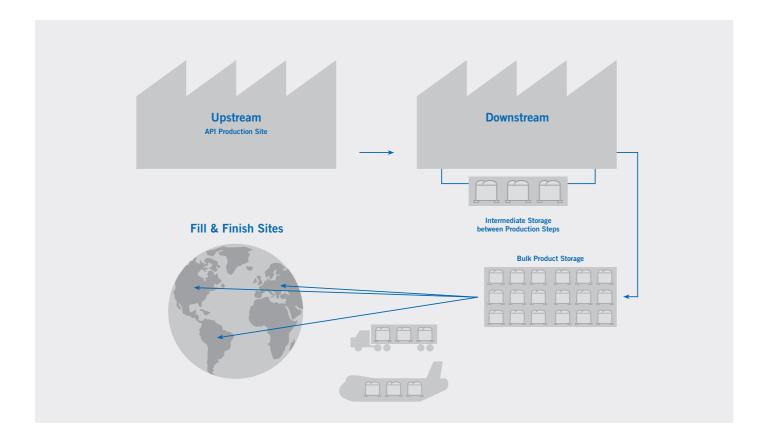






# Bridging Time and Distance

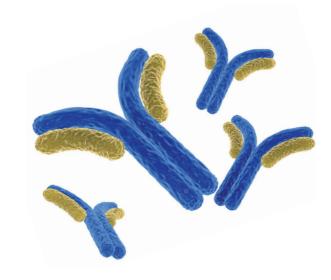


# The Challenge

The biopharmaceutical sector needs to

- respond flexibly to momentary demand and supply,
- distribute production steps between locations, and
- hold intermediate forms of products for some time between processing steps.

This makes it essential to have a method of storing and transporting sensitive products such as pharmaceutical proteins.





## **The Solution**

Zeta offers a solution in the form of a complete range of equipment for controlled freezing, transport, storage and thawing of sensitive biopharmaceuticals. In the frozen state, biopharmaceuticals generally have good stability, and they are also protected against microbial growth.

Zeta Freeze & Thaw Systems are based on transportable stainless steel vessels linked to sophisticated cooling systems. Since the product quality of biopharmaceuticals is often sensitive to the exact conditions of freezing and thawing, Zeta Freeze & Thaw Systems also include lab-scale and pilot-scale devices to ensure rational and economical development of the freezing process.





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# **Preserving Quality**

### Kind to proteins

Biopharmaceutical products are usually stable in frozen form, but the process of freezing them is critical. Zeta Freeze & Thaw Systems are specially designed to make the freezing step as safe for your product as possible. Here are some of the features that reduce the stress factor for your proteins:

- Fully automated and controlled temperature profiles
- Highly efficient and homogeneous heat transfer
- Freezing and thawing without agitation
- Process design and process prediction supported by Zeta FreezeSimulation

## **Advantages of Stainless Steel:**

- Safe, reliable, robust
- Free of leachables and extractables
- Long operational life
- Ideal process control with inline and online sensors

## **Zeta Freeze & Thaw Systems**



## Zeta LabFreeze System

Investigative apparatus for initial studies of protein-specific behaviour (working volume: 200 ml)



### Zeta PilotFreeze System

Miniature industry-grade system for testing process methods (working volume: 700 ml)

### A scalable product family

Since the exact freezing conditions are critical for avoiding damage to the product, product-specific development of the freezing method is key to success. Zeta Freeze & Thaw Systems are a family of equipment that offer you an economical, logical and reliable path from initial lab experiments through pilot scale to full production volumes of 10 to 300 l.



## Zeta FreezeController Temperature control u

Temperature control unit for controlled freezing and thawing of products

### Zeta FreezeContainer

Specially designed stainless steel container, designed to PED or ASME

### Zeta FreezeSystem

Production-scale system for freezing, transport/storage and thawing (working volume: up to 300 l)

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# Navigating Development

The dynamics of the freezing process hold significant risks for product quality. However, with a careful and logical approach to process design, these risks can be controlled. Zeta Freeze & Thaw Systems offer you a safe path through the development of product-specific freezing and thawing processes.

## **Understand your Process**

#### The Zeta LabFreeze

is made for initial experiments and maximizes the amount of data you can obtain from a very small volume of product.

It can deliver first insights into effects such as cold denaturation, cryoconcentration, pH shifts and surface stresses.

This data can be used to model the freezing process for the specific product and to derive starting conditions for the next stage of testing.

#### The Zeta PilotFreeze

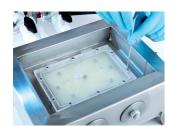
is a step up to a miniature version of the production-grade system.

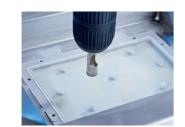
It allows closer simulation of the production process and further refinement of the method. This stage minimizes unpredictable effects when you move up to full production scale.

Scaling up the process is guided by Zeta FreezeSimulation, a process modeling solution that makes each step in development more predictable and also provides a basis for Quality by Design (QbD), opening up the possibility of abbreviated validation of the freezing process.

## **Expert Support**

Zeta Freeze & Thaw Systems come with full backup in the form of an expert support and development service. Our experienced team of experts in biotechnology and bioprocess engineering can guide you through experimentation, modeling and optimization of process parameters and can also support you in carrying out protein stability studies.







## **Step by Step to Improved Protein Quality**

1	Gather prior knowledge about behaviour of the specific protein	
2	Plan experiments using the Design of Experiments (DoE) tool	Tree Tree
3	Do experiments in Zeta LabFreeze	
4	Use experimental data for Zeta FreezeSimulation	Simulation    Simulation   Simu
5	Transfer protein-specific freezing model to Zeta PilotFreeze	
6	Verify freezing model in Zeta PilotFreeze, optimize process parameters	Description of the second of t
7	Transition to production-scale Zeta FreezeSystem	

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As a technology supplier of the biotechnological and pharmaceutical industry, we design, manufacture and install customised solutions for renowned companies around the world.

- Biopharmaceutical systems (USP/DSP)
- Preparation and formulation systems
- CIP/SIP- and media systems
- Process equipment
- Sterile plant installation
- Engineering services
- Automation solutions
- Agitation and mixing technology
- Freeze & thaw systems

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