



BIOMAN JOURNAL 2010

Biomanufacturing educators converge, join with industry at Indiana Life Sciences Center

Educators in biomanufacturing from around the nation gathered at the Indiana Life Sciences Center at Ivy Tech Community College in Bloomington from July 11 to 15, for the 2010 BIOMAN conference.

These four days of hands-on laboratories, panel discussions, lectures, and keynotes provided much more than enhanced skills and information. BIOMAN is known for its networking - the connections people make here prove valuable. Faculty return home with enlarged understanding of the biomanufacturing field, tips in running sophisticated hands-on labs, NBC² lab manuals, plus ideas for new equipment and supplies to help them engage their students in this growing field.



Biotech faculty learn from workshop presenter Barbara Bielska (above, right) how the enzyme linked immunosorbent assay can be used for diagnostic tests and as research tools. Plus, the antibody-antigen interactions, which are key to ELISA technology, are used by the biopharmaceutical industry to target cancer.

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July 11-14 in San Diego, California
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Pichia pastoris workshop



Using the tools, processes and regulations of the biomanufacturing industry, the workshop on production of Human Serum Albumin (HSA) in *Pichia pastoris* - part of the global biomanufacturing curriculum produced by NBC² - replicated a several week process in four days. The first day began with inoculation of *P. pastoris* into a five liter New Brunswick bioreactor previously filled with sterile media for upstream processing. Students took samples for quality control biochemistry analysis on all four days. Downstream processing, using a Bio-Rad low pressure liquid chromatography system, was used to purify HSA from *P. pastoris* cell culture on day three. Examination of upstream and downstream samples using SDS-PAGE analysis looked for the presence and concentration of the protein of interest, HSA, on the final day.

NBC² works to ready a skilled biomanufacturing workforce

Biomanufacturing uses the forces of life to manufacture important products, from therapeutic proteins to biofuels. Jobs require advanced technology training in well-equipped biotech/biomanufacturing facilities. Thanks to growing demand from industry for skilled biomanufacturing workers, from 1998 to 2007 the number of active biotech and pharmaceutical programs at two year colleges grew from 49 to more than 90. Nearly all these college programs are partnered with a neighboring biomanufacturing company. NBC² provides education and training materials in the form of hands-on laboratory manuals and other curriculum available at www.biomanufacturing.org/biocurriculum.html. The beginning of a support site for these materials can be found at www.biomanonline.com and a textbook is promised for fall 2011. The materials are suitable for training entry level and incumbent workers.

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Sonia Wallman

Technicians are key to biomanufacturing growth

A study conducted by Battelle, BIO, and the Biotechnology Institute in 2009 revealed some good news: post secondary bioscience graduates at all levels (associate, bachelor, master's and doctorate) grew by a robust 12.8 percent from 2006 to 2008. But the report also raises concerns.

Surveys show the United States continues to fall behind in math and science education at the K-12 level. The nation may have trouble meeting the needs of bioscience companies for skilled, technical workers. Three high school teachers attended BIOMAN 2010, stimulated by earlier Protein is Cash workshops they attended: Matthew Christian and Greg Panzanaro from upstate New York and James Leach from Rhode Island.

Industrial biomanufacturing facilities are located in each region and the faculty seek information and hands-on activities to bring back to their biology, chemistry, physics and biotechnology courses. These stimulate student understanding and interest in biomanufacturing careers.

"BIOMAN brings educators together to network; engage in hands-on science, technology, engineering and mathematics, share ideas, curriculum and new techniques. Tours

of biomanufacturing sites, keynote speakers, the vendor show, and hands-on work all inspire faculty and teachers and bring new industry contacts," said Dr. Wallman.

This high growth industry is driven by demand for technicians who know the good manufacturing practices required in the highly regulated biopharmaceutical manufacturing industry. Two year associate degrees and certificates in biomanufacturing bring opportunities as technicians in upstream processing (cell culture), downstream processing (purification), quality control, quality assurance and several other areas. At an average age of 29, many two year graduates have more experience than their four-year counterparts. Some are returning students who have already earned degrees and are seeking to change or expand their careers.

Vendor Show



Greg Panzanaro, who teaches high school science, tries his hand at Artel's annual pipetting contest.



Biomanufacturing supplier reps (from left) BioTek, Buck, Artel, Wards, New Brunswick, Promega and BioExpress. Also participating were Bio-Rad and NBC². Along with learning about industry innovations from these vendors, participants benefit from raffle prizes they bring.

Making Biofuels: enzymes and energy

Biofuel derived from plant matter, ethanol reduces hydrocarbon emissions of fossil fuels. It's produced through the earliest biotechnology technique known - fermentation. Most ethanol comes from starches or sugars in food crops such as corn. But ethanol can also be produced from plant wastes by using enzymes. "Cellulose is the most abundant substance on the earth" said Bio-Rad's Sherri Andrews, "Cellulose is a polysaccharide found in the cell walls of plants. We have the enzymes - called cellulases - to get glucose from cellulose." Microbial fermentation processes produce ethanol from glucose.



Bio-Rad's workshop presenters Sherri Andrews and Michelle Gilbert

Bio-Rad's biofuel enzyme kit reveals the power of enzyme kinetics utilizing a cellulase in mushrooms. It illustrates by providing a real-world experience of one stage of cellulosic ethanol production. "We've written production and quality control procedures as they are used in biomanufacturing," said Bio-Rad's Michelle Gilbert.

Students can test and calculate the rate of conversion of cellulosic raw material to glucose in the presence or absence of enzymes that are part of the cellulase family. "Kits make teachers' jobs easier. It's not just science, it's engaging!"



Educator Judith Fitzpatrick works with enzymes and new teaching tips



Melissa Britton (left), a student and lab assistant in the biomanufacturing program at Ivy Tech, stands beside the AKTA with Travis Holle and April Wheeler - two technicians from Cook Pharmica who conducted the workshop for BIOMAN 2010.

Cook Pharmica and Ivy Tech - a productive partnership

A glass-walled room, filled with workstations, buzzes in activity. "This is what we call the fishbowl," said Chris Keith, a Cook Pharmica Quality Engineer. "This is where we control the whole facility." He was leading a tour for the BIOMAN group. Interested educators moved through halls where bioreactors, centrifuges, two 3500-liter harvesting tanks and other large scale biomanufacturing equipment could be seen in operation. Keith and his company value their relationships with Ivy Tech, the nearby Indiana community college hosting BIOMAN.

"I worked as a manufacturing quality en-

gineer in the automotive industry. I took the certificate program at Ivy Tech. It helped me learn the basics. I felt more confident. I was able to get in the door with no pharmaceutical background," said Keith. "Cook has a good partnership with Ivy Tech, we look to hire workers from there because they know what we need. We hire interns from Ivy and some of our employees also teach there." Indeed, a demonstration and workshop on AKTA liquid column chromatography was conducted for BIOMAN by Travis Holle and April Wheeler - two technicians from Cook Pharmica.

Building the Indiana Center for the Life Sciences

Working together for years to plan, design, and build, many people and organizations celebrated when the Indiana Life Sciences Center first opened for business in 2009. It culminated a building program created to meet many vital needs. In some ways, the project began with the Northeast Biomanufacturing Center and Collaborative. When Ivy Tech was seeking ideas and advice in the early planning stages, the NBC² responded.

Dr. Sengyong Lee, Associate Professor and Program Chair in Biotechnology at Ivy Tech Community College said: "When I attended my first BIOMAN in 2005, I saw the perfect model for our lab in New Hampshire. Dr. Wallman helped provide resources, examples and information in our planning process. The NBC² also provides a model for the Midwest regional biomanufacturing alliance - BEAM."

John Stephens, Director of the Indiana Center for Life Sciences, and Executive Director of the Life Sciences Initiatives at Ivy Tech Community College said: "Along with the four complete laboratories, we used the industry and expert input to



Sengyong Lee

help design our flex space. We left this four thousand square foot training area open so biomanufacturing companies, our industry partners, can bring in their own equipment and do their own incumbent training here, supported by our labs. It's surpassed our expectations. We've averaged eight hours a day utilization since January. The life science companies feel some ownership, and our students have gained about fifteen adjunct faculty and guest speakers through these relationships. We want to grow it. Dr. Lee and I got a grant to hire an outreach coordinator, Reuben Lidster, who will contact more companies and develop more programs. Plus this building is a model and a center for developing a Midwest alliance of bioscience partners, along the lines of NBC². We are passionate about growing this."



John Stephens

A BEAM into the Future

The United States bioscience industry, despite the economic downturn, added 19,000 industry jobs in 2008. As bio-based materials take the place of petroleum-based products, even more trained technicians will be needed. The Northeast Biomanufacturing Center and Collaborative is a successful model with more than two hundred collaborators, from education, industry and organizations. They serve together fostering learning communities in biotechnology/biomanufacturing clusters in thirteen states.

Community colleges cut training times for industry partners, delivering well-qualified, skilled workers. Biomanufacturers, in turn, teach for community college biomanufacturing programs, provide apprenticeships and internships, along with in-kind contributions



Reuben Lidster

of equipment, supplies and financial support.

With the successful completion of the new Indiana Life Sciences Center, interest in duplicating the NBC² increases. Calling for a new biomanufacturing alliance, more than a dozen motivated participants attended a workshop conducted by the Ivy Tech faculty Sengyong Lee, Reuben Lidster, and Sarah Cote. Representing many areas of the nation, educators discussed grant opportunities, best practices, curriculum issues and what skills are best. "All the pieces are out there," said Tom Deitz, describing grants and funding flowing now to Lansing Michigan bio-based projects. "I want to see more industry involvement here in Indiana," said Reuben Lidster, the Outreach Coordinator for the Indiana Life Sciences Center. Surveys and applications for funding are being pursued to create a new alliance, the Biosciences Educators Alliance of the Midwest - BEAM.



Sarah Cote

Microbiology Tool Kit

Participants learned and used a full spectrum of tools and processes common to Quality Control Microbiology, including environmental monitoring devices and tests for endotoxin.



Sandra J. Kattermann is assistant professor of regulatory affairs in the biotechnology department at Ivy Tech. She has an MS in Jurisprudence and Pharmaceutical Health Law. She is a diversified, seasoned professional from industry, with experience working with Johnson and Johnson, Pfizer, Knoll and Bayer Consumer Care. She conducted three sessions of her professional development workshop: Introduction to the Regulatory Affairs and the FDA; A Case Study: HPV Vaccine Clinical Trials; and Risk Management: Why is it important?

Keynote Speakers

Medical Devices: Magical Mystery Tour
Dr. David Chadwick, Cook Medical (Monday)
Principles and Applications of Lyophilization
Dr. Michael Akers, Baxter BioPharma Solutions (Tuesday)
Cell Line Development for Biomanufacturing
Dr. Aaron Pilling, Cook Pharmica (Thursday)

Participants in the Virtual Chromatography workshop with Yakov Cherner, Ph.D. experienced amazingly life-like simulations of actual biomanufacturing equipment and processes. Cherner's "Active Learning" approach, combined with teacher instruction and hands-on experiences in the lab (called blended learning) produce quick results. "We help learners by making science, technology, engineering and mathematics engaging, interactive and visual," said Cherner.



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Shuffling the data: Statistical Issues in Biomanufacturing (Lot Acceptance and Clinical Trials)

Surrounded by hundreds of bio-related businesses in San Diego County, Miracosta Community College bioprocessing professor Mike Fino is well versed in the industry. In his well-attended workshop on Statistical Issues in Biomanufacturing, he expanded educators' understanding of this challenging subject. Using data from actual clinical trials in a clear and carefully organized presentation, Fino delighted participants with card tricks. That is, he passed out decks of cards to use and simulate the clinical trial process.

Not all crucial processes of biomanufacturing happen in laboratory conditions. The complex ways companies bring their discoveries to market is vital to the industry as well. Compliance with government regulations is required at every step.

Among the statistical concepts Fino covered is the "null hypothesis." This skeptical notion assumes what's being studied actually has no effect on the results measured. It's similar to what a jury faces. A null hypothesis would be the accused is innocent. Prosecutors must prove the null is wrong. But a jury rejecting the argument does not necessarily mean innocence. It could mean evidence is insufficient. Studying statistics, scientific processes can be used to show how close the null is to being true - or the opposite.

The first study Fino focused on was an evaluation of the neuroprotective effect of procrit (a glycoprotein that stimulates red blood cell production) versus placebo in patients with cancer who develop chemotherapy-induced peripheral neuropathy. Projecting a slide, Fino pointed out some initial results - patients using procrit who developed the neuropathy numbered 26 percent. The group receiving the

placebo was much larger, 55 percent. "We want to know: if the procrit is truly not effective in helping, how often would the random assignment process alone lead to such a difference between the treatment groups?" said Fino. "We answer this by replicating the randomization process, while assuming procrit is not effective." Then Fino had everyone take out the cards. "We each pull out 11 face cards - these are the afflicted patients. Then take out 19 number cards - the non-afflicted. Then we take all 30 cards, shuffle them and deal. We randomly assign 19 to the procrit therapy group and the remaining 11 to the placebo group."

Working together, participants then employed versions of actual trial procedures to analyze their card dealing data. They used statistical formulas in their calculations to compare results to the null hypothesis.

"Oohs" and "aahs" were heard as participants became surprised or fascinated as Fino plotted results in graphs designed to determine the efficacy of procrit.

More importantly, educators in attendance were developing a deep understanding of how the biomanufacturing sector of the biotechnology industry really works. They were also learning new ways to integrate statistical analysis into their biomanufacturing courses.



Mike Fino illustrates complex statistical analysis



Educators shuffle cards in a statistical simulation of the clinical trial process so crucial to biomanufacturing.

Among the comments heard after the workshop were:
 "Excellent, helped demonstrate how to clear up statistics misconceptions."
 "This would be great exercise for students to show the importance of stats in manufacturing."
 "Mike did a great job explaining the concepts and statistical views."
 "Stats is something used in my job daily. Yet I need more information on what I'm doing in my stats work and this content was spot on."



Mike Fino

Tours

BIOMAN 2010 participants (right) examine aquatic and algal growth near Indiana's largest coral reef. Consensus is building around algae as the bio-fuel that can most quickly be put into massive production. At the winery (below) biomanufacturing educators took a tour to learn more about fermentation, one of the basic elements of biomanufacturing technology.



Bloomington is the American home of the Dalai Lama



Some BIOMAN participants visited the shrines and temples of the Dalai Lama in Bloomington



Socializing at BIOMAN 2010



The winery featured wine tasting (above) and dining al fresco (above right). With Indiana University campus right next door, downtown Bloomington streets feature international restaurants along with numerous bistros, bars and boutiques.



This Tibetan restaurant (right) was a big hit.

Participant Quotes

George Twaddle (Biotechnology Program Chair at Ivy Tech Community College, Indiana): "It's inspiring to meet colleagues confronting the same problems in education with force. We're learning more about how students can learn. It's a giving community. Not like scientists who meet and say, 'I can do this.' Here it's 'I can show you how to do this.' Feeling part of a community means we become resources for each other."

Judith Fitzpatrick (Assistant Professor, Bergen Community College, New Jersey): "I had a good time! It's a great way to see how other people's classes run. A great way to keep up with what teachers are doing. There's so much power in collaboration. But you can't collaborate if there isn't a sense of trust. Developing that is impossible on the internet!"



Amrutha Kuraguntla tests BSC for particulates and air flow.

Amrutha Kuraguntla (Biology Professor, Cecil College, Maryland):

"Our college is a small world. When I was in BIOMAN I learned there is a community. I've gained strength and courage to carry on and create a new program. The exceptional friendships I've made here will help me. I have lots of things to take back."

Matthew Christian (Science Teacher, Berlin High School, New York):

"It's a wonderful opportunity for me to meet tons of colleagues from around the country who can help me with my projects."

Matthew Christian (right) makes a sensitive adjustment to the bioreactor during the Pichia workshop.



James Leach (Teacher, Burrilville high school, Rhode Island):

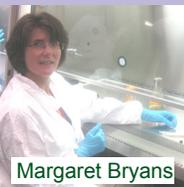
"Friendly, outgoing and fun makes it better. Sarah gave us electronic files of her lectures and syllabus to use. We got a lot of hands-on help in the labs. It's not just talk about it, we do it. Ivy Tech's facility is amazing."

Janice McKenzie (Biotechnology Program Chair at Ivy Tech Community College, Indiana):

"The nicest thing is to share challenges with the team, commiserate, troubleshoot. Sonia's built a community that really works. Students forget what they read, but if you do something hands-on, they remember."

Margaret Bryans (NBC² Program Manager, Montgomery County Community College, Pennsylvania):

"BIOMAN 2010 was a great success! A great opportunity for high school and community college teachers to learn techniques and possibly new topics to introduce into their curriculum. It also gives them the opportunity to network, meet experts in the field and start collaborations. The informal nature of the presentations and workshops allows people to ask questions and get all the take home information they need. Knowing the price of reagents and other supplies is very useful when setting up a new program or lab."



Margaret Bryans

Reuben Lidster (Outreach Coordinator, Indiana Center for the Life Sciences): "As an educator this is the most productive conference I go to every year. And as a person working with industry this is the best conference for a lab technician."

Vivian Ngan-Winward (Director, Biomanufacturing Program, Salt Lake Community College, Utah. Active in the InnovaBio program, promotes entrepreneurship):

"Registration: \$400

Travel: \$500.

Time taken: 4 days.

Networking with engaged, passionate instructors and industry representatives: Priceless!"



Vivian Ngan-Winward



www.biomanufacturing.org

VISION

To be the nationally recognized center of excellence that develops a world-class sustainable biomanufacturing workforce to improve the quality of life.

MISSION

To coordinate local and regional efforts into a national biomanufacturing education and training system to promote, create, and sustain a qualified workforce.

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