



BIOMAN 2012 JOURNAL

Alamance Community College Hosts BIOMAN 2012 - focus on stem cells, biofuels, regenerative medicine, and biopharmaceuticals

The Seventh Annual NBC2 BIOMAN Conference brought biomanufacturing educators together with industry experts to the advanced laboratories and facilities of Alamance Community College in Graham, NC, from July 23 to 26, 2012. This was the largest group ever assembled for BIOMAN's hands-on workshops, keynotes, panel discussions, vendor show, tours and other activities. The event helps prepare highly-trained technicians for the growing biomanufacturing industry. Participants value this unique opportunity to meet new contacts. It's a chance to spend time with people from around the country who teach biomanufacturing. "It's perfect for learning what others are doing and sharing," said one participant.

Participants spend time in large or small groups, mostly doing hands-on lab activities together. Off-site visits to active biomanufacturing companies offer even more first-hand, useful information. At the popular Vendor Show, educators can see and try out the latest biomanufacturing equipment.

Educators come to BIOMAN with different levels of knowledge about biomanufacturing; NBC2 provides tracks - introductory, intermediate and advanced - so participants can match their needs. It's clear that sustainable biomanufacturing will create millions of jobs nationwide. More and more skilled technicians will be needed; learning necessary technical operations in actual working situations, shoulder-to-shoulder, hands-on, means students will directly benefit. BIOMAN educators take away these new, innovative means of engaging students.



Tim Bertram

Keynote address: Regenerative Biomanufacturing with Tim Bertram

Tengion is a leading regenerative medicine company discovering more about the body's healing processes, in order to create products that support healing. One product is in clinical trials now, already aiding bladder cancer patients with regeneration. Tengion has launched its pilot cGMP manufacturing facility in Winston-Salem, NC. No one knows more

about this emerging biomanufacturing industry than Tim Bertram, Tengion's Chief Scientific Officer since 2004. In his keynote address to BIOMAN 2012 participants, he spoke specifically to educators about the technician (*continued on page 4*)



Advanced Track: Stem Cells

Biotechnology Professor and BIOMAN 2012 host Bill Woodruff adjusts fluorescence microscope to show CHO cells expressing fluorescently tagged actin (green) and a second protein that localizes in the mitochondria (red).

Bill Woodruff kicked off a three-afternoon workshop series on stem cells with hands-on cell culture instruction on how to grow and maintain mouse embryonic stem cells (ESCs). Media requirements and supplements required to prevent spontaneous differentiation were covered. Participants prepared feeder layers using mitomycin C treated mouse embryonic fibroblasts for inoculation with stem cells. Pluripotent embryonic stem cells have the potential to become any cell type in the mature organism. One of the main research areas in stem cells has been, and continues to be, understanding the many elements that go into directing the differentiation of stem cells to meet

(*continued on page 3*)



Sarah Cote of Ivy Tech Community College prepares stem cells, aseptically, using a BSC (Biological Safety Cabinet)



BIOMAN 2012 and BIOFUELS



NBC2 is a National Science Foundation Advanced Technological Educational Center for Biomanufacturing located at Montgomery County Community College in Blue Bell, PA



Sonia Wallman, Ph.D.
NBC2 Executive Director

The bioeconomy currently comprises 2% of the United States GDP. Biofuels and industrial biotechnology manufacturing is the biggest (\$115 billion) and fastest growing segment of the bioeconomy, which also includes biopharmaceuticals (\$75 billion) and agriculture (\$110 billion). BIOMAN 2012 featured many opportunities to explore the expanding world of biofuels including:

- Keynote speaker W. Steven Burke, President and CEO of the Biofuels Center of North Carolina
- Switch to Switchgrass, a hands-on laboratory presented by Kellie Aitchison of Finger Lakes Community College in New York
- Integrating Biofuels into Your Biotechnology Program, a panel with Danny Kainer of Lonestar College in Texas and Jim Hewlett of Finger Lakes Community College in New York
- Tour of the Piedmont Biofuels Center, Raleigh, North Carolina
- Meet-Up to Plan a Biofuels Workforce Summit

Keynote speaker Steven Burke presented an interesting perspective on biofuels production – they should be made and utilized locally/regionally. The Biofuels Center of North Carolina funds local and regional production of various biofuels throughout the state. One of these places is the Piedmont Biofuels Cooperative in Raleigh - one of the three sites for BIOMAN 2012 tours of biomanufacturing facilities. The Piedmont Biofuels Cooperative is part of a Community Supported Agriculture (CSA) group. Over the last 20 years CSAs have become a popular way for consumers to buy local, seasonal food directly from a farmer. The farmer offers a certain number of “shares” (also called a “membership” or “subscription”) to the public. Typically, *(continued on page 4)*

Panel Discussion: How to Write A Successful Grant Proposal

Celeste Carter led the panel and offered her own tips on negotiating the world of National Science Foundation (NSF) grants. FastLane, for example, is an online feature NSF uses to interact with professional collaborators. Using slides and graphics, Carter gave a tour of the vast NSF website resources - specifically for biomanufacturing educators. Pointing out the “QuickLinks” button on the top of the www.nsf.gov homepage, she suggested clicking on the Education and Human Resources banner to find a range of relevant choices. She pointed out the Division of Undergraduate Education as being important for community college and high school instructors.



Of special interest is the exciting Transforming Undergraduate Education in Science (TUES) program. Grant opportunities here include Creating Learning Materials and Strategies; Implementing New Instructional Strategies; Developing Faculty Expertise Strategies; Developing Faculty Expertise; and Assess- *(continued on page 5)*

Online Tools and Resources for Biomanufacturing Education and Training

A buzzword at BIOMAN was the “reverse” classroom - students today can watch and learn anywhere on video. Class time can then become time for hands-on learning experiences together. An interactive BIOMAN session presented by Mike Fino, Biotechnology Program Coordinator



at MiraCosta College, Oceanside, CA, and Lara Dowland, Chair of the Biotechnology/Biomanufacturing Department at Mount Wachusett Community College, Devens, MA, looked at the ways online tools can be used in teaching biomanufacturing. “I can record my voice and what I do on the screen. Students can then follow along, or use the pause button to reorient or go back,” said Fino. “First students gain a background in the new subject. Then we do hands-on work together.” Fino recommended Camtasia, a program educators can use to create videos that students can watch anywhere, even on their own mobile devices.

Speaking from personal experience, the professors recommended breaking the course curriculum into modules, keeping material in sequence, with graded assignments and significant deadlines to keep students progressing together. “How you design and implement the structure of your online class is important,” said Dowland. “Follow a pace; you don’t have to have everything all out there at once.” The teachers embraced the potential of this “social network style” of learning. “We have online ‘discussion chambers’ that are required. Different options and opinions are offered, we need to see good questions,” said Dowland. “The socialized environments allow more time for discussion, more thoughtful feedback,” said Fino. “We can take feedback, revamp things that aren’t working.” The North Carolina BioNetwork site was recommended for engaging and useful videos. “And don’t forget YouTube, you can find some amazing things on there.” The hardest part, BIOMAN participants agreed, was getting an online program started. Said Dowland, “It takes a long time to prepare a program like this and get the technology to start it. You might consider starting small, building up in stages or phases.”

www.biomanufacturing.org

Beginner Track

For those participating in the NBC2 BIOMAN Beginner Track, the cloning, expression, purification and analysis of Taq Polymerase - a most useful enzyme in biomanufacturing - was the starting point. Tom Burkett, Ph.D., Professor of Biotechnology at the Community College of Baltimore County in Catonsville, MD, conducted lab exercises focused on Taq Polymerase used in biotechnology and biomanufacturing courses.

On the last day of BIOMAN he also conducted the "Now that you have a bioreactor what are you going to do with it?" workshop. This included things to keep in mind when purchasing a bioreactor: how to set up and maintain it; what you can do with a basic system; a look at different models of bioreactors available today. Considerations in purchasing and setting up a reactor were discussed, including failure modes and preventive maintenance. Examples of how students can use a bioreactor and the data it generates to design and operate a robust expression system for



producing useful substances were included.

The Beginner Track exercises included Quality Control Microbiology on day two with John Hasyn, Sheila Byrne and Margaret Bryans, Ph.D., of Montgomery County Community College, Blue Bell, PA, and Linda Rehfluss, Ph.D., Assistant Professor of Biotechnology and Biology at Bucks County Community College, Newtown,

PA. They presented experiments and techniques used in the industry to prevent microbial contamination of products. The hands-on Limulus Amebocyte Lysate (LAL) gel clot assay was used to measure endotoxin levels in cell culture samples. Gram stain was used to identify Gram positive and negative bacteria. Lastly, the colorimetric API assay was used to identify bacterial strains. Participants also learned how to conduct microbial air monitoring.



Tom Lucier, Professor of Biotechnology at Alamance Community College and Sherri Andrews of Bio-Rad presented a series of three workshops using the Dihydrofolate Reductase (DHFR) expression and purification system by Bio-Rad. Participants harvested and lysed induced E. coli cells and prepared lysates for affinity chromatography on the Biologics Low Pressure Chromatography System, after a virtual training module for using the BioLogics Chromatography System was introduced. During the DHFR Activity Assay, participants prepared samples for flow through, wash and fraction elution for analysis by SDS-PAGE. Fractions were collected for determination of the level of purity and activity. Finally, participants used the Biologics Low Pressure Chromatography system to perform affinity chromatography of DHFR.

Intermediate Track

Advanced Track: Stem Cells

(continued from page one)

the needs of a viable individual. Workshop participants treated the ESCs with retinoic acid which directs them to neurons, beating myocardiocytes and other cell types. Differentiation was successful and in the third and final workshop: beating myocardiocytes were observed, much to the excitement of the participants. Dr. Woodruff also introduced the concept of mammalian cell transfection with the introduction of DNA vectors expressing fluorescently tagged proteins in CHO cells. Transfected cells were viewed under a fluorescent microscope and the pattern of expression was observed.

Bill Woodruff (seated) NBC2 CO-PI, Professor/ Department Chair of Biotechnology at Alamance Community College - hosting site for this year's BIOMAN in Graham, North Carolina - leads a discussion.



BIOFUELS *(continued from page two)*

the share consists of a box of seasonal produce each week throughout the farming season, but other farm products may be included.

In the case of the Piedmont Biofuels Cooperative, the CSA share provides the right to tank up with biodiesel. Piedmont Biofuels in Raleigh is one of the small, local projects being funded by the Biofuels Center of North Carolina. It creates biodiesel from a local feedstock: waste vegetable oil from fast-food suppliers. Making this biodiesel becomes a new engine to drive both local economic development and local education. BIOMAN's educational tour revealed all the equipment and processes required to manufacture biodiesel fuel from waste oil. Participants observed filtering the oil, heating it, treating it with methoxide and then saw how the glycerin settles out from the biofuel.

Back in the well-equipped laboratories of Alamance Community College, a hands-on biofuels production laboratory is being piloted. This lesson explores digestion of switchgrass using various enzymes, including a cellulose enzyme provided by Genencor (now Danisco DuPont) in Rochester, NY. Switchgrass is glucose-poor and cellulose-rich. Breaking down cellulose is more difficult, but using biomass derived from non-food crops is preferable and can be treated using bacteria and fungi or enzymes. Biomass sources for this second generation biofuel includes organic human waste and garbage, agricultural residues (such as corn stover) and woody crops. 2014 will welcome the opening of commercial-scale cellulosic biofuels

TENGION *(continued from page one)*

jobs that must be filled today. "I'm so impressed by the impact your training programs are bringing in biomanufacturing today," said Bertram in his keynote address. "The US is fighting for its life in the global market. You bring a foundation the country can build success on, especially in new, innovative areas. You are working to introduce a new wave of technology that will put the United States back in the forefront of world biomanufacturing markets. I'd like you to go back and talk to your students about this science of regenerative medicine. As we begin to manufacture products it will become a new opportunity for your students and their careers. It's not magic - it's robust science that goes deeply into how the body works. What we do allows the body to do what it wants to do. Then complete and whole healing occurs."

Using autologous, living cells, Tengion's Neo-Urinary Conduit™ product is made from a patient's own stem cells that are grown outside the body and then implanted. The implant catalyzes regeneration of native urinary tissue. Another product, the Neo-Kidney Augment™, is designed to increase renal function by provoking the formation of kidney glomeruli. The procedure delays or prevents the need for kidney dialysis or transplantation in patients at risk.

Moving out of the laboratory and into full-scale manufacturing is a long, difficult process, Bertram said. "It takes years, decades sometimes to move through trials. The industry is heavily regulated. Each process must be tested and quality controlled. Once a product reaches approval, the company may finally realize returns on its investments - and offer products so physicians can treat patients." Achieving this goal can make the long difficult process worth it; Bertram ran through some numbers. "There are 26 million individuals in the U.S. who have chronic kidney

projects around the United States, including in North Carolina, Kansas, Iowa, Michigan and Oregon.

In the panel on Integrating Biofuels into your Biomanufacturing Program, Danny Kainer and Jim Hewlett described their local approaches to providing students new job opportunities. By learning about the production, manufacture and analysis of biofuels, through research opportunities in partner biofuels companies or developed in-house, biotechnology/biomanufacturing students are preparing for career pathways in biofuels and the bioeconomy.

In the course of BIOMAN 2012, twenty faculty members representing fourteen community colleges met to plan a Biofuels Workforce Summit that will help understand what skills and knowledge are needed by biofuels technicians. The Summit is planned for May 23 and 24, 2013 at Kapiolani Community College in Honolulu, HI.

Some BIOMAN participants received draft copies of the NBC2's *Biofuels Production and Analysis* textbook. A companion *Biofuels Production and Analysis Laboratory Manual* is being published in 2013, along with the textbook. This cutting-edge curriculum to train biofuels technicians was written and is being piloted by Elmar Schmid at MiraCosta College in San Diego, CA, as part of the Educating and Developing Workers for the Green Economy (EDGE) initiative. NBC2 published an industry-written *Introduction to Biomanufacturing* first edition textbook in November 2012. Several lab manuals to support hands-on biopharmaceutical manufacturing that were published in 2009 are also available. All publications can be found at www.biomanufacturing.org

disease, with 100,000 new patients who start on dialysis each year. At \$45 billion, it is the single largest Medicare cost center. There is an organ shortage, and only a five year life expectancy on dialysis. Our product can delay dialysis, reducing cost with an enormous increase in benefits. It's designed to administer the cells needed to get the kidney to regenerate. The patient then may not need a transplant."

Bertram talked about how the Neo Kidney Augment™ works, and what a student might do if he or she became a technician working on its manufacture. "Cells know where they come from and will do what they were designed to do. We take one biopsy the size of the tip on a ballpoint pen. That's all we need. In four weeks we deliver the product. Think of that bioreactor you have in your lab - that is our biomanufacturing plant. There's a whole array of organs we can create.

"What is your student going to do? Well, my employee, anyone entering this career, would begin with cell isolation, then identification with a series of markers and genes. Then we use different ways to expand the cells. People think of manufacturing as thousands of people doing massive procedures. But biomanufacturing will become simplified. This opportunity is great; we want to employ a workforce in a competitive way that will change the future.

"It's exciting to make something to help people. I always wanted to help things change; bring a benefit to other human beings. I get to work with brilliant people now, some Nobel Prize winners. We're all targeted on a single goal, creating a new product that will do that." After strong applause, Bertram took questions. The most common: "Can our students get in? Bertram's response: "Absolutely - manufacturing is open and workers are needed now." (Bertram emphasized these are forward looking statements and investors bear the risk.)

Panel Discussion: How to Start a Biomanufacturing Course

Programs with a biomanufacturing emphasis are a growing need at community colleges because this advanced technology industry is expanding. Participants focused on how to incorporate biomanufacturing into a current or planned biotechnology program: how to add biomanufacturing modules, or an entire course, several courses or a complete program devoted to biomanufacturing laboratory skills. Panelists spoke to regional biomanufacturing curricula needs - with first hand industry experiences in their geographic areas.



Panelists (from left) Lara Dowland, Ph.D., Professor of Biotechnology, Mt. Wachusett Community College; Vivian Ngan-Winward, Ph.D., Chair, Biomanufacturing Program, Salt Lake Community College; Sonia Wallman, Ph.D., Executive Director of NBC2; Linda Refhuss, Ph.D., Assistant Professor of Biotechnology, Bucks County Community College

Off Site Learning: First hand biomanufacturing experiences

Groups of BIOMAN attendees visited Biogen Idec, the Piedmont Biofuels Center or (shown) the Tengion biomanufacturing facility.



How to Write A Successful Grant Proposal *(continued from page 2)*

Strategies; Developing Faculty Expertise; and Assessing and Evaluating Student Achievement. Projects here, which can be funded up to \$900,000 for three years, include Program Development, Implementation and Improvement; Professional Development for Educators; Curriculum and Educational Materials Development; and Teacher Preparation. Carter also discussed the Small Grants for Institutions program. New to the ATE Program (\$200,000, 3 years) it encourages development of business and entrepreneurial skills for students in technician education programs. In conclusion, Carter urged BIOMAN participants to become familiar with the NSF website. She advised carefully reading program solicitations. The NSF Grant Proposal Guide (GPG) is available for download on PDF. "Register early on FastLane" Carter said. "And practice, contact your grants officer as well as a program officer. Solicit a colleague's opinion on your proposal."

Tim Anderson (right) of Kimble Chase at the BIOMAN Vendor Show: "It's great, I'm talking to people involved in a lot of different labs, including new labs just starting to train people. Every conversation is different, that's good because we concentrate in five areas of supply. But our growth is in new labs."



Vendor Show

Industry representatives from around the country set up exhibitions of the latest biomanufacturing equipment and supplies for BIOMAN participants to learn about, inspect and try out. The always-popular raffle sent more than a dozen happy winners home with new lab equipment, NBC2 textbooks and more prizes.



Trying out new pipettors (above) was a popular activity at the vendor show.

Golden LEAF Biomanufacturing Training and Education Center



Biomanufacturing Boot Camp

The week prior to BIOMAN, NBC2 sponsored 12 biomanufacturing educators to attend a week-long Biomanufacturing Boot Camp at the BTEC Biomanufacturing Training and Education facility at North Carolina State University (shown at left).

All aspects of the biomanufacturing process were covered including hands-on experiences in a 30-liter CIP/SIP bioreactor, inoculation with *E. coli* / GFP, harvest, isolation and purification of the protein, analysis of product and sterile fill-finish.

Register for **BIOMAN 2013**
July 15-18 at Blue Bell, PA



Participant Quotes

The best way to understand BIOMAN - listen to participants:



"NBC2 BIOMAN is amazing - I get to hear ten colleges give me feedback on what skills my students will need."
Janice Wagman, Biology Teacher, Perkiomen Valley High School, Collegetown PA

"I teach chemistry and I want to do biodiesel, including engineering and design. We have lots of native Hawaiians in our high school. I would love something to do like that, and bring skills they can use."
Kathleen Ogata, Assistant Professor, Kapiolani Community College, Honolulu HI

"We have biotechnology and are considering adding biomanufacturing. This conference tells us how."
Jim Tuohy, Professor, Glendale Community College, Glendale, AZ

"This is my first NBC2 BIOMAN. I've wanted to come for a long time. It's great! I met a whole group of people involved in biomanufacturing, made new contacts and learned new things. It's been really excit-

ing to learn about regenerative medicine. We don't have that but we will be teaching the exercises in our labs. We don't have a lot of biomanufacturing in our area - yet. We anticipate it will be coming."
Luanne Wolfram, Professor and Chair, Biotechnology, Johnson County Community College, Overland Park, KS

"Biofuels open up whole new areas for biomanufacturing. Biofuels take the ideas and principles of biotechnology and incorporate them into a program that can lead to a biomanufacturing certificate. It can start a person's learning curve."
Danny Kainer, Director, Biotech, Lone Star College, Montgomery TX

"Life sciences uses all sciences trying to help solve problems, academic or corporate."
Kris Gorman, Coordinator, Biomanufacturing Certificate Program, Erie Community College, Buffalo NY

"We're exploring ideas here. We need them. Wonderful using the BioRad protein comparison, it includes PCR plus protein. That will help us get our biofuel program going."
John Vickrey, Instructor, McLennan

Community College, Waco TX
"It's great seeing equipment I don't have and how they're using it to teach the same types of things we are. Love meeting other people who are helping each other figure out solutions to teaching problems. I can help others too. I enjoy getting to know them. We can see different approaches."
Alicia Manfre, Biotechnology Program Coordinator, Hagerstown Community College, Hagerstown MD

"BIOMAN is an excellent opportunity for instruction. We show teachers how true hands-on works here. This makes it more real for their students."
John Hasyn, Professor of Microbiology, Montgomery County Community College, Blue Bell PA

"We're starting our first biomanufacturing course this year and it is daunting. The most impressive thing is the curriculum. I love seeing the new NBC2 textbooks. We are developing this same sort of approach so they are perfect. Seeing these materials and getting the support helps make it more exciting. Coming to BIOMAN for the first time, it's great to meet people sharing what they're doing. There's a lot of innovation here."
Trish Phelps, Professor, Austin Community College, Austin TX



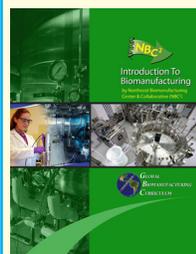
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VISION

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.

NSF Awards 0501953 and 0903208