



## Connecting People, Science and Regulation

### Sept 9<sup>th</sup> Dinner Meeting

“Hot Topics in Environmental Monitoring”

**Speaker:**

**Jeanne Moldenhauer**

**Facility Tour:**

Lyophilization Services  
of

New England's

New 35,000 sf contract fill/finish  
manufacturing facility located at 25  
Commerce Drive

Bedford, NH



**2009 PDA/FDA JOINT  
REGULATORY CONFERENCE**



SEPTEMBER 14-18, 2009 | WASHINGTON, D.C.  
[www.pda.org/pdafda2009](http://www.pda.org/pdafda2009)

**Securing the Future  
of Medical Product Quality:  
A 2020 Vision**

**Confirmed Keynote Speaker  
Joshua M. Sharfstein, MD**

**FDA Principal Deputy Commissioner**

[www.pda.org/pdafda2009](http://www.pda.org/pdafda2009)

## Massachusetts Life Sciences Center Internship Challenge and More!

**By Melissa J. Smith**

Principal Consultant

MJQuality Solutions

[melissa@mjqualitysolutions.com](mailto:melissa@mjqualitysolutions.com)

Wondering what the Massachusetts Life Sciences Center is?

The Massachusetts Life Sciences Center (MLSC) is a quasi-public agency of the Commonwealth of Massachusetts, created by the Massachusetts legislature in June 2006. The MLSC is funded through a new Massachusetts Life Sciences Initiative from the Deval Patrick administration which includes a \$1 billion investment package (over ten years) to enhance and strengthen the state's internationally recognized leadership in the life sciences.

The MLSC was established to promote the life sciences within the Commonwealth of Massachusetts and is tasked with investing in life sciences, research and economic development in public and private institution.

Looking for a Summer Internship?

The Massachusetts Life Sciences Center may be able to help. This year the MLSC announced an internship program in the fields of Science, Technology, Engineering, and Math. To be eligible, you must currently be a Massachusetts resident or enrolled in a four-year college or university in Massachusetts and have completed at least your junior year of study, or, have completed your Bachelor's Degree in the past year. For students enrolled in a community college, you must have completed your Associate's Degree, Certificate, or the equivalent of one year's course work related to the internship placement within the past year.

The MLSC encourages all students interested in the life sciences to apply and take advantage of this opportunity! You can find out more about this program by going to this link.

<http://www.masslifesciences.com/grants/challenge2.html>

What are some of the grants that have been made through the Center?

The Center has approved a \$7.4 million grant to Canton-based Organogenesis, Inc. to facilitate a major expansion that will create hundreds of jobs. The Center will provide \$3.7 million this fiscal year and \$3.7 million during FY 2010.

UMass Lowell (Dr. Rudolf Faust) and Boston Scientific have received a joint grant for \$199,596 per year for three years for work with three postdoctoral and two graduate students at the University of Massachusetts

Lowell and at Boston Scientific Corp. of Natick, Massachusetts to collaborate on the design, precision synthesis, and nanomanufacturing of new biocompatible and functional materials for better performance in several medical devices. **(Continued on Page 2)**



**(Massachusetts Life Science Center - Continued from Page 1)**

Harvard University School of Engineering and Applied Sciences (Dr. David Weitz) and Raindance Technologies have a grant for \$250,000 per year for three years to develop and demonstrate the use of a new form of fluorescence activated cell sorter (FACS), used to collect biochemical information about individual cells.

What is the basic core of grants through the Center?

These are examples of some of the grants awarded through the center in a series of strategic programs: the Life Sciences Tax Incentive Program, the Life Sciences Accelerator Program, Cooperative Research Grants, Matching Grant Program, Internship Challenge, and the Corporate Consortium Program.

What's next?

I recently attended a presentation by MLSC President & CEO Dr. Susan Windham-Bannister. In the next newsletter issue, we will detail more of the work involved at the Center. If you have a question regarding the Center, please email me ([melissa@miqualitysolutions.com](mailto:melissa@miqualitysolutions.com)). In the meantime, please check out this link to have a look at the great work that this Center is doing for our industry in Massachusetts.

<http://www.masslifesciences.com>

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## Student Chapter News

**By Jessie Klein**

Associate Dean of Math and Science  
Middlesex Community College

It has been a very busy quarter for the student chapter with elections and three chapter meetings. Many thanks to Matt Piasecki, the first President of the student chapter, for all his hard work getting this chapter off of the ground. Matt stepped down and Maurice Perez, the first President-elect has assumed the Presidency until May 2010. Newly elected officers are Thelma Cromwell-Moss - President-elect, Wayne Landis – Secretary, and Kamal Patel - Treasurer. Congratulations to all and best wishes for success in your new roles!

We have had three meetings so far this year with NEPDA speakers. Louis Zaczkiewicz, past NEPDA Chapter President spoke to us about the benefits of PDA membership and gave us a tour of the member's only sections of the website to show all the valuable information that is available only to members. **(Continued on Page 4)**



## NEPDA PRESIDENT'S MESSAGE

**By Jerry Boudreault**

President

Drug Development Resources, Inc.

Greetings NEPDA Members,

It has been a very busy first quarter of this, the 20<sup>th</sup> anniversary of PDA New England Chapter and I would like to take this opportunity to fill you in on progress toward our goals. I have good news and bad news to share. Let's start with the good news.

We started the first ever PDA student chapter at Middlesex Community College (MCC) in 2007 and the Chapter held its first election last month. We are looking forward to working with the new officers to build a strong student chapter at MCC and send a hearty *THANK YOU* to Jessie Klein and Paul Patev, faculty sponsors from MCC. Without their efforts the chapter would not be possible.

I am happy to announce that the Chapter Board approved three scholarships totaling \$8,000 for Student Chapter members. Applications have been received and we are looking forward to awarding the scholarships this summer. You can expect an announcement in the September PDA letter.

The Chapter held three successful dinner meetings so far this year. Topics included *Visual Inspection of Parenterals*, *Container Closure Integrity*, and *Validation of Tangential Flow Filtration in Biopharmaceutical Applications*. We are ahead of budget and on track to achieve our 5 meeting per year objective with meetings on *Hot Topics in Environmental Monitoring* and *Depth Filtration* in September and November, respectively. I hope to see you there.

The revenue from these meetings provides the operating funds for chapter initiatives such as the scholarships and speaker expenses. Sponsors enable us to fund programs while keeping event prices down member. *THANK YOU* to our sponsors and the Planning Committee volunteers who make it happen!

I recently received a New Member Report from PDA Global that showed that we had 84 new members since January 1<sup>st</sup>. I was ecstatic! We had achieved our goal of increasing the chapter by 80 members! After my brief celebration, I reminded myself that it was only part of the equation and requested a report on non-renewals. There were 150 non-renewals! That is the bad news. We are down 66 members from 2008.

I sent out an email to each of the members that didn't renew and received four types of responses. First was "Oops, I forgot – will get right on it". If you happen to fall into that category, please remember to renew. Second was a bounce back. Please, keep your membership profile up to date at [www.pda.org](http://www.pda.org) so that we can find you. If you find yourself unemployed as a result of the current economic situation, you are still a member and need to know that PDA has authorized a 6 month extension for unemployed persons. Please take advantage of it. Also note that the New England Chapter offers \$10 admission to our events for those between positions. NEPDA events are great networking opportunities. Make sure we can find you! Third and fourth reasons were related to steps firms are taking to reduce costs. They are either limiting the number of individuals in an organization that can belong to a society like PDA, or restricting personnel to one society only...and we weren't selected. We have lost people to both causes.

If you are affected by corporate belt tightening we would still like to see you at meetings, but would rather make PDA so relevant that you can make the economic case for renewal. We are member driven, so please tell us what you need to make that case and we will do it. It is your chapter.

With the state of today's economy, there is no better time than now to be reaching outside your routine and get involved, so please come join us in continuing the tradition of excellence.

Best Regards,

Jerry Boudreault



**(Student Chapter News Continued from Page 2)**

Mike Harrison, President of Biotechnicians Network, Inc. spoke at our March meeting about sterilization techniques. In April, Jeff Anderson, Cell Culture Manager at Biogen/dec, discussed large scale cell culture.

A big "thank you!" to our speakers. All were very informative. If you are interested in speaking to the chapter for 45 minutes or so about a biotech topic of interest, please contact me at [kleinj@middlesex.mass.edu](mailto:kleinj@middlesex.mass.edu).

Middlesex appreciates donated supplies and equipment. We currently are in need of an HPLC. If you have surplus items please contact Jessie Klein [kleinj@middlesex.mass.edu](mailto:kleinj@middlesex.mass.edu). Chapter meetings will resume in September.

## Instructor needed for course in Microbiology, Membranes and Microorganisms

Middlesex Community College is looking for an instructor to teach a course in Microbiology, Membranes and Microorganisms for a large biopharmaceutical manufacturing company in Bedford, MA. If you are interested, please contact Audrey Nahabedian at 978-656-3136 or e-mail your resume to [nahabedian@middlesex.mass.edu](mailto:nahabedian@middlesex.mass.edu). This course will include a lecture and lab component. Topics include: introduction to the microbial world; environmental microbiology; aseptic processing; isolation, nutrition, detection and control of microbes; relevance of microbiology to the company's products; environmental monitoring (using TSA, TSB and SDA) and sterilization of membranes. Qualified candidates should have a background in the topical areas and some industry and teaching experience. Familiarity with Millipore products would be helpful.

## Trying to get Noticed??

*We offer vendors, consultants, operating companies and other organizations the opportunity to promote themselves and also support the NE PDA Chapter by purchasing advertising in our newsletter. A business-card size advertising opportunities in our newsletter; at a cost of \$100 per newsletter.*

The newsletter has the following reach:

- Our direct e-mail distribution reaches over 1,800 contacts throughout New England.
- Our membership includes people from manufacturing, research, QA, QC, engineering, contract manufacturers, consultants, and regulatory.
- We promote the newsletter at New England PDA's bi-monthly dinner meetings, often with company tours, which regularly attract 50-100 attendees.
- We post the newsletter on our chapter's website at Global PDA ([www.pda.org](http://www.pda.org)), an organization that has over 10,000 members.

Deadline	Publication Date
July 15, 2009	August 2009
October 15, 2009	November 2009
January 15, 2010	February 2010
April 15, 2010	May 2010

If you are interested in advertising in the newsletter or need more information, contact Melissa Smith at [melissa@mjqualitysolutions.com](mailto:melissa@mjqualitysolutions.com)