sheila Byrne, Grant Assistant, Department of Biotechnology, Montgomery County Community College, Blue Bell, PA
Tim Kull, Biotechnology Lab Assistant, Montgomery County Community College, Blue Bell, PA

Microbiological control is a key issue in pharmaceutical manufacturing. This workshop is designed to introduce you to experiments and techniques used in the industry to prevent microbial contamination of products. In this hands-on workshop participants will perform three microbiology experiments. The Limulus Amebocyte Lysate (LAL) gel clot assay will be used to measure endotoxin levels in cell culture samples, the Gram stain will be used to identify Gram positive and negative bacteria, and finally the colorimetric API assay will be used to identify bacterial strains. Participants will also learn how to conduct microbial air monitoring using equipment commonly used in Microbiological Control laboratories such as an Air Sampler and Particle Counter.

OR

Hands-On Workshop: Downstream Processing: TFF Principles

S104

Sengyong Lee, Ph.D., Biotechnology Program Chair, Co-Principal Investigator NBC2, Ivy Tech Community College, Bloomington, IN

Tangential Flow Filtration technique is one of the essential filtration steps during the drug substance and drug product manufacturing operation. Ivy Tech Community College Bloomington developed a short (4 hours) teaching module on the topic through a collaboration with its local industry partner, Cook Pharmica. This session will introduce the filtration basics, the comparison between NFF and TFF, the main steps in the TFF operation, the validation test methods, the main applications of TFF, and two hands-on exercises developed for bench scale TFF operation units.

OR

Hands-On Workshop: Detection of Rabbit IgGs using ELISA

S107

Barbara Bielska, Ph.D., Professor of Biotechnology and Biotechnology Program Coordinator, Northampton Community College, Bethlehem, PA

Enzyme-Linked ImmunoSorbent Assay (ELISA) is designed for detecting and quantifying substances such as peptides, proteins, antibodies, and many other molecules. ELISA is a powerful immunological method used by the QC departments and as a diagnostic tool in the health care industry. The method is easy to perform and yields graphic results making it well suited for the teaching laboratory.

In this experiment a goat-anti-rabbit IgG antibody (conjugate) is used to study the specificity of an antibody-antigen reaction. Goat-anti-rabbit-IgG antibodies will recognize and bind to IgG molecules present in rabbit serum.

The objective of the experiment is the comparison of binding of Goat-anti-rabbit IgG to IgGs in serum from rabbit, chicken and horse. The anti-rabbit IgG has been chemically linked to enzyme peroxidase, which causes a color-producing reaction. This reaction enables studying the antibody-antigen interactions.

Noon – 1:00 PM *LUNCH*
S102

1:00 – 5:00 PM **FIELD EXPERIENCE**

Cook Pharmica

OR
Cook Medical

OR
Eli Lilly

*****Please note: A dress code of closed-toe shoes and pants will be strictly enforced on all tours. Participants must also bring government-issued identification, such as a driver's license or passport.***

Thursday, July 16, 2015

8:30 – 9:00 AM *Continental Breakfast and Networking*
Training Suite, ICLS

9:00 – 10:00 AM *Keynote Speaker*
Training Suite, ICLS

"Biologics Formulation and DP Process Development"
Frank Li Ph.D., Director of Process Development, Cook Pharmica, LLC

10:00 – 10:15 AM *Break*

10:15 AM – Noon *Interactive Sessions*

Interactive Session: Strategies for Developing Local Biomanufacturing Career Pathways
S102
Sonia Wallman, Ph.D., NBC2 Principal Investigator and Executive Director

OR

Interactive Session: Biopharmaceutical Development and Production

S101

Mike Fino, Department Chair, Biotechnology, Co-Principal Investigator NBC2, MiraCosta College, Oceanside, CA

The development of biopharmaceuticals increasingly utilizes a Quality by Design (QbD) approach to improve process understanding. Process understanding comes from the ability to explain the variability of process inputs and outputs. QbD is a framework that helps to connect product quality attributes (outputs) with process parameters (inputs). The ability to explain sources of variability is a hallmark of industrial design of experiments (DOE).

This workshop will extend the basic statistics needed to understand DOE and see how examples of DOE are used to build process understanding towards quality biopharmaceutical production.

OR

Interactive Session: Quality Systems for Bioscience Manufacturing

S109

Gretchen Ingvason, Senior Learning Specialist, Analytical Laboratory and Quality Systems, Mount Wachusett Community College, Devens, MA

Manufacturing quality products or providing quality services (e.g. testing services) are essential for companies to thrive in today's global marketplace. Quality Assurance and Quality Control functions are present in organizations to maintain both customer satisfaction and loyalty, while reducing the risk and costs of replacing faulty goods or incorrect analysis results. Companies build a reputation for quality by: a) following regulations such as the US FDA requirements for medical devices and pharmaceuticals, or b) gaining accreditation with a recognized quality standard such as ISO 9001, published by the International Organization for Standardization. This presentation will discuss quality systems from a manufacturing perspective and demonstrate how QA/QC can be integrated into a variety of curriculums.

Noon – 1:00 PM *LUNCH*
S102

1:30 – 4:30 PM *Hands-On Workshops*

Hands-On Workshop A, Beginner Track

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OR

Hands-On Workshop B, Intermediate Track
Drug Product Manufacturing: Formulation, Fill and Finish — *Parenteral Drug Product Inspection, Packaging, and Labeling*
S104 ICLS
Jo Anne Jacobs, Cook Pharmica, LLC
Jonathan Balash, Cook Pharmica, LLC
Cindy Webster, Cook Pharmica, LLC

OR

Hands-On Workshop C, Advanced Track
Myoblasts to Osteocytes: Multipotent Stem Cells for Regenerative Medicine
S108, ICLS
Bill Woodruff, Dept. Head, Biotechnology, Co-Principal Investigator NBC2, Alamance Community College, Graham, NC
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Presentation on the need and methods to determine if directed differentiation results in the actual cell type planned for and expected. Hands-on lab will be an assay to determine that the myoblast (non-alkaline phosphatase producers) have become osteoblasts (prolific alkaline phosphate producers) by the detection of AP activity.

NSF DUE #1204974