LYOhub.org

EST. 2014

5TH YEAR ANNIVERSARY

Advanced Lyophilization Technology Consortium

Annual Report

2019

Table of Contents

Directors' Message

Greetings and Happy 5th Birthday LyoHUB!

We're excited to share this LyoHUB 2019 Annual Report with our member companies, colleagues and friends. We welcomed two new member companies at the end of 2018 and added five more in early 2019, bringing the membership to **23**. Our newest member companies have expertise in lyophilization equipment and processing, bulk API manufacture and animal health, and expand the major pharmaceutical companies represented in our consortium.

Throughout the year, we offered **workshops and training** on lyophilization technologies, and disseminated new ideas through webinars. We hosted Lyo Summer School at Purdue in July 2018, with training on design space and computational fluid dynamics (CFD), and presented on-site training at several companies. With funding from the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL), we'll be developing an online introduction to lyophilization ("Lyo101") in 2019. We supported pre-competitive collaborative **research** projects in vial-fogging and vial stoppers, and hosted **190+** lyophilization runs in our Demonstration Facility. We continue to disseminate **best practices** in lyophilization and enhancing our **regulatory interface**. Our newest best practices paper on equipment performance qualification was submitted for publication in 2018 and a new best practices working group on validation of pharmaceutical lyophilization was formed. LyoHUB joined the American Society for Testing and Materials (ASTM) in 2017, providing a route to convert best practices papers into consensus standards. In 2018, we introduced our first ASTM ballot – "Standard Practice for Process Monitoring Instrumentation in Pharmaceutical Freeze Drying" – as a step toward a consensus standard in lyophilization. We hosted the 2018 LyoHUB/ASTM E55 Workshop on Pharmaceutical Manufacturing Research at Purdue in October 2018, which included invited speakers, panel discussions, tours and a poster session.

We're so grateful to all our members for their continuing engagement and enthusiasm.
Thanks, too, to the Birck Nanotechnology Center for hosting our Demonstration facility, our LyoLaunchPad participants, our visiting scientists, and our students and postdocs for contributing to the successes we're sharing in this report. We are especially grateful to Jen Gray, our communications coordinator, who continues to be the heart and "hub" of LyoHUB. We look forward to celebrating our fifth anniversary as a consortium in 2019, and to continuing to work with all of you to advance lyophilization technology.

With best wishes,

Alina Alexeenko and Liz Topp
Co-Directors

Membership

IMA LIFE Freeze Drying Solutions

Member Since 2014

Pfizer

Member Since 2014

janssen | Pharmaceutical Companies of Johnson & Johnson

Member Since 2015

MILLROCK TECHNOLOGY Innovative by Design millrocktech.com

Member Since 2015

INFICON

Member Since 2015

SP SCIENTIFIC

Member Since 2016

Baxter

Member Since 2016

abbvie

Member Since 2016

Allergan

Member Since 2016

Roche

Member Since 2016

THE McCRONE GROUP

Member Since 2016

Pfanstiehl

Member Since 2016

SIEMENS

Member Since 2017

FRESENIUS KABI

Member Since 2017

Bristol-Myers Squibb

Member Since 2017

Abbott

Member Since 2018

OPTIMA EXCELLENCE IN PHARMA

Member Since 2018

AMGEN®

Member Since 2018

Greene Tweed

Member Since 2019

Merck & Co.

Member Since 2019

AstraZeneca

Member Since 2019

EVONIK POWER TO CREATE

Member Since 2019

Daiichi Sankyo

Member Since 2019

LyoHUB Timeline

2014
2 members

- April, planning meeting held at ISLFD Midwest conference in Chicago.
- May, www.lyohub.org launched.
- September, NIST AMTECH proposal submitted.

2015
5 members

- May, awarded NIST AMTECH $453,000 2-year Roadmapping Grant.
- October, 2015: Roadmap Workshop at Purdue where 50+ industry, academic and government participants met at Purdue to develop a Lyophilization Roadmap.

2016
12 members

- April, LyoHUB Annual Meeting held at Big Ten Headquarters with Strategic Doing Roadmapping Workshop.
- January, the LyoHUB Demonstration Facility opens and trains 6 users.
- May, LyoHUB receives consortium start up grant from IN-MaC.
- May, LyoLaunchPad program is initiated with Nanovis gelatin sponge project.
- September, LyoHUB/NIPTE workshop at NIST
- October, first training workshop on CFD and freeze dry microscopy

2017
15 members

- February, first best practices paper published.
- March, hosted visiting scholar from Daiichi Sankyo.
- April, LyoHUB Annual Meeting held at McCrone Group.
- September, the LyoHUB Lyophilization Technology Roadmap is launched at ISLFD-East meeting in Cambridge, MA.
- September, LyoHUB/BPOG Workshop held in Cambridge, MA.
- June, LyoHUB hosts first two SURF students for summer research projects.
- December, freeze dry microscope, mass spectrometer and lab scale lyophilizer added to the LyoHUB Demo Facility and 15 users trained.
- December, LyoHUB joins ASTM and leads creation of the E55.05 Lyophilization subcommittee.

2018
18 members

- January, LyoHUB becomes a Purdue University Center.
- July, Lyo Summer School Fundamentals of Freeze Drying course offered.
- LyoHUB Demo Facility adds MicroFD and Mass Flow Meter, and 28 new users trained.
- April, LyoHUB Annual Meeting held at Big Ten Headquarters, Chicago
- April, two collaborative non-competitive projects commence: vial stoppers and vial fogging.
- January, first on-site freeze drying short course offered at Allergan and July at Fresenius Kabi.
- LyoHUB/ASTM Workshop on Pharmaceutical Manufacturing Research held at Purdue.

2019
23 members

- January, NIIMBL funding awarded to develop lyo online course.
- March, LyoHUB welcomes its 23rd member company.

LyoHUB 5 Year Photos

Planning Meeting, April, 2014

Planning Meeting, January, 2015

LyoHUB Roadmapping Workshop Purdue University October 6-7, 2015

2016 Annual Meeting

2017 Annual Meeting

2018 Annual Meeting

Awards/Grants

Online Lyophilization Short Course

- Funded by NIIMBL
- $50,000 over 6 months
- **Goal:** Create eight online lyophilization 101 learning modules, together with assessment tools and instructions for a virtual laboratory exercise
- **Investigators and Contributors:** Elizabeth Topp (PI, Purdue), Alina Alexeenko (Co-PI, Purdue), Kari Clase (Co-PI, Purdue), Jen Gray (PM, Purdue), Gary Galleskie (Consultant, NC State), Akhilesh Bhambhani (Contributor/Presenter, Merck), Arnab Ganguly (Presenter, IMA Life), Ehab Moussa (Presenter, AbbVie), Steve Nail (Presenter, Baxter), Greg Sacha (Presenter, Baxter), Drew Strongrich (Virtual Lab Exercise, Purdue)

Improving Lyophilization of Recombinant Proteins with ssHDX-MS

- Funded by NIIMBL
- $450,000 over 18 months
- **Goal:** Evaluate solid-state hydrogen deuterium exchange with mass spectrometric analysis (ssHDX-MS) as a method to test stability of proteins in solid powders.
- **Investigators:** Lokesh Kumar (Genentech), Ben Walters (Genentech), Andrea Allmendinger (Roche), Deborah Bitterfield (Lindy Biosciences), Michael Doherty (Lindy Biosciences)

PFI-RP: Sensors, Computational Modeling, and Bioanalytical Technologies for Closed-Loop Lyophilization

- Funded by NSF, Partnership for Innovation program
- $750,000 over 3 years
- **Goal:** The proposed project addresses three interconnected technical challenges by co-development of: (i) Noninvasive product temperature monitoring using wireless probes that are compatible with aseptic processing requirements; (ii) Accelerated biomolecule stability analytics by solid-state hydrogen-deuterium exchange mass spectrometry; and (iii) Real-time lyophilization rate measurement and closed-loop process control based on distributed wireless probes and computational modeling of the heat and mass transfer in the product, container and the lyophilizer equipment.
- **Investigators:** Alina Alexeenko (PI, Purdue/AAE), Timothy Peoples (Co-PI, Purdue Foundry), Elizabeth Topp (Co-PI, Purdue/IPPH), Dimitrios Peroulis (Co-PI, Purdue/ECE)
- **Industry Partner:** Millrock Technology

Affiliations

E55.05 Lyophilization subcommittee of E55 Committee on Manufacture of Pharmaceutical and Biopharmaceutical Products: https://www.astm.org/COMMITTEE/E55.htm

ASTM INTERNATIONAL

E55.05 CHAIRS

Dr. Arnab Ganguly
Chair
IMA Life

Dr. Serguei Tchessalov
Vice-Chair
Pfizer

- Work commenced in 2018 on the Standard Practice for Process Monitoring Instrumentation in Pharmaceutical Freeze Drying process through ASTM. The technical working group has provided feedback on the draft circulated after the last E55.05 meeting on the on-going work item for process instrumentation. This will be discussed during the annual meeting and finalized before ballot.
- LyoHUB hosted ASTM Meeting at the Indiana Manufacturing Institute, Purdue in October 2018

Meetings

Ehab Moussa provides group report

The LyoHUB 2018 Annual Meeting was held at the the Big Ten Conference Center in Chicago. A workshop took place where next best practices paper ideas were generated. Funding for the study of plasma sterilization and sponsorship of the 2019 Gordon Conference on Formulation were approved.

Serguei Tchessalov, Arnab Ganguly, Steve Nail, Alina Alexeenko, TN Thompson and Feroz Jameel at Annual Meeting

Zak Yusoff, Michael Runion and Rui Fang

Best Practices brain storming session

Steve Nail shares his memories of Mike Pikal

A reception was held at the close of the 2018 Lyohub Annual Meeting in memory of Dr. Pikal.

In February of 2018, Dr. Michael Pikal passed away. He left a huge legacy in freeze drying and beyond.

Rui Fang, Alina Alexeenko and Elizabeth Topp view a poster about the life of Mike Pikal

2018 LyoHUB/ASTM E55 Workshop on
Pharmaceutical Manufacturing Research

Importance and future of pharmaceutical manufacturing, regulatory interface, lyophilization tutorials, resources and more

TUESDAY, OCTOBER 23, 2018
Workshop: 8:00 am -2:30 pm
Lawson Computer Science Room 1142, Purdue
305 N University St, West Lafayette, IN

ASTM INTERNATIONAL

Poster Session and Facility Tours: 3:00-5:00 pm
Birck Nanotechnology Center
1205 W State St, West Lafayette, IN

All events Free and Open to the public
but **must register** by 10/10/18 at
www.astm.org/E55WorkshopOct2018

LYOhub.org PURDUE UNIVERSITY ASTM INTERNATIONAL JN-MaC

To register a poster, e-mail gray160@purdue.edu by 10/10

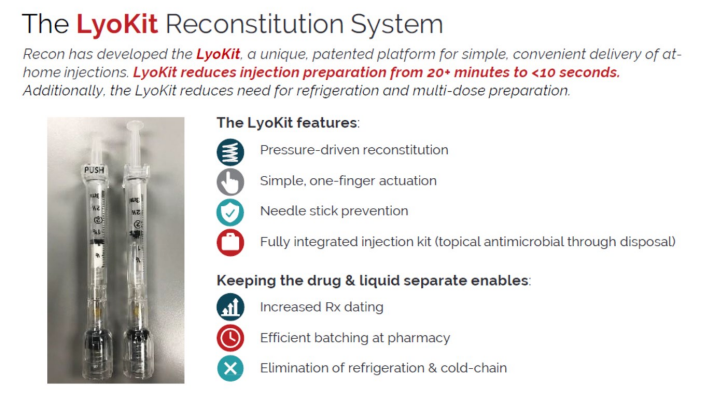
LyoHUB members: IMA LIFE Pfizer janssen MILLROCK TECHNOLOGY INFICON SP SCIENTIFIC Baxter abbvie Allergan Roche McCRONE ASSOCIATES, INC. Pfanstiehl SIEMENS FRESENIUS KABI Bristol-Myers Squibb Abbott OPTIMA AMGEN

Joan Byrne, Guest Speaker from AbbVie, Elizabeth Topp, Drew Strongrich and Sherwin Shang visit the LyoHUB Demonstration Facility during the 2018 LyoHUB/ASTM Workshop

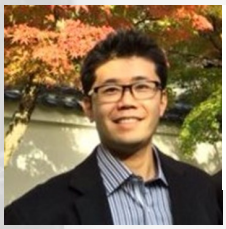
Workshop Panelists (Left-Right): Chris Roberts (NIIMBL), Eric Munson (Purdue), Carl Wassgren (Purdue), Lynne Taylor (Purdue), Tony Zhou (Purdue), Rex Reklaitis (Purdue)

Workshop Poster Session in Birck Nanotechnology Center

Special Presentations



Christopher Lee, June, 2018
http://recontherapeutics.com/



Dr. Satoshi Ohtake, Pfizer
"Lyophilization in the Manufacturing of Biotherapeutic Products"

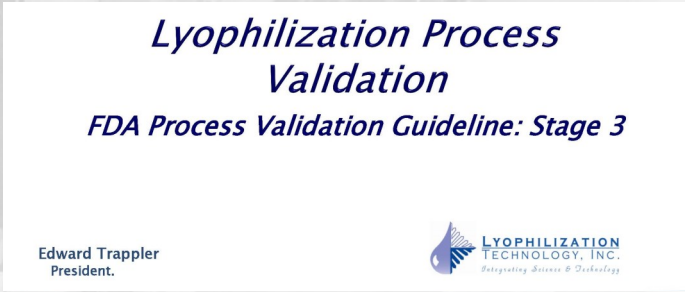
Satoshi Ohtake, July, 2018

Scott Knackstedt, August, 2018
www.path.org

Dr. Ekneet Sahni, Sterile Injectable MSAT, Global Technology Services, Pfizer
"Modeling the Secondary Drying Stage of Freeze Drying: Development and Validation of an Excel-Based Model Products"

Ekneet Sahni, September, 2018
https://www.sciencedirect.com/science/article/pii/S0022354916418320

Diana Loeber, January, 2019
https://www.us.schott.com/english/index.html



Ed Trappler, February, 2019
https://www.lyotechnology.com/

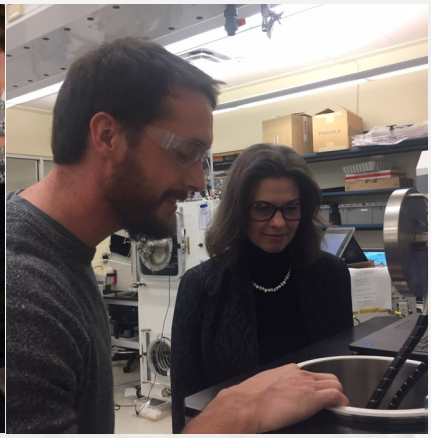
RF and Lyo
How could electromagnetics enhance Lyophilization?

Ahmed Abdelraheem, Purdue, March, 2019

Industry Visits/ Conferences

Reza Eivaskhani and Ehab Moussa at poster session

Sherwin Shang and Chuck Zona at LyoHUB Annual Meeting



Chandra Kelley, Pfanstiehl, visits demo facility

Industry Visits to LyoHUB:

- Amgen, April 2018
- Eli Lilly, April 2018
- CUDDO, April 2018
- Geoff Smith, DMU, UK, April 2018
- Cook Biotech, May 2018
- Siemens, July 2018
- AbbVie, July 2018
- IMA Life, July 2018
- Pfizer, July 2018
- Optima Packaging, July 2018
- Elanco, July 2018
- Baxter, July 2018
- McCrone, July 2018
- Lighthouse Instruments, July 2018
- Pancopia, August, 2018
- Roquette, August 2018
- SeroColombia, September 2018
- Inficon, October 2018
- ASTM, October 2018
- Surface Measurement Systems, October 2018
- AbbVie, October 2018
- LabConco, October 2018
- Zoetis, October 2018
- Surface Oncology, October 2018
- BSI, October 2018
- Optima Packaging, October 2018
- CA Agents, October 2018
- IFPAC, October 2018
- Johnson & Johnson, October 2018
- DuPont, October 2018
- Metrohm USA, October 2018
- Global NEP, October 2018
- Truvian Sciences, October 2018
- NIIMBL, November 2018
- RheaVita, December 2018
- Baxter, February 2019
- AbbVie, February 2019
- IMA Life, February 2019
- Lyophilization Technology, February 2019
- Merck, February 2019
- NIST, March 2019
- Pfizer, April 2019
- Roche/ Genentech, April 2019

Conference Presentations or Posters:

- CPPR, May, 2018
- Garmisch Conference, September 2018
- ISL-FD Chicago, April 2018
- ASTM, April 2018
- CPPR, Purdue, October 2018
- Lyophilization USA, November 2018
- Biotech, Pharma, Cancer Research Conference, August 2018

LyoHUB Visits to Companies:

- AbbVie, June 2018
- Fresenius Kabi, July 2018
- Baxter, December 2018

Plasma Sterilization for Lyophilization

Principal Investigator: Alex Shashurin, Purdue/AAE **Graduate Student: Animesh Sharma**

Sterilization is a key process in the production cycle of lyophilized injectable pharmaceutical drug products. Plasma generated radicals and species have long been used for the sterilization. Specifically, reactive oxygen species and reactive nitrogen species are important for the process. In this project, we are investigating the feasibility of cold atmospheric DC plasma and RF Plasma as a source for radicals to use for sterilization of a lab-scale lyophilizer.

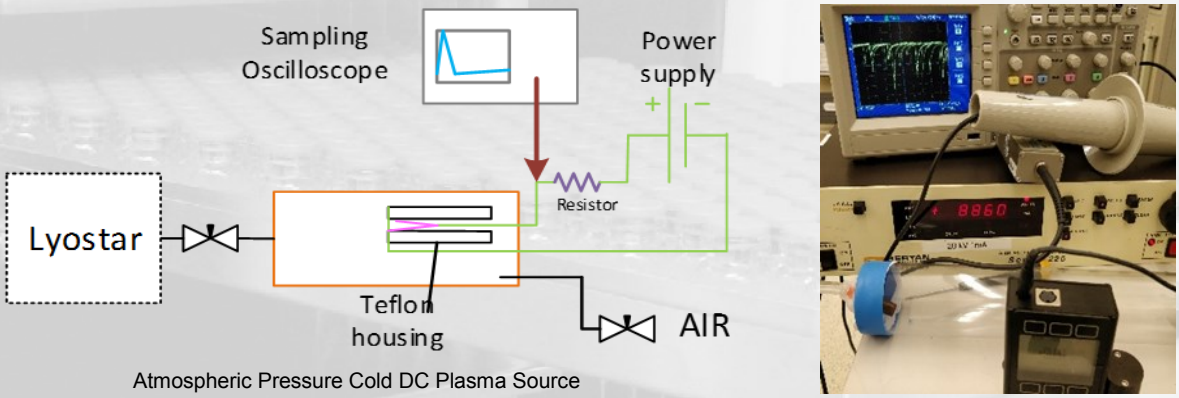


Figure 1. Experimental setup Atmospheric Pressure Cold DC Plasma Source

The cold DC plasma source (Figure 1) is a low-power device made in house which can be operated with a variety of process gases like air, N_2, *He, Ar* to generate desired species. The source operates at atmospheric pressure using breakdown voltage of U~9kV, radicals and species generated are fed into the freeze dryer. A resistor of 1 MΩ was used to limit the current in the circuit. The discharge current (I) measurement is presented in Figure 2. One can see that source operates as a series of breakdown events separated in time about T=200 μs (the frequency of breakdown events was about 5 kHz). The breakdown is characterised by a fast current peak of about 230 μA. The energy associated with each discharge event is determined by calculating the integral $E= \int_0^T UIdt$ and is equal to 3.78 x10^{-5} J. The power consumed was then calculated as $P=E\times f$. It was determined that average power consumed by the DC cold plasma source was 189 mW. Ozone level created in the 590cm^3 air volume was measured by the ozone sensor. We measured excess of 2 ppm of O_3 with 20s operation of the source. The source is capable of producing more ozone but it saturated the sensor, so the operation of the discharge was only set to 20s to produce enough ozone to remain in the dynamic range of the sensor. The temporal evolution of O_3 is presented in Figure 3. The discharge begins at t=5s and stops at t=25s. It can be seen that O_3 has life time was about 100s.

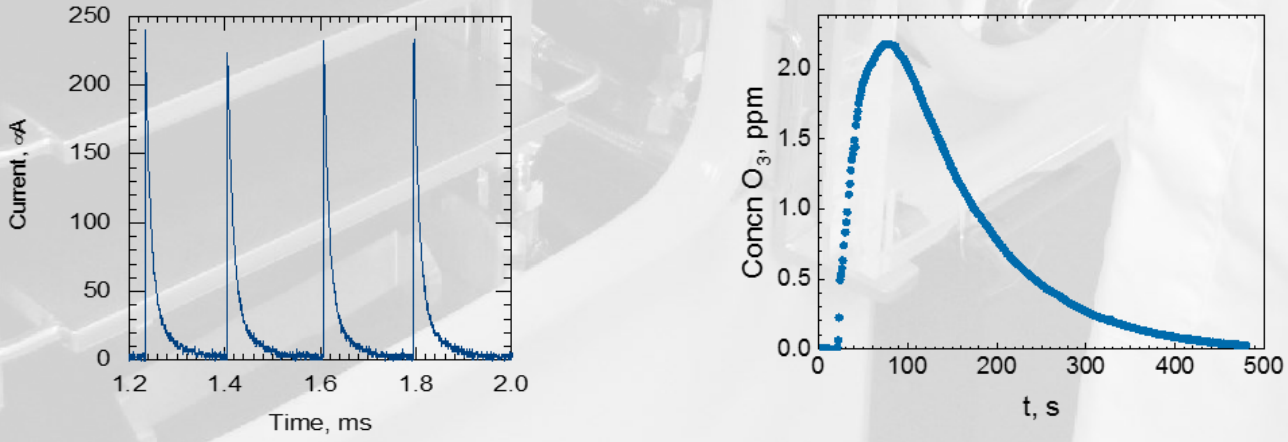


Figure 2: Current (left) and temporal evolution of O_3 concentration associated with the DC plasma source.

Plasma Sterilization for Lyophilization

EVACTRON 25 DE-CONTAMINATOR by XEI Scientific an RF plasma source was tested as well and is presented in Figure 4. The device was mounted onto the Revo Lyophilizer. RF discharge at 13.56 MHz was created inside the chamber at 10mTorr using air as the process gas. The pressure was set to 100 mTorr on the device to drive the flow into the chamber. 10 W of forward power and 1.1 W of reflected power were measured. Mass Spectrometer was used for residual gas analysis (Figure 5). It was found that hydrogen peroxide was produced during the discharge. The plasma sources will be tested against spore based bioindicators for their effectiveness in sterilization.

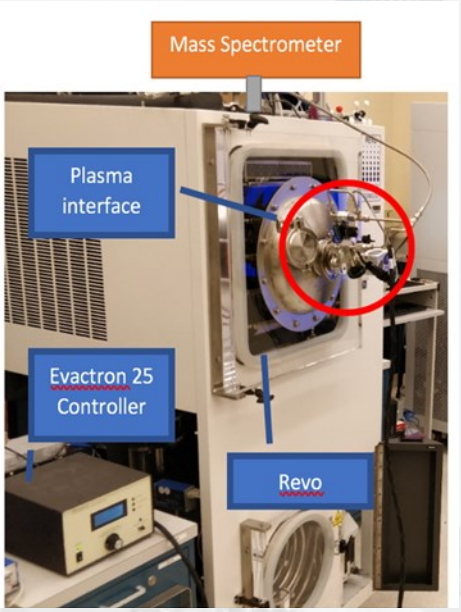


Figure 3: RF Plasma source setup on the lyophilizer

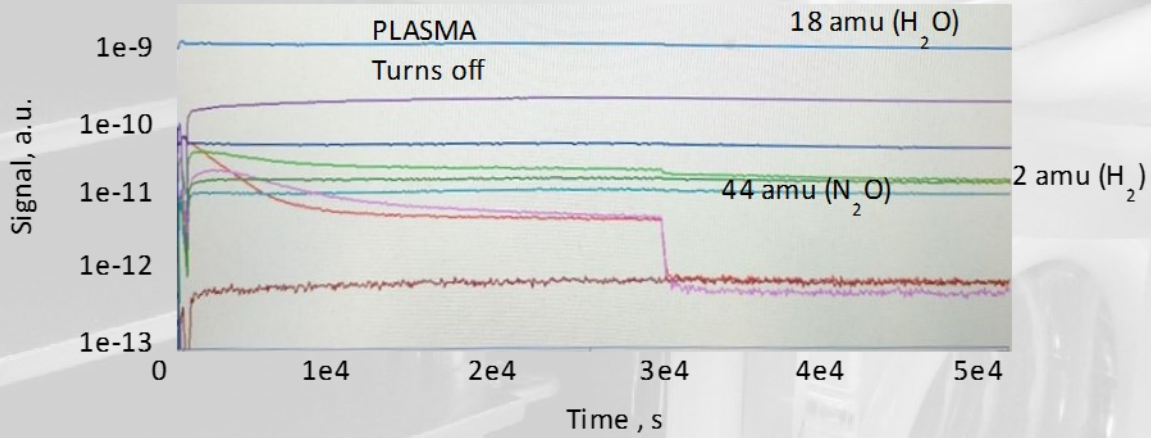
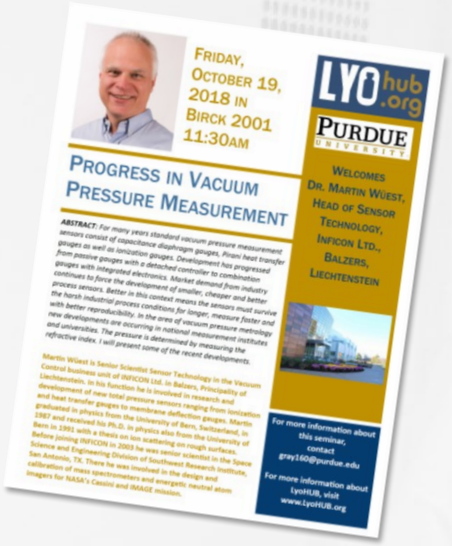


Figure 4: Gas composition in lyophilizer during and after RF plasma

	Evactron RF Source	Cold DC Plasma
Spec	13.7MHz	9 kV
Power consumed	9 W	0.189 W
Pressure set at device	100 mTorr	760 Torr
Process gas	Air - 0.01 slpm	Air -stagnant
Sensing Device	RGA	Electro Chemical sensor
Species detected	H_2O_2	O_3

Summary The ability of cold DC plasma source and Evactron RF plasma source to produce various radical species was tested. Ozone was produced by the cold DC plasma source at 2.4 ppm in 590 cm^3 reacting chamber using air at atmospheric pressure. The plasma source was operated for 20s and ozone decayed to half its concentration in 100s. No ozone was detected when the gas from the reacting chamber was fed to the lyophilizer. Evactron RF plasma source was attached to the Revo and operated under vacuum with the room air as the process gas. RGA attached to Revo detected hydrogen peroxide during the operation of the source.

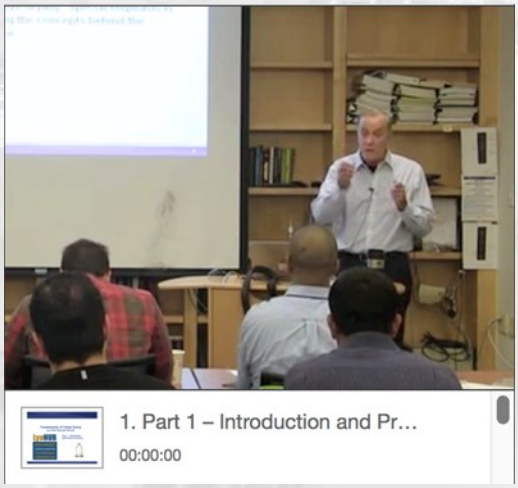
Resources Available on the LyoHUB Website



The NIST-sponsored Lyophilization Technology Roadmap was published and distributed in September 2017. Since September 12, it has been downloaded 1,200+ times. It is available to all on the LyoHUB website at

https://pharmahub.org/groups/lyo/roadmap

Lecture Number/Topic	Online Lecture	Video	Lecture Notes
Fundamentals of Freeze Drying I: Introduction and Process Overview	View HTML	View	Notes (pdf)
Outline Introduction Advantages and limitations of freeze drying Product quality attributes Secondary drying The Freezing Process Supercooling and ice...			
Fundamentals of Freeze Drying II: The Freezing Process	View HTML	View	Notes (pdf)
Fundamentals of Freeze Drying III: Primary and Secondary Drying	View HTML	View	Notes (pdf)
Fundamentals of Freeze Drying IV: Process Monitoring	View HTML	View	Notes (pdf)
Fundamentals of Freeze Drying V: Formulation Consderations	View HTML	View	Notes (pdf)



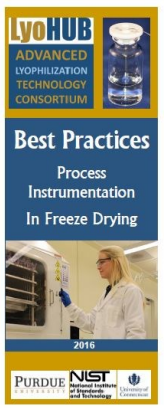
Tools available on Website:

LyoHUB Training July 2018:

- Freeze drying: https://pharmahub.org/resources/773
- CFD: https://pharmahub.org/resources/778

- Dr. Martin Wuest (Inficon) Talk, "Progress in Vacuum Pressure Measurement" https://pharmahub.org/resources/756
- Jos Corver (RheaVita) "Continuous Freeze Drying" talk https://pharmahub.org/resources/792
- LyoCalculator https://pharmahub.org/resources/lyocalculator
- Lyo Chamber Pressure Variation Calculator https://pharmahub.org/resources/pressurevar
- LyoHUB Best Practice Paper, Recommended Best Practices for Process Monitoring in Pharmaceutical Freeze Drying http://link.springer.com/article/10.1208/s12249-017-0733-1
- LyoHUB Lyophilization Technology Roadmap https://pharmahub.org/groups/lyo/lyohub_roadmapping
- Presentations, such as "Developing Transferable Freeze Drying Protocols using Accuflux® and a MicroFD®" https://pharmahub.org/groups/lyo/tools

Best Practices



LyoHUB published our first lyophilization best practices paper, ***"Recommended Best Practices in Instrumentation Process Monitoring in Pharmaceutical Freeze Drying"*** in 2017**.** It is available with open access and as of March 2019 has been downloaded over 7,500 times!

http://link.springer.com/article/10.1208/s12249-017-0733-1

Best Practices Papers in Progress:

Scale Up and Tech Transfer

Led by Serguei Tchessalov and Bakul Bhatnagar (Pfizer)

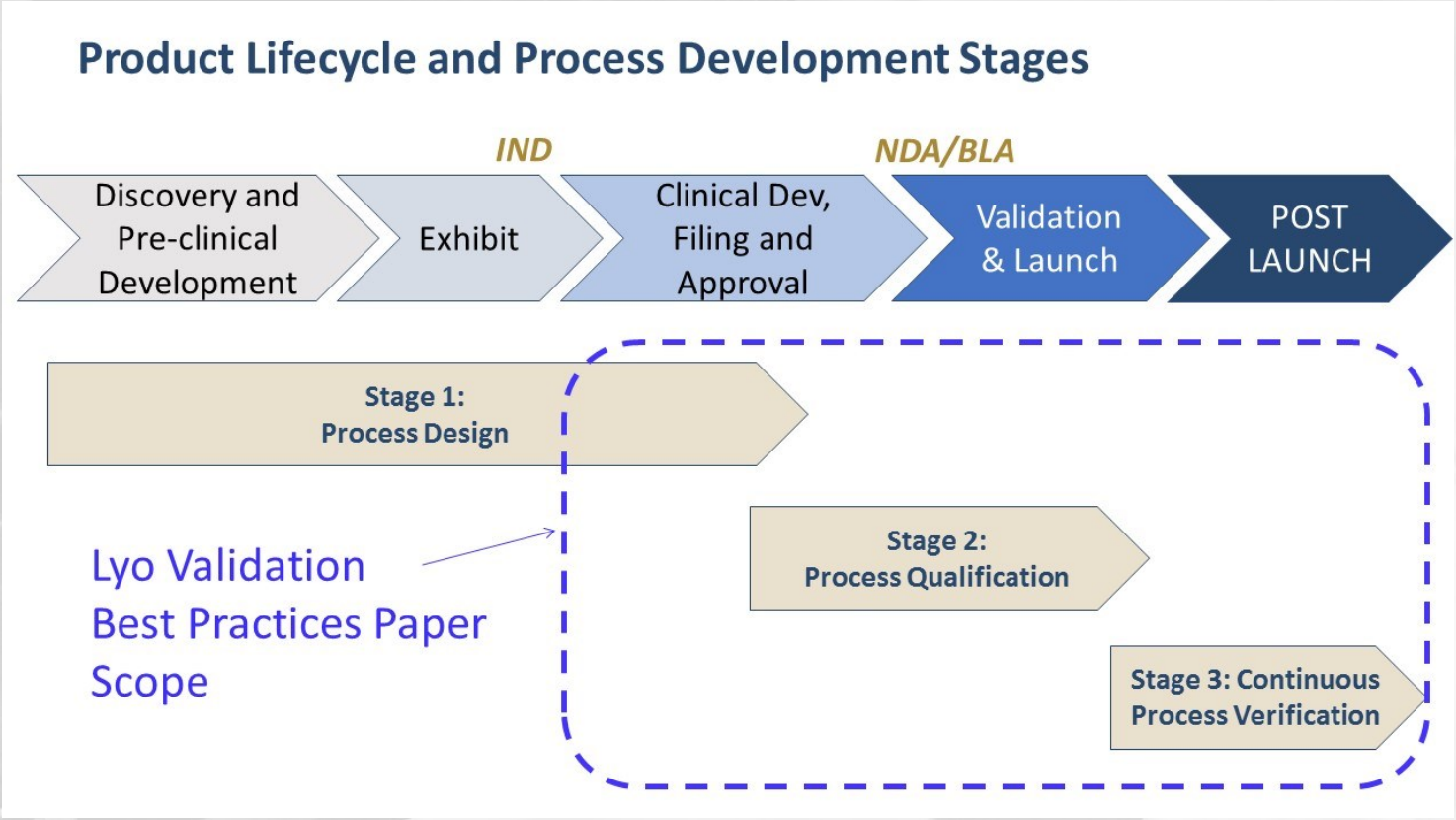
Equipment Performance Qualification

Led by Arnab Ganguly (IMA Life)

Submitted to AAPS PharmSciTech Jan. 17, 2019

A Practical Guide for Validation of Pharmaceutical Lyophilization

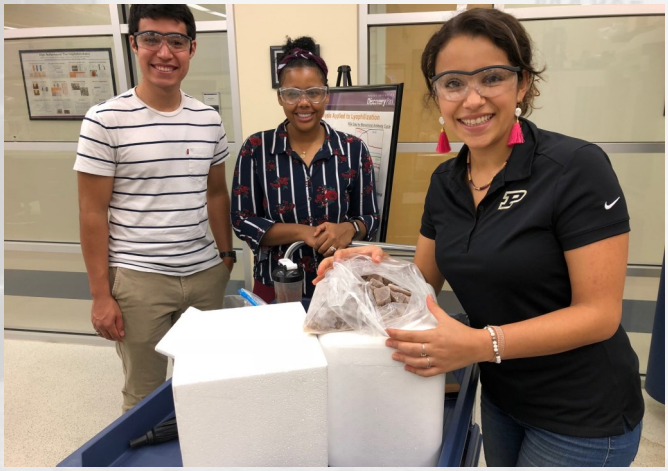
Led by Feroz Jameel (AbbVie)



LyoLaunchPad

New LyoLaunchPad projects:

- **Lyophilization of Cricket Protein** for Food Science (Purdue) freeze drying cricket protein hydrolysates (CPH)
- **Lyophilization of HP-ß-CD/SBE-ß-CD Poly-rotaxanes** for Dr. David Thompson (Purdue)
- **Freeze-Drying of Chicory Inulin**
- **Lyophilized formulation for an amphipathic peptide** for Corvidia



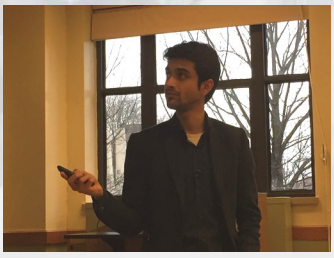
Gabriela Calzada Luna (Food Science) with team preparing to freeze-dry cricket protein.

Zach Struzik (Chemistry) and Drew Strongrich with a sample of cyclodextrin for lyophilization.

New Purdue Course

Principles of Pharmaceutical Engineering: This course is designed to provide engineering, science and pharmacy students with an understanding of the structure, economic and regulatory context, product discovery and development pipeline dynamics, intellectual property considerations and common manufacturing technology of the global pharmaceutical industry.

Ted Tharp, AbbVie, lectures on ***Campaign Operation, Multiproduct Manufacture and Process Design***



Arnab Ganguly, IMA Life, lectures on ***Batch Process Fundamentals***

Greg Sacha, Baxter, lectures on ***Introduction to Dosage Forms***

Demonstration Facility

In February 2016, LyoHUB opened the **Lyophilization Technology 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 offers various hands-on training opportunities for academic and industry users. Full equipment listings and capabilities can be found on the LyoHUB website at https://pharmahub.org/groups/lyo/demofacility

LyoHUB demo facility is located in Birck Nanotechnology Center, Room 2261.

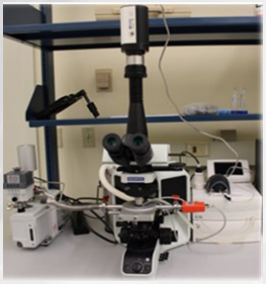
Computrac® Vapor Pro ®

Lighthouse FMS-1400 Headspace Pressure/ Moisture Analyzer

REVO lyophilizer with controlled nucleation and in-situ mass spectrometer.

LYOSTAR™ 3 Freeze-Dryer with controlled nucleation and mass flow meter

Development Freeze-Dryer/ Lyophilizer MICROFD



McCrone Freeze-Drying Microscope

Contacts

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astrongr@purdue.edu

Karthik Chandrababu
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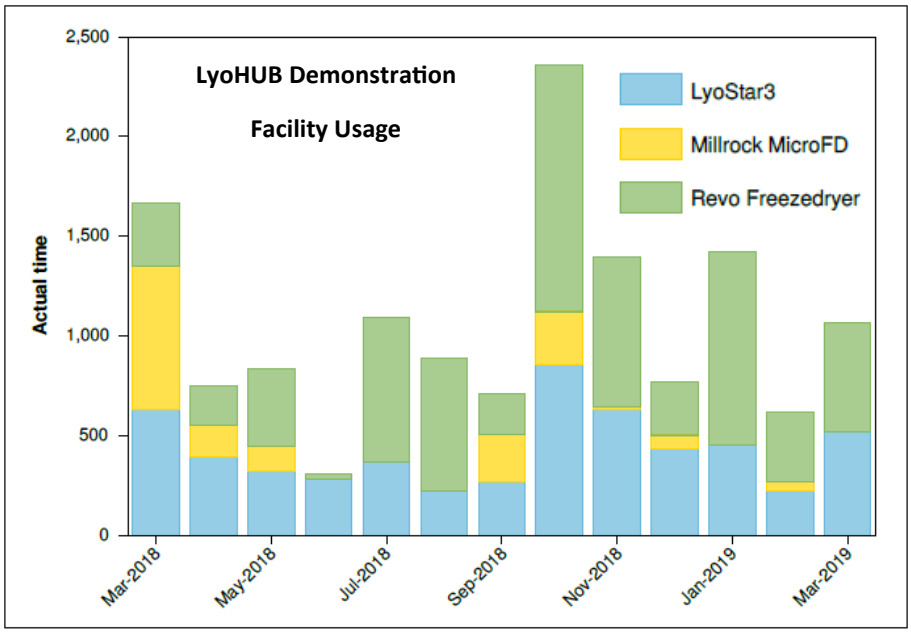
Demonstration Facility



Total Number of Lyophilization Runs:
(2/26/16-3/26/17): **87**
(3/1/17-3/30/18): **178**
(4/1/18-3/27/19): **190**

Average Time for Lyophilization Run (in hours):
(2/26/16-3/26/17): **33.25**
(3/1/17-3/30/18): **51.83**
(4/1/18-3/27/19): **73**

Total Lyo Run Time:
(2/26/16-3/26/17): **2,971.37 hours**
(3/1/17-3/30/18): **9,227.17 hours**
(4/1/18-3/27/19): **13,944 hours**

Ongoing Projects in the LyoHUB Demonstration Facility:

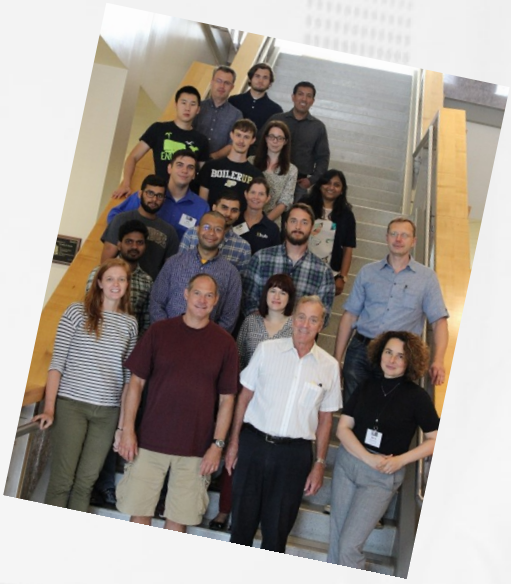
- Wireless pressure sensor characterization (Purdue AAE)/National Science Foundation (NSF) project
  - ◊ Real-time in-situ ambient gas pressure and temperature monitoring for enhanced process control and sublimation rate quantification.
- RGA analysis of drying performance in co-solvent formulations/Center for Pharmaceutical Processing Research (CPPR) and Baxter project
  - ◊ Quantification of the relative extraction rates between water and a co-solvent under various process conditions. Results are directly correlated with dried cake properties (both amorphous and crystalline).

Edward Trappler (Lyophilization Technology, Inc) and Drew Strongrich

New Users Trained on Lyophilization Equipment from March 2018-2019

Name	Affiliation		Name	Affiliation
Ahmed Mahmoud Mahrous Abdelraheem	Purdue Electrical and Computer Engineering		**Heejun Park**	Purdue IPPH/Zhou Lab
Gabriela Calzada Luna	Purdue Food Science		**Zachary Struzik**	Purdue Chemistry/ Thompson lab
Adithye Menon	Purdue AAE		**Lia Bersin**	Purdue IPPH/Topp Lab
Siamak Shams Es-haghi	Purde Materials Engineering/Cakmak Lab		**Rajashekar Kammari**	Purdue IPPH/Topp Lab
Dylan Morris	Purdue Materials Engineering		**Ahmed Abdelraheem**	Purdue Computer Engineering/Peroulis Lab
Ming-Hsu Chen	Purdue Food Science		**Shahzad Hameedi**	Purdue Computer Engineering/ Peroulis Lab
Nathan Wilson	Purdue IPPH/Zhou & Topp Labs		**Xiaofan Jiang**	Purdue Electrical & Computer Engineering
Sonal Bhujbal	Purdue IPPH/Zhou Lab		**Israel Sebastiao**	Purdue AAE/Alexeenko Lab
Tarun Mutukuri	Purdue IPPH/Zhou Lab		**Gayathri Shivkumar**	Purdue AAE/Alexeenko Lab
Shahin Mohseni	Purdue ChemE			

Education & Training



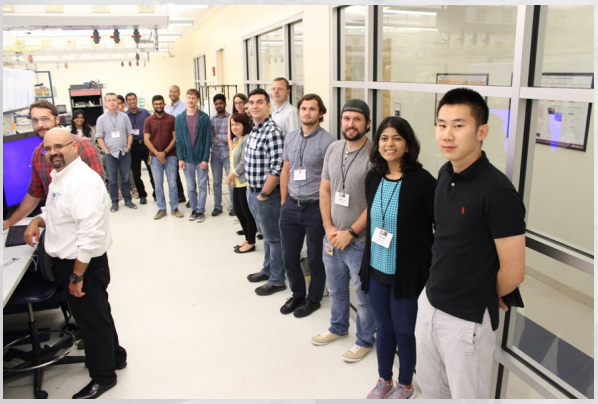
LYO101 Summer School 2018 featured Formulation, Design Space and CFD training

2.5-day workshop for Purdue and industry users

Participants:

- **17 students and postdocs**
- **10 industry participants:** Fresenius Kabi (1), IMA Life (1), AbbVie (2), Baxter (2), Pfizer (1), Optima Packaging (1), Elanco (1), Siemens (1)
- **2 Equipment demos:** McCrone (Freeze Dry Microscope) and Lighthouse Instruments (Residual Moisture Analyzer)

Steve Nail (Baxter) leads the formulation and design space training



Ruben Nieblas, McCrone leads a demonstration on freeze dry microscopy in the LyoHUB demo facility

Teams compete to "Escape the Lyo Lab"

On-Site Customized Training at Fresenius Kabi

TOPICS:

- Introduction and Process Overview
- The Freezing Process
- Primary Drying
- **Secondary Drying**
- Process Monitoring
- Freeze Drying Equipment, and Measurement of Equipment Capability
- Formulation Considerations
- Hands-on exercise in constructing a graphical design space for primary drying

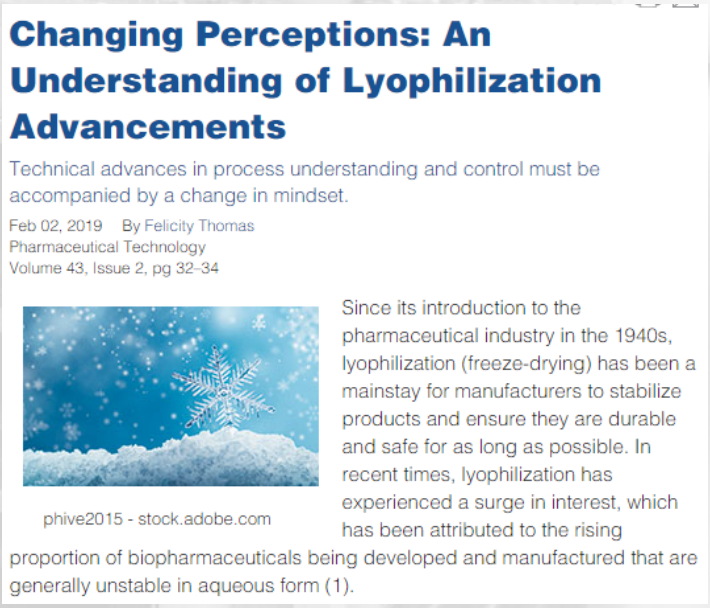
Diverse group in terms of location and function within company: 3 sites in North America plus India and Europe Included Scientists, Process Engineers, Manufacturing Director and a Vice President among others.

Steve Nail, Baxter, leads training at Fresenius-Kabi, July 2018

LyoHUB in the News

- **Key Process to be Modernized in Food Preservation and Production of Lifesaving Drugs**, Winter 2017 *Tech Titans*
- **Changing Perceptions: An Understanding of Lyophilization Advancements,** February 2019, *PharmTech.com*
- **Optimization of Lyophilization and Alternatives to Conventional Freeze-Drying Methods,** July 2018 *pharmaphorum.com*
- **Purdue to Host Drug Manufacturing Standards Meeting**, August 2018 www.powderbulksolids.com
- **Purdue to Host Pharmaceutical Manufacturing Standards Meeting**, August 2018 purduefoundry.com
- **Purdue to Host Pharmaceutical Manufacturing Standards Meeting**, August 2018 contractpharma.com
- **OPTIMA pharma now part of LyoHUB,** October 2018, Healthcarepackaging.com
- **Purdue University Workshop on Pharmaceutical Lyophilization**, October 2018 www.azic.com

LyoHUB/ASTM Workshop October 2018
1st Place Poster Award to Gayathri Shivkumar
CFD Modeling of Lyophilization Equipment Capability



Changing Perceptions: An Understanding of Lyophilization Advancements

Technical advances in process understanding and control must be accompanied by a change in mindset.

Feb 02, 2019 By Felicity Thomas
Pharmaceutical Technology
Volume 43, Issue 2, pg 32–34

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Since its introduction to the pharmaceutical industry in the 1940s, lyophilization (freeze-drying) has been a mainstay for manufacturers to stabilize products and ensure they are durable and safe for as long as possible. In recent times, lyophilization has experienced a surge in interest, which has been attributed to the rising proportion of biopharmaceuticals being developed and manufactured that are generally unstable in aqueous form (1).

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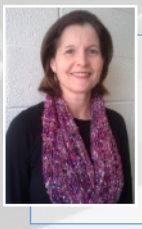

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Annual Member Meeting, April 2018, Chicago

www.LyoHUB.org

https://twitter.com/lyohub

https://www.linkedin.com/company/lyohub/