

LyoHUB

**ADVANCED
LYOPHILIZATION
TECHNOLOGY
CONSORTIUM**

**Advanced Lyophilization
Technology Consortium**

ANNUAL REPORT

2017



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*Word Cloud based on the LyoHUB
Lyophilization Technology Roadmap*

DIRECTORS' MESSAGE



Greetings from LyoHUB!

This has been an exciting year of growth and accomplishment for LyoHUB. We expanded the number of industry members— from 5 companies to 13, and added expertise in microscopy and analytical instruments, high-purity cGMP excipients and digital engineering.

Since the early stages of consortium planning in 2013, the development and dissemination of best practices in lyophilization has been a priority for our members. In February 2017, the first in a series of LyoHUB Best Practices Papers, entitled “**Recommended Best Practices for Process Monitoring Instrumentation in Pharmaceutical Freeze Drying—2017**” was published in AAPS PharmSciTech. The open-access paper is available to all and has already been downloaded over 700 times. Kudos to Dr. Steve Nail for leading the team in this important effort, and to all the authors!

Just over a year ago, we launched the **LyoHUB Lyophilization Technology Demonstration Facility** in Purdue’s Discovery Park. Fifteen new academic and industry users have been trained on lyophilization equipment since February 2016. LyoHUB also hosted two workshops on freeze-drying microscopy and modeling software. We welcomed over 150 participants to annual LyoHUB meetings and our Lyo Lunch & Learn events in the Purdue Research Park. The Demonstration Facility has already brought together researchers from fields as distinct as pharmaceutical science, electrical engineering, materials science and engineering, biomedical engineering... and, of course, rocket science!

We thank everyone who contributed to the **Lyophilization Technology Roadmap** which will be published in 2017 as part of the NIST AMTech program. The lyophilization technology roadmap presents the collective view of trends, drivers and technology development opportunities with a time horizon to 2025 and beyond. Some exciting destinations have been identified in the roadmapping process, which involved over a dozen workshops and LyoHUB member webinars. We look forward to continuing this journey towards advancing lyophilization together with all of you.

MEMBERSHIP



MAX85





LyoHUB & NIPTE invite you to participate in the **Lyo Synergy Session**



You are invited!

Monday, September 19

Come any time between 11:30-12:30 if you would like to get some lunch in the cafeteria and network with other participants. Meeting will start promptly at 1pm and run until 5pm.

NIST, West Square Room

100 Bureau Drive, #101, Gaithersburg, MD 20899

There is no cost to attend, other than any lunch items you purchase. Please provide full name, company name and e-mail address when responding, as these will be needed to clear you through security. Parking pass and other information will be e-mailed to you before Friday, September 16, 2016. Please bring ID with you when you arrive. A passport is required if you are a foreign national.

Don't miss this unique opportunity to meet with other industry, academia, NIST, FDA and NIPTE representatives to discuss lyophilization technology development needs, standardization and regulatory support in lyophilization technology roadmapping and database effort.



RSVP to gray160@purdue.edu by Sept. 8
Questions? 765-496-1340



LyoHUB invites you to participate in the

LyoHUB Fall Meeting



CD-adapco Software Training
Date: Tuesday, October 11, 2016
Time: 8am-2:30pm
Location: Birck Nanotechnology Center, 1205 West State Street, Purdue University, West Lafayette, IN, Room 1001

McCrone Freeze Dry Microscope Training
Date: Tuesday, October 11, 2016
Time: 3pm-5pm
Location: Birck Nanotechnology Center, 1205 West State Street, Purdue University, West Lafayette, IN, Room 1001

LyoHUB Fall Meeting
Date: Wednesday, October 12 from 8:00am(breakfast at 7:00am)-4:30pm
Location: Purdue University's Discover Learning Center (207 South Martin Jische Dr, Suite 203, West Lafayette, IN)
During this meeting participants will hear updates on LyoHUB activities, and will be invited to provide input into Lyophilization roadmap, and Best Practices papers. There will also be 3 minute thesis presentations. There will be an update on Strategic Doing projects and other talks and presentations.

Opening Reception & Tours of LyoHUB Demonstration Facility
Tuesday, October 11 from 6-7:30pm in the Atrium of Purdue University's Birck Nanotechnology Center

Accommodations:
A block of rooms is available at the Purdue Union Club Hotel on campus. Deluxe Double is \$125/night + tax for Deluxe Double and Queen rooms are \$99/night + tax for a Queen room (parking included). Call 800-320-8291 or 765-494-8900 and request a room in the LyoHUB room block. Limited rooms available.



There is no cost to attend this meeting; however, reservations are required.
RSVP to gray160@purdue.edu by October 2
Questions? 765-496-1340



Attendees to the Fall LyoHUB meeting receive a tour of the Demonstration Facility

Full meeting agendas and slide presentations available in member section of www.lyohub.org



Dr. Moogega Stricker, M2020 Planetary Protection Co-Lead Engineer, Biotechnology and Planetary Protection Group at the Jet Propulsion Laboratory, provided an interesting and motivational keynote presentation.



SPECIAL PRESENTATIONS



FDA Experience with Continuous Manufacture

January 19, 2017

Celia N. Cruz, Ph.D.
Division Director
CDER/OPQ/OTR/DPQR at FDA

Maxwell Korang-Yeboah, Ph.D.
Pharmacologist at FDA



Special Opportunity for LyoHUB Members

From **batch** to **continuous** freeze-drying Presentation via Webex with Q&A

Recording Available on Website

Bernhardt Trout

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Massachusetts Institute of Technology

email: trout@mit.edu

Roberto Pisano

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Politecnico di Torino

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Slides and presentation recording available in member section of www.lyohub.org

PRESENTATIONS/COMPANY VISITS/CONFERENCES

Indiana Companies:

- SSCI (Jan. 2017)
- Lunch and Learn for 13 Indiana Companies (June 2016)

Visits to Indiana Companies:

- Baxter (April 2017)
- AB Biotechnology (Nov. 2016)
- Biologics Modular (Nov. 2016)

Potential Member Visits to LyoHUB:

- Sensient (Feb. 2017)
- West Pharma (Feb. 2017)

Conference Presentations or Posters:

- CPPR Freeze Drying Conference (July 2016)
- ISL-FD East (Sept. 2017) & Chicago (April 2016 & 2017)
- AAPS National Biotechnology Conference (Nov. 2016)
- PepTalk (Jan. 2017)

Visit to LyoHUB by Members:

- McCrone (May 2016)
- Pfanstiehl (March 2017)
- Janssen (March 2017)
- Pfizer (Oct. 2016)
- Abbvie (Jan. 2017)
- Baxter (Jan. 2017)

Visits to Member Companies:

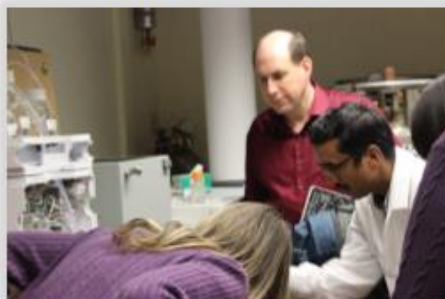
- Millrock (Dec. 2016)
- Abbvie (April 2016)
- IMA Life (Sept. 2016)
- McCrone (Jan. & Feb. 2017)
- National Academies of Science Symposium (April 2016)
- Controlled Release Society Annual Meeting (July 2016)
- NIPTE/FDA (Oct. 2016)



Sensient representatives visit Purdue's Demonstration Facility, 2017



LyoHUB team tours Biologics Modular, Fall 2016

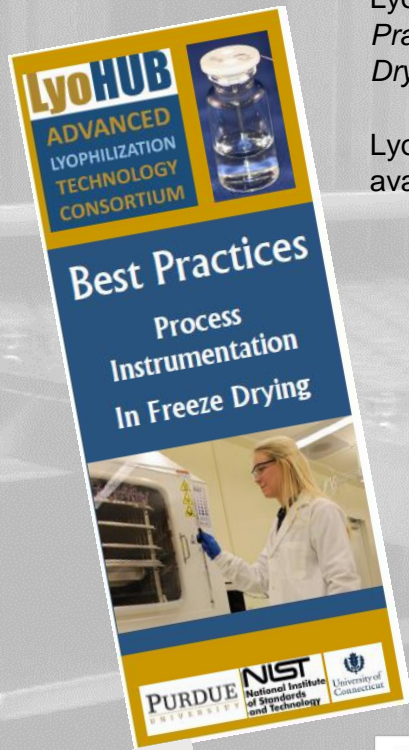


Representatives from SSCI visit Purdue's Industrial & Physical Pharmacy Lab, 2017



FD Microscope demonstration for Representatives from SSCI visit Purdue's Demonstration Facility, 2017

BEST PRACTICES PAPER



LyoHUB published its first Best Practices Paper, *Recommended Best Practices for Process Monitoring Instrumentation in Pharmaceutical Freeze Drying—2017* in February 2017 in AAPS Pharm Sci Tech.

LyoHUB arranged for open access to this best practices paper which is now available to all at <http://link.springer.com/article/10.1208/s12249-017-0733-1>

ABSTRACT

Paper led by Steve Nail (Baxter)

Recommended best practices in monitoring of product status during pharmaceutical freeze drying are presented, focusing on methods that apply to both laboratory and production scale. With respect to product temperature measurement, sources of uncertainty associated with any type of measurement probe are discussed, as well as important differences between the two most common types of temperature-measuring instruments—thermocouples and resistance temperature detectors (RTD). Two types of pressure transducers are discussed—thermal conductivity-type gauges and capacitance manometers, with the Pirani gauge being the thermal conductivity-type gauge of choice. It is recommended that both types of pressure gauge be used on both the product chamber and the condenser for freeze dryers with an external condenser, and the reasoning for this recommendation is discussed. Developing technology for process monitoring worthy of further investigation is also briefly reviewed, including wireless product temperature monitoring, tunable diode laser absorption spectroscopy at manufacturing scale, heat flux measurement, and mass.



Led by Steve Nail (Baxter)



AAPS PharmSciTech
pp 1–15

[AAPS PharmSciTech](#)

Recommended Best Practices for Process Monitoring Instrumentation in Pharmaceutical Freeze Drying—2017

Authors

[Authors and affiliations](#)

Steven Nail , Serguei Tchessalov, Evgenyi Shalaev, Arnab Ganguly, Ernesto Renzi, Frank Dimarco, Lindsay Wegiel, Steven Ferris, William Kessler, Michael Pikal, Greg Sacha, Alina Alexeenko, T. N. Thompson, Cindy Reiter, James Searles, Paul Coiteux

[Open Access](#) | White Paper

First Online: 15 February 2017

DOI: 10.1208/s12249-017-0733-1

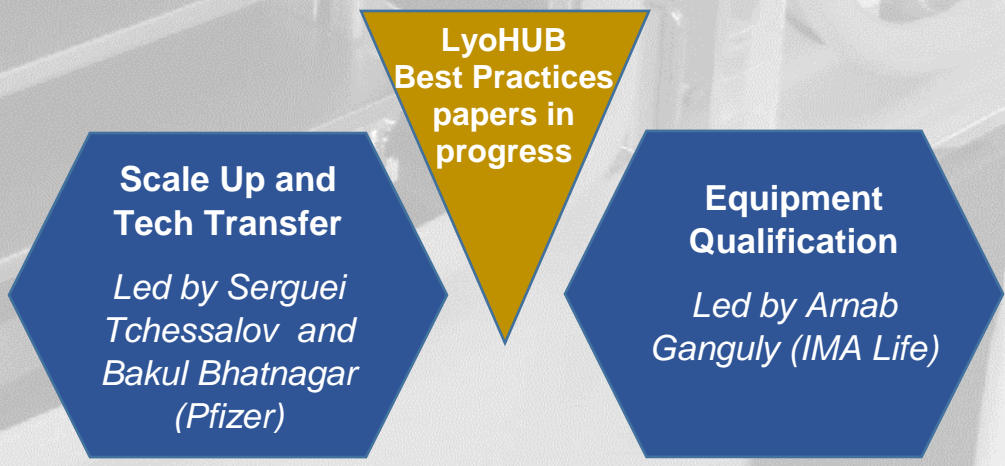
Cite this article as:

Nail, S., Tchessalov, S., Shalaev, E. et al. AAPS PharmSciTech (2017). doi:10.1208/s12249-017-0733-1

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Shares Downloads



LYOHUB LYOPHILIZATION TECHNOLOGY ROADMAP

Since the last LyoHUB Annual Meeting, several meetings and calls were set up in order to work on the LyoHUB Lyophilization Technology Roadmap. The following chart shows the overall summary chart of the Roadmap.



LyoHUB Lyophilization Technology Roadmap Meetings:

- October 6-7, 2015- Purdue University
- January 20, 2016 – PepTalk, San Diego, CA
- April 13, 2016 – ISL-FD, Chicago, IL
- September 19, 2016 – ISL-FD East, Washington DC
- October 12, 2016 – Purdue University
- January 10, 2017 – PepTalk 2017, San Diego

Roadmap Topic Area Webinars:

- February 9, 2017, facilitated by Bakul Bhatnagar (Pfizer) and Shailaja Gupta (Janssen)
- February 17, 2017 facilitated by Evgeniy Shalaev (Allergan) and Greg Sacha (Baxter)
- February 23, 2017, facilitated by Ted Tharp (Abbvie) and Zak Yusoff (SP Scientific)
- March 8, 2017, facilitated by Arnab Ganguly (IMA) and Steve Nail (Baxter)



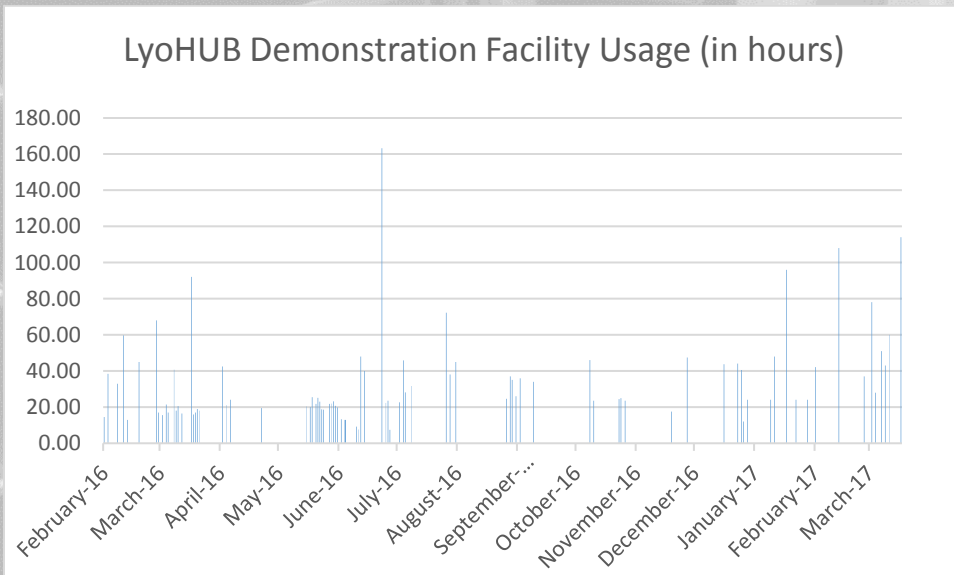
The participants of the 2015 LyoHUB Roadmapping Workshop

DEMONSTRATION FACILITY

In February of 2016, LyoHUB opened the Lyophilization Demonstration Facility located in the Birck Nanotechnology Center at Purdue Discovery Park. The facility, where collaboration on breakthrough technologies can be advanced with a goal of accelerating adoption and decreasing time to market, is equipped and supported by LyoHUB's industry members. The facility also supports various hands-on training opportunities for academic and industry users.



Lyophilization Demonstration Facility located in Birck Nanotechnology Center at Purdue University for use in lyophilization research, development and pilot demonstration projects



Total Number of lyophilization Runs: **87**
 Average Time for Lyophilization Run: **33.25 hours**

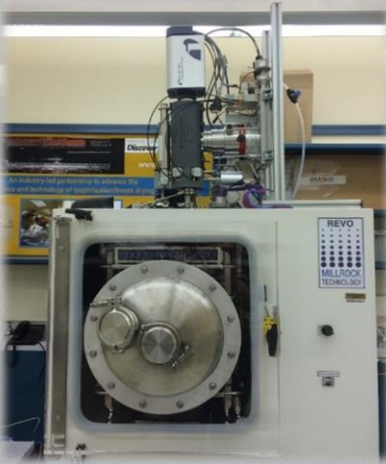
Total Lyo Run Time (2/26/16-3/26/17): **2,973.37 hours**



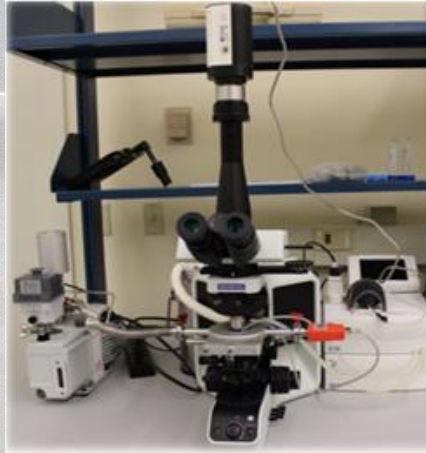
Total Freezing Time: **386.11 hours**

DEMONSTRATION FACILITY

Current Equipment in the LyoHUB Demonstration Facility:



Millrock REVO



**McCrone Freeze Dry
Microscope**



**Inficon Mass
Spectrometer (RGA)**



**SP Scientific
LyoStar III**



**MicroFD with
LyoPAT-II:
Simulate
production/pilot lyos
with just 19 vials**



**Excipients
from
Pfanstiehl**

DEMONSTRATION FACILITY



Summary of projects in the LyoHUB Demonstration Facility:

- Operational qualification of lyophilizers
 - Develop design space for freeze-dryers for process development
- Wireless temperature sensor characterization (Purdue ECE)
 - Real-time in-situ wireless monitoring of product temperature
- Lyophilization of Anammox bacteria mix (Pancopia/NASA)
 - Optimization of freeze-drying formulation and process for biological wastewater treatment at the space station
- Freeze-drying with organic solvents
 - Characterization of organic solvent sublimation dynamics by RGA
- Comparison of lyophilized and spray-dried protein formulations using hydrogen deuterium exchange with mass spectrometric analysis

Users Trained on Lyophilization Equipment from January 2016 to March 2017

Name	Email	Affiliation
Andrew Strongrich	astrongr@purdue.edu	LyoHUB Superuser; AAE
Nithin Rangunathan	nithin@purdue.edu	LyoHUB Superuser; Birck Nanotech Center, ECE
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Nathan Wilson	wilso242@purdue.edu	IPPH
Karthik Balakrishna	balakrk@purdue.edu	IPPH
Tatsuhiko Kodama	tkodama@purdue.edu	LyoHUB



Undergrad Interns
Evan Liechty (left)
Nick Huls (right)



Graduate Student
Vaibhav Kshirsagar



Dr. Moorthy Balakrishnan Accepted job with Pfizer (India)



Dr. Ehab Moussa Accepted job with Abbvie

EDUCATION & TRAINING



CFD and Optimization Software Training by CD-adapco/Siemens

- Simulation overview (workflow, terminology, interface layout, etc.)
- Hands on walk-through of STAR-CCM+ simulation build/run
- Design exploration of a parametric simulation. Participants will quickly change/test different designs to achieve desired engineering goal
- Simulation overview of single vial heat transfer analysis and optimization



Hand-on training of Freeze Dry Microscope by McCrone



LyoHUB Demonstration Facility, October 2016

ABOUT PARTNERS LYO FEATURES - GROUP MEMBERS ONLY

LyoHub

Home of great resources for members and Interactive Process Simulation Tools such as LyoCalculator:
Most Active Tool on PharmaHUB



LyoLaunchPad Project Opportunity Introduced:

A program, called “LyoLaunchPad”, was initiated during the spring of 2016 in the LyoHUB demonstration facility. LyoLaunchPad provides introductory access to lyophilization equipment and expertise for investigators and companies who are novices in lyophilization. LyoLaunchPad provides:

- Free training and limited access to LyoHUB demonstration facility to complete a short-term project (~5 days = 1 week of run time)
- An opportunity for prospective SME members of LyoHUB to test drive the LyoHUB demonstration facility before joining as a member or fee-based use
- An opportunity for LyoHUB to broaden membership and applications base and to form new partnerships outside traditional bio/pharma and equipment manufacturers

Sample LyoLaunchPad projects:



Nanovis LLC
Test lyophilization to aid in the manufacture of gelatin sponges for medical applications



Prof Lia Stanciu
(Purdue Materials Engineering)
Lyophilized BPA Antigen for Lateral Flow Assay



CONTACTS



MAX85



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www.LyoHUB.org



<https://twitter.com/lyohub>

Background photo credit: Courtesy Millrock Technology, Inc



Annual Member Meeting, April 2016, Chicago