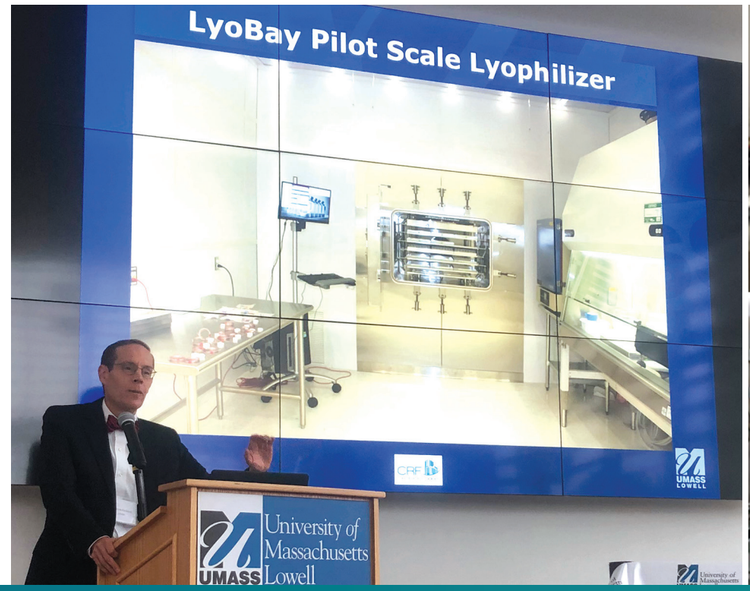
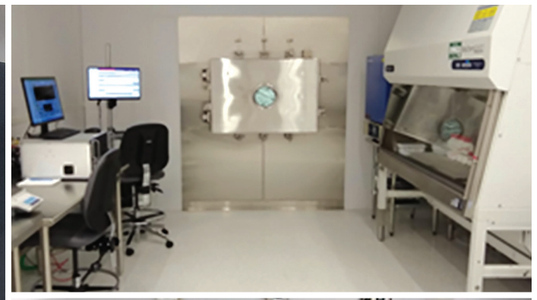
SOFTWARE AND HARDWARE TOOLS FOR LYOPHILIZATION SCALE-UP

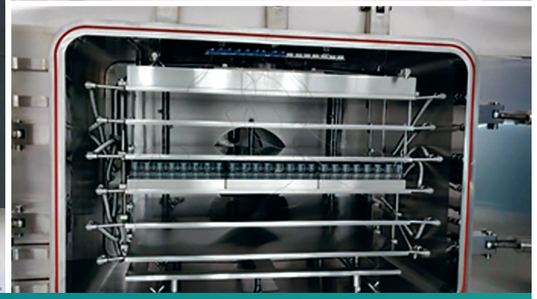
Improving product stability through new lyophilization tools

When companies come to me asking if they can implement this broadly through their organization, that is one of the biggest validations that our project was a success.

BILL KESSLER
Physical Sciences, Inc.







PHYSICIAL SCIENCES, INC.

Andover, Massachusetts

Type:
Small-Med Size Company

Participating Organizations:
University of Massachusetts Lowell, National Institute for Pharmaceutical Technology and Education, Inc. (NIPTE) (Uconn), Massachusetts Life Sciences Center, Purdue University, Merck & Co., Inc., Genentech

INDUSTRY NEED

Lyophilization, commonly known as freeze drying, is used in biopharmaceutical manufacturing to stabilize products and maximize shelf life. The share of approved lyophilzed injectable/infusable drugs has grown tremendously in recent years from 11.8% between 1990 – 98 to approximately 50% between 2013-15.[1] However, lyophilization is a complicated process that currently lacks predictive modeling. Further, despite its growing prevalence in the industry, there is generally a lack of expertise on the freeze drying process. This knowledge gap puts the industry at risk for disruptions that may lead to wasted products or supply shortages.

SOLUTION

This project built universally accepted software and hardware tools to help manufacturers better understand their lyophlization process to reduce the risk of errors and lost product. These tools will not only increase expertise but also ease companies through scale-up. The project creates modeling tools that helps manufacturers understand the impact of process errors and addresses heterogeneiety to ensure consistency across the batch.

OUTCOME

The team successfully built the new software and hardware tools that provide companies with a complete understanding of the lyophilization process. The tools were then tested by large industry partners Merck & Co., Inc. and Genentech. The project led to the opening of the new Lyophilization Lab at the University of Massachusetts Lowell, which is available to the biopharmaceutical community for research and development. This pilot-scale, non-GMP facility can be used to further R&D to support advancements in freeze drying technology.

[1]LyoHub. Lyophilization Technology Roadmap (2017).

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