LYOHUB CONSORTIUM

An industry-led Partnership to advance the science and technology of lyophilization (freeze drying). In response to identified needs of LyoHUB members, current activities are aimed at:

- **Development of best practices** for lyophilization equipment performance, formulation, testing and validation;
- **Advancement of process analytical technologies and sensors** for process development, monitoring and control.
- **Creation and dissemination of education and training materials** describing the state-of-the-art scientific understanding and best practices in lyophilization technology;
- **Conducting pre-competitive research, development and pilot demonstration projects** in the LyoHUB demonstration facility at Purdue University.

MEMBERSHIP

Industrial membership in LyoHUB includes participation in all activities, including working groups on standards and advanced technologies, roadmapping activities, education and training materials and access to the LyoHUB demonstration facility for member company representatives.

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STAY CONNECTED

https://twitter.com/lyohub
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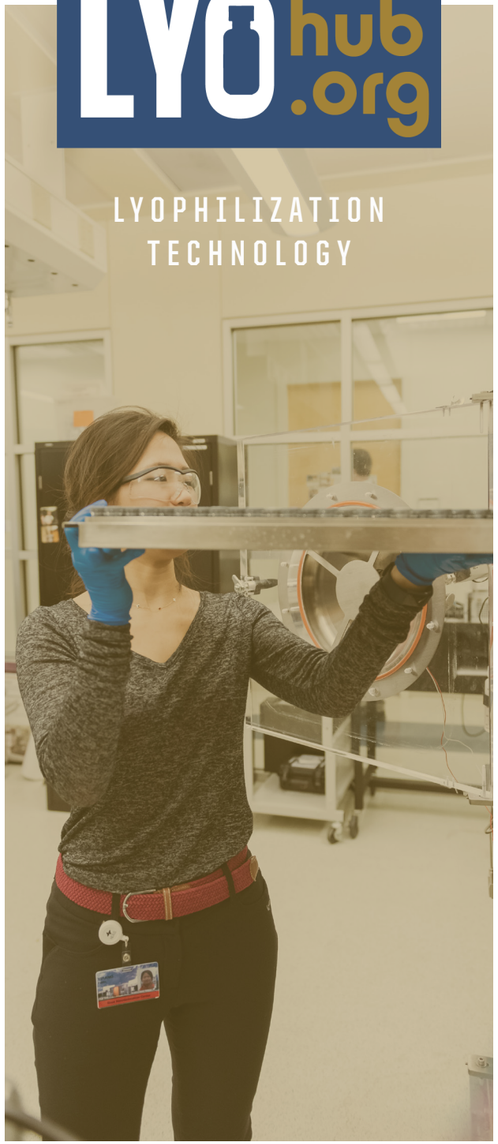
LYOhub.org

LYOPHILIZATION TECHNOLOGY



ADVANCED LYOPHILIZATION TECHNOLOGY CONSORTIUM

RESOURCES AND QUALIFICATIONS

LyoHUB builds on existing expertise in the area of freeze-drying in the Colleges of Pharmacy and Engineering at Purdue, as well as expertise in manufacturing in both the pharmaceutical and food processing sectors.

In addition, LyoHUB is synergistic with related activities at Purdue, including the Center for Pharmaceutical Processing Research (CPPR), the NSF ERC on Structured Organic Particulates (ERC-CSOPS), and the new Center for Particle Processing (CP3). Additional synergies exist in terms of training and educating the future workforce through developing degree programs in pharmaceutical engineering, food science, and the ongoing efforts in pharmaceutical biologics and drug discovery.

LYOHUB.ORG

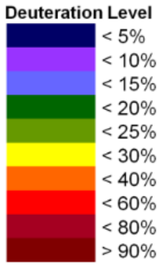
BACKGROUND

For many high-value proteins, peptides and vaccines, lyophilization is the only way to produce stable, biologically active products with long shelf-life. The U.S. is currently the leader in the pharmaceutical biotechnology sector with 43% global market share, a projected annual growth rate of 9.6% and a stronger development pipeline than any other nation. About 25 percent of new injectable drugs, vaccines and biological products are formulated in lyophilized form. Advances in freeze-drying technology are required to meet the growing demand for high-capacity and efficient freeze-dryers.

LyoHUB is a university-industry consortium, formed in 2014 under a NIST AMTECH (Advanced Manufacturing Technology Consortia) grant (Award Number: 70NANB15H067) with the goals of starting an industry consortium and developing a 10 year technology roadmap for lyophilization. The 10 year roadmap can be downloaded from our website at https://pharmahub.org/groups/lyo/lyohub_roadmapping

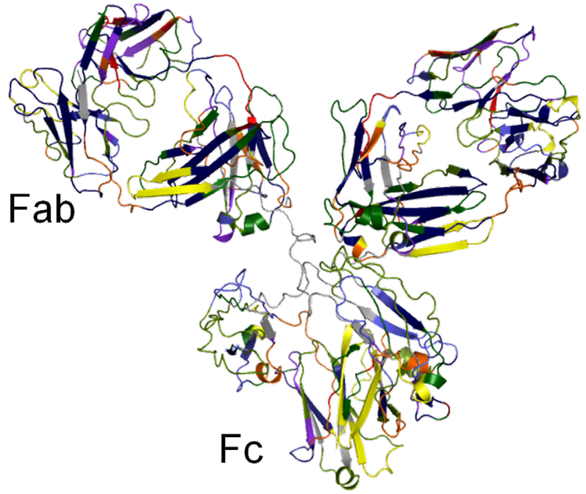
INITIATION OF PILOT TECHNOLOGY DEVELOPMENT AND DEMONSTRATION PROJECTS

LyoHUB operates a demonstration facility in Birck Nanotechnology Center in Purdue's Discovery Park, where collaboration on breakthrough technologies are advanced with a goal of accelerating adoption and decreasing time to market for new instruments, equipment and processes. The facility is equipped with state-of-the-art lyophilization equipment and is supported by LyoHUB's industry members including equipment manufacturers. The facility also offers various hands-on training opportunities for academic and industry users. To view the facility's equipment, support and capabilities, visit https://pharmahub.org/groups/lyo/demofacility.



AN INDUSTRY-LED PARTNERSHIP TO ADVANCE THE SCIENCE AND TECHNOLOGY OF LYOPHILIZATION

LyoHUB offers a program called LyoLaunchPad which allows groups to do an approved, non-proprietary, short-term project in the LyoHUB demonstration facility at no charge. Participants are then asked to do a short presentation for LyoHUB members at the completion of the project. Proprietary research agreements are also available.



ONLINE HUB RESOURCES

LyoHUB hosts the online www.lyohub.org, which provides collaboration tools and a repository of data and working group materials.

The online hub includes:

- Interactive process simulation tools
- Training for freeze-drying equipment and tutorials for analytical techniques
- Repository of standards and working group studies and reports
- Lyophilization Online Short Course
- LyoPRONTO (an open source Lyophilization PRocess OptimizatioN Tool)
- Lyophilization in Review
- Lyophilization Technology Roadmap
- Published Best Practices Papers