

• The Promise of Science

Baxter's Lyophilization Center of Excellence



BioPharma Solutions' facility in Bloomington, Indiana, USA, is home to the LCOE, staffed by scientists with expertise in parenteral product formulation, process and analytical development.

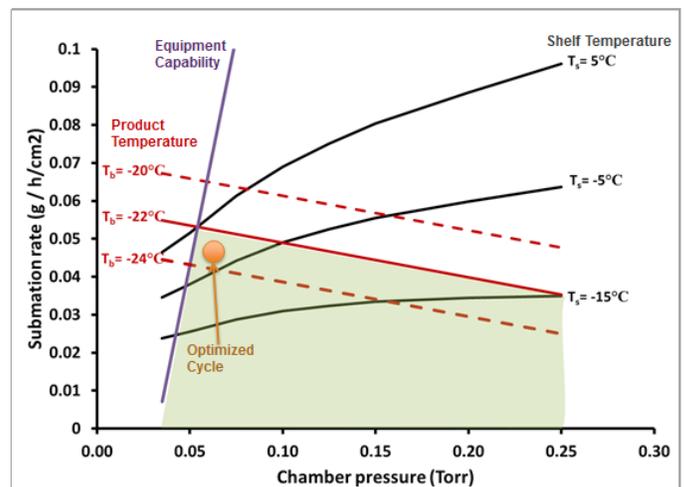
Baxter's approach to freeze-dry cycle development provides advantages over traditional cycle development:

- Reduces amount of API required for development
- Reduces time required for development
 - Use of TDLAS allows for rapid determination of Kv and Rp
 - Remaining definition of design space requires mathematical calculations only.
- Includes edges of failure of equipment and product
- Helps to ensure pharmaceutically acceptable product
- Facilitates handling of deviations
- Provides experimentally determined residual moisture specification
- Identifies the fastest possible robust cycle
- Reduces manufacturing cost

Experience Makes the Difference

Optimizing lyophilization cycle times and improving stability for complex injectables is a critical component of parenteral product development. With this understanding, BioPharma Solutions established the Lyophilization Center of Excellence (LCOE), an industry-leading resource center, to focus on the development of high-quality freeze drying. Dr. Steven Nail and Wendy Saffel-Clemmer, distinguished scientists and educators, lead our team of scientists who can assist with modifications and formulas to help maximize the potential of your lyophilized products.

Staffed by 18 scientists with average experience of 18 years, you can feel confident knowing that your molecule is in good hands.



Example: Design Space Created Using TDLAS Data to Determine the Most Optimized Cycle

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Lyophilization Tools and Techniques:

- 6 Research Freeze-Dryers
 - All LyoStar (Sample Thief)
 - One capable of controlled nucleation
- MicroFD Freeze Dryer
- DSC (2 systems, one Nano)
- TGA
- Freeze-dry microscopy
- FTIR microscopy
- KF, NIR, Vapor Pro for moisture analysis
- 3 Tunable Diode Laser Absorption Spectrometers (TDLAS)
- Thermal Activity Monitor (TAM)
- XRPD

Quick facts about the LCOE staff:

- 18 scientists
- Average experience: 18 yrs
- Industry-Recognized Educators/Authors/Speakers on Lyophilization
- Collaborative and customer-focused
- Research collaborators and members of university/industry consortia



We offer:

- Targeted lab-to-product correlation for optimum manufacturing and cost efficiencies
- Six research freeze-dryers for development of freeze-dry cycles for future clinical manufacture
- Robotic loading/unloading of lyophilizers to minimize handling and microbial exposure
- State-of-the-art instrumentation for the detection of aggregation and other physical stability issues
- Proven scientific approach to cycle development vs. traditional trial-and-error techniques
- State-of-the-art analytical methodologies for protein biophysical characterization and measurement of protein aggregates
- Expertise in capillary electrophoresis, including cIEF and cGE

For more information, visit our website at baxterbiopharmasolutions.com or contact:

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