

The image shows a lyophilizer chamber with its door open. On the left, the circular door is visible, showing the internal shelves. On the right, a person wearing white gloves is carefully handling a tray filled with PCR reagents. The background is a clean, industrial setting.

A Lyophilization Webinar that's 'Not-So-Dry':
The Benefits, Challenges, and Best Practices of
Freeze-Drying PCR Reagents

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Before we get started...



Please use the Q&A button at the bottom of your screen to submit any questions.

There will be a 10-minute Q&A session at the end of this webinar. If we do not have time to answer your questions, we will reach out by email following the webinar.



This webinar is being recorded. The recording as well as on-demand link will be released following the webinar.

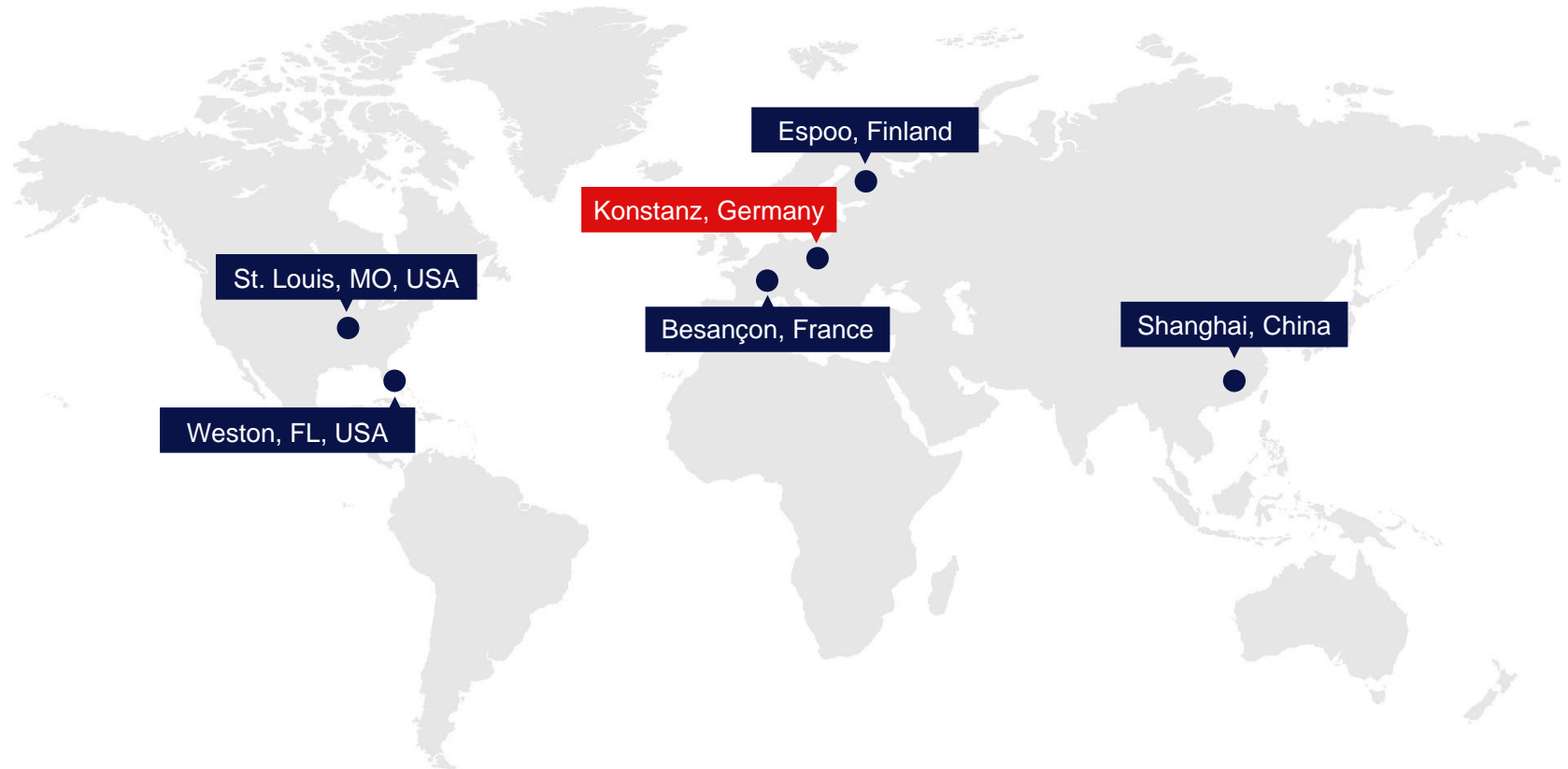
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We're Wherever You Are

- A truly global company with a proudly Finnish background
- Our products are used in over 70 countries
- Offices and manufacturing facilities all around the world

Employee Expertise

- Decades of dedication to developing essential raw materials for diagnostic applications
- Over 270 employees, with 1 in 5 people work in R&D



Engineered Polymerases for Molecular Diagnostics and more...

- Unique Polymerases for DNA/RNA
- ISO:13485 Conformity
- Assay Development Services
- Lyophilization Services
- Lyo-Ready PCR Products





Today's Speaker:

Xenia Lindt
Scientific Projects Manager

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Lyophilization Overview

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What is Lyophilization?

Definition

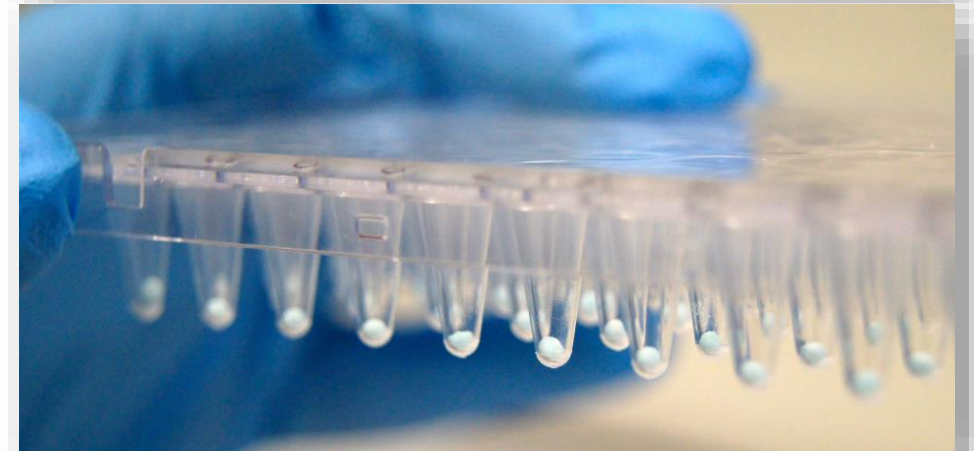
- Lyophilization, also known as freeze-drying, is a process to remove moisture from a substance via freezing and application of vacuum for the stabilization of biological materials.

Steps

1. Freezing
2. Primary Drying (Sublimation)
3. Secondary Drying

Uses

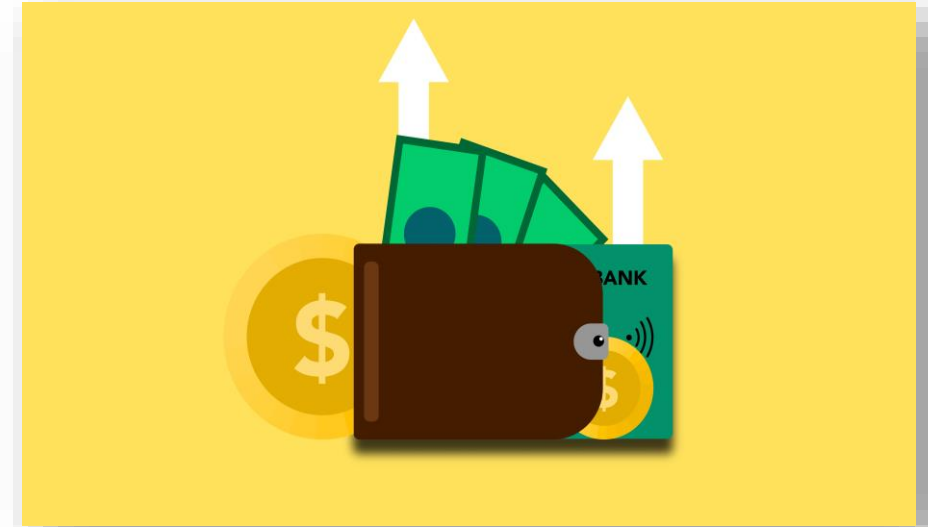
- Preservation of biological samples.
- Stabilization of pharmaceuticals.
- Long-term storage of lab reagents.



Advantages of Freeze-Dried Products

For the Manufacturer and the End-User

- Enhanced product stability in a dry state
 - Reduction in storage costs
 - Reduction in shipping costs
- Removal of water without having to heat the product excessively
- Ready to Use / Simplified Workflows
 - Enables use by un-trained personnel
 - Ideal for Point-of-Care Testing



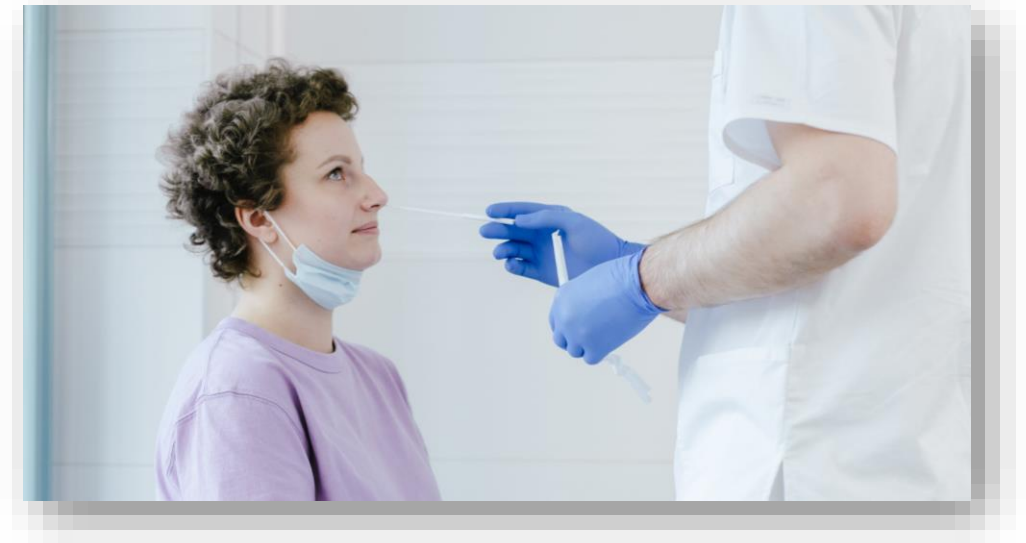
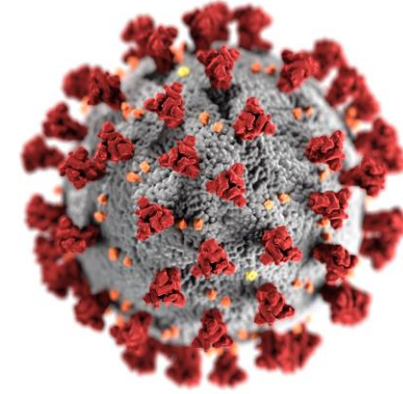
Lyophilization's Growing Demand

Recently, lyophilizing PCR reagents has gained importance for both end users and manufacturers

Driven by **COVID-19 Pandemic** and **shift in market trend**, lyophilization can:

- Improve Stability/Shelf-Life
- Simplify Transport/Storage
- Improve Convenience
- Reduce likelihood of errors (simplified workflows)
- Enable de-centralized testing
- etc.

Lyophilization is becoming a key part of Point-of-Care testing

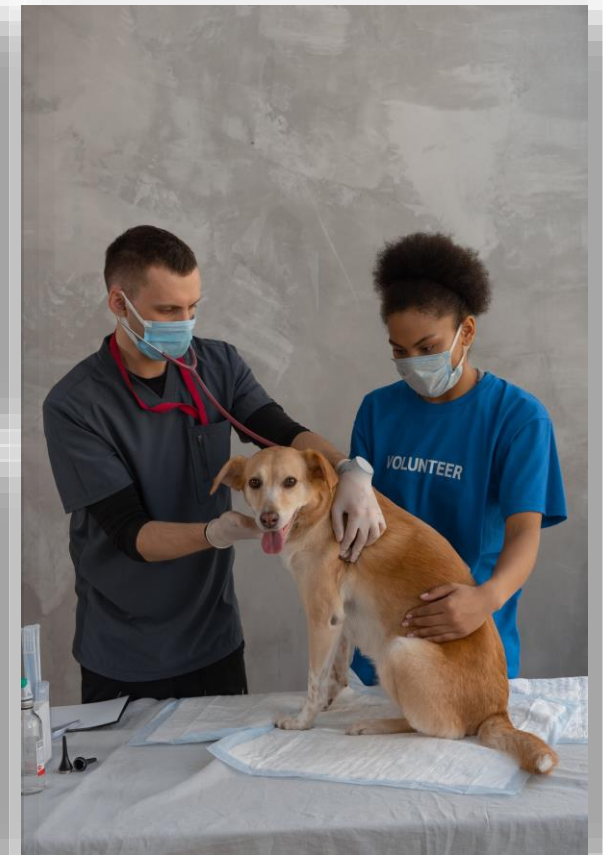


Lyophilization's Growing Demand

Not just for IVD

- Agriculture (Plant Pathogen Detection)
- Food Safety Testing
- Veterinary Medicine
- Wastewater Screening
- Forensic Science
- etc.

Where “Point-of-Need” testing is required,
lyophilization can help



Different Types of “Lyo” Products

Lyo-compatible products

Enzymes in liquid format that have low or no glycerol content (below 0.1–0.5%)

Lyo-ready products

Master Mix in liquid format that do not need any additional excipients to be lyophilized.

Lyophilized products

Customized solutions for specific applications.



Challenges with Lyophilization of PCR Reagents

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What challenges do we face?

- Small volumes (μL vs. mL)
- Glass vs. plastic
- Single components vs. mixtures
- Low collapse temperatures
- Need of excipients
- Protection from humidity



[Grundlagen der pharmazeutischen Gefriertrocknung \(gea.com\)](http://gea.com)

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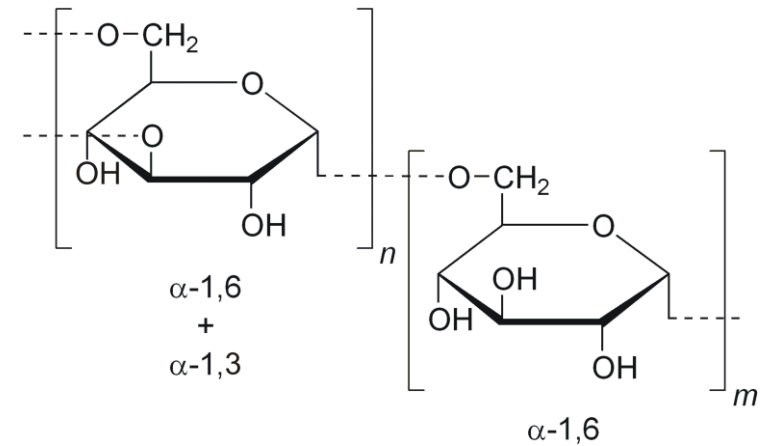


How to overcome
the challenges with
Lyophilization of
PCR Reagents

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Excipients - what are they, and why are they needed?

- Small molecules often have low transition temperatures, which may require **thermal stabilisers** to increase transition temperature into the normal working temperature range of a lyophilizer.
- Biomolecules often need **lyoprotectants** to stabilise them during freezing and drying, where water molecules important to the 3D structure may be removed.

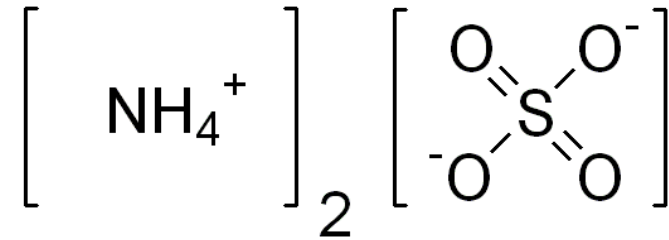
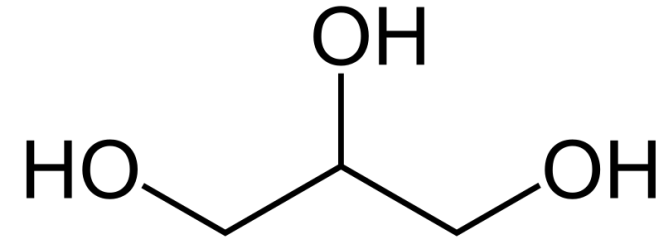


Common Excipients

Thermal Stabilizers	Lyoprotectants	Bulking Agents	Buffering Agents
Dextran	Sucrose	Mannitol	Citrate
Proteins	Trehalose	Lactose	Tris
PEG (1kD+)	Lactose	Sucrose	PBS
Mannitol	Glucose	Dextran	Glycine
	Amino Acids	PEG	Histidine
	Proteins		

No-Go Substances

- Glycerol
- Volatile components/ organic solvents
 - E.g. Hydrochloric acid, acetic acid, trifluoroacetic acid & carbonic acid, DMSO, DMF
- Ammonium Sulphate



Equipment Needed





Freeze-Drying Procedure Overview

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Three Stages of Lyophilization

Freezing

Gradual freezing vs.
rapid cooling



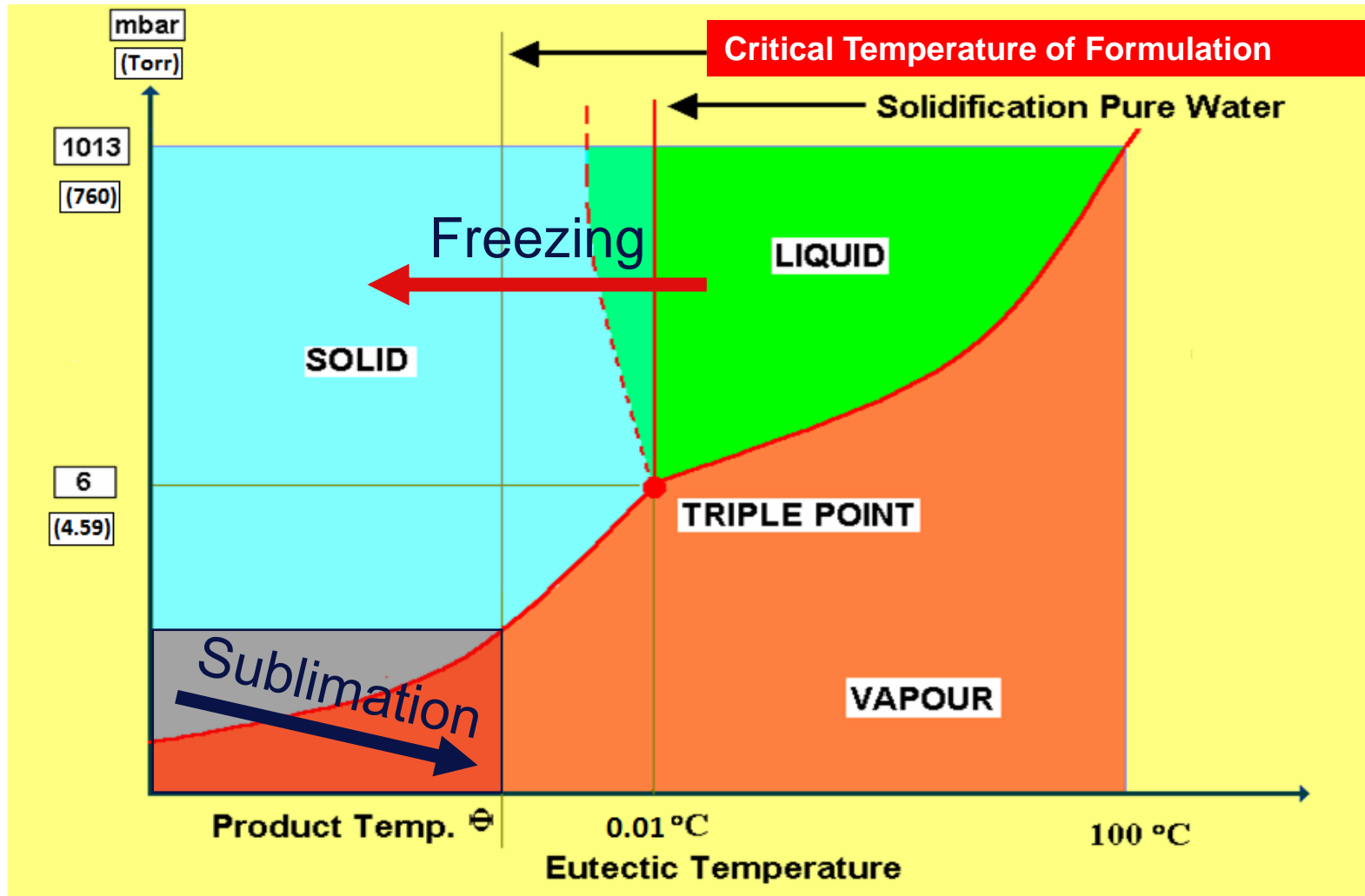
Primary
Drying

Primary drying is the
removal of bulk solvent
(water) by sublimation



Secondary
Drying

Amended Phase Diagram for Pure Water



Three Stages of Lyophilization

Freezing

Gradual freezing vs.
rapid cooling



Primary
Drying

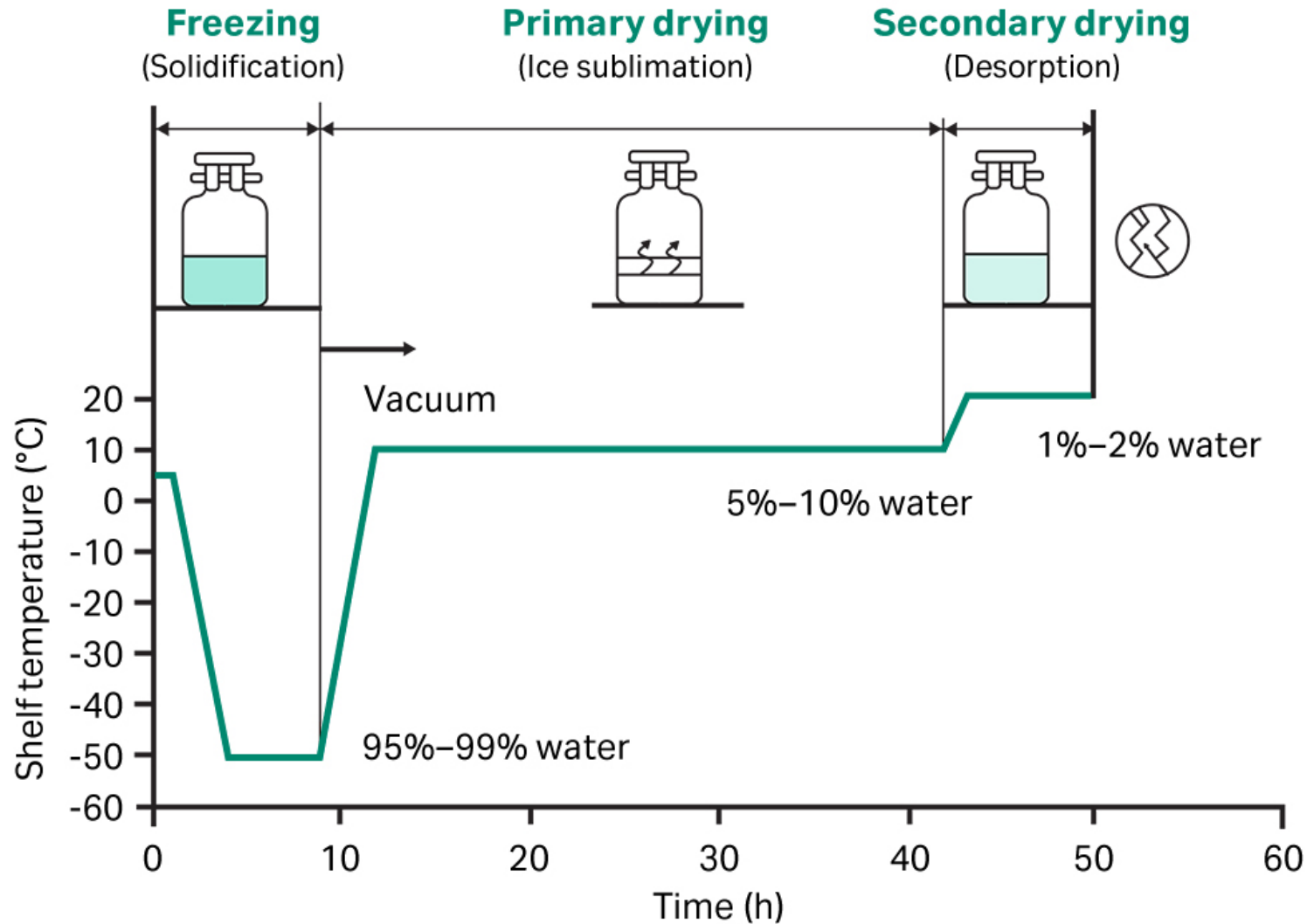
Primary drying is the
removal of bulk solvent
(usually ice) by
sublimation



Secondary
Drying

Secondary drying is
the removal of solvent
(usually water) by
desorption

Three Stages of Lyophilization



Different Forms of Lyophilized Products: LyoCakes vs LyoBeads





Summary

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Summary

Overview

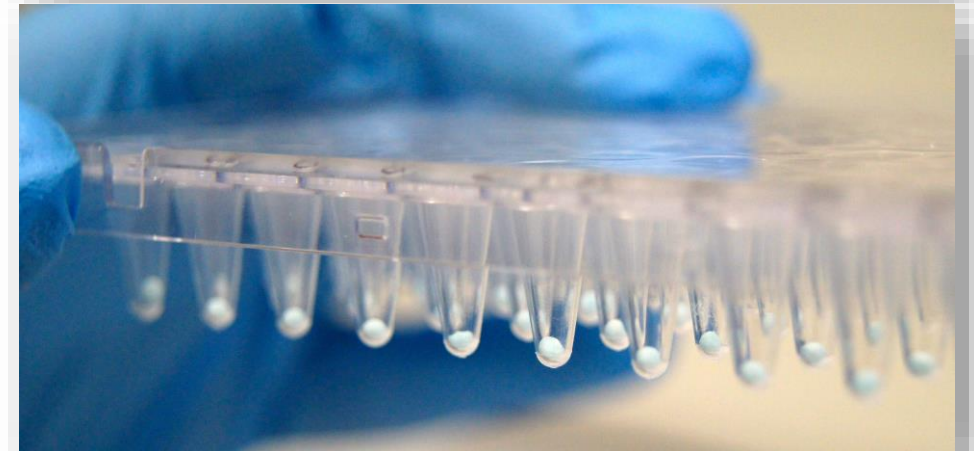
- Lyophilization, is a process to remove moisture from biological materials.

Challenges

- Need of special equipment
- Choosing right formulation requires expertise

Advantages

- Variety of products to choose as starting point
- Improve Stability/Shelf-Life
- Easy storage conditions
- Shipping at room temperature
- Simplified workflows



Q&A Session



Xenia Lindt



Dr. Giuseppina Sannino



Dr. Ramon Kranaster

Thank You

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