

[WWW.BIOPHARMA.CO.UK](http://WWW.BIOPHARMA.CO.UK)

# ANALYTICAL LYO LAB & CRO SERVICES

 **biopharma  
group**  
intelligent freeze drying

# WHO AND WHERE ARE WE?

**4**  
MAIN OFFICES

**12**  
DISTRIBUTORS  
WORLDWIDE

**30+**  
COUNTRIES  
SUPPORTED

## GLOBAL PRESENCE

**30+**  
YEARS  
IN FREEZE  
DRYING

**3000+**  
FORMULATIONS  
DEVELOPMENT

**15+**  
DEDICATED  
SCIENTISTS

**15+**  
AREAS OF  
EXPERTISE

**70+**  
PEOPLE

**50+**  
YEARS OF COMBINED  
R&D EXPERIENCE

**150+**  
INSTRUMENTS  
SOLD SINCE  
2010

**600+**  
SUPPORTED  
SYSTEMS

# HOW CAN WE HELP?

1

## CONTRACT RESEARCH IN FREEZE DRYING, SPRAY DRYING AND LIQUID FORMULATIONS

- Proof of concept studies
- Formulation development for liquid and dried products
- Process development
- Freeze drying design space
- Freeze drying trial cycles
- Development of freeze dryable spheres
- Product characterisation (pre- / post- freeze drying)
- Controlled nucleation
- Stability Studies
- Freeze drying vs Spray drying: comparative studies
- Dedicated cytotoxic suit

2

## CONTRACT MANUFACTURING IN FREEZE DRYING

- Procurement of chemicals and consumables
- Compounding
- Freeze drying
- Packaging & Kitting
- QC analyses
- Dedicated on-site service and maintenance team
- Bespoke and non-standard formats catered for

3

## CONSULTANCY IN FREEZE DRYING AND SPRAY DRYING

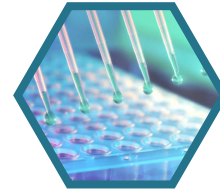
- Cycle audit and Risk assessment
- Technology transfer and scale up
- Desktop study
- Remote product and process development
- Troubleshooting assistance
- Process validation
- Regulatory support
- On-site and remote support

# WHOM CAN WE HELP?



## FOOD & NUTRACEUTICALS

Fruit & Vegetables  
Meat & Fish  
Beverages  
Early life products  
Food supplements



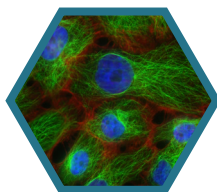
## DIAGNOSTICS

PCR and LAMP products  
Antibody tests  
Fluorescent probes  
Mastermixes



## PHARMACEUTICALS

Small molecules  
Proteins  
Cytotoxic compounds  
Vaccines  
Antibodies  
Antibiotics  
Conjugated compounds



## BIOTECH

Collagen  
Hydrocolloids  
Liposomes/Exosomes  
Human tissues  
Cells and bacteria



## MATERIALS

Stopper & Vials  
Well plates

# WHY CHOOSE BIOPHARMA GROUP?



## PROCUREMENT

- Contractual Flexibility ✓
- Access to Biopharma Group's Services / Instrument Training at Premium Price ✓
- Long-term Strategic Choice ✓



## EXPERTISE

- R&D and Troubleshooting (15+ Freeze Drying Specialists & Scientist) ✓
- Cycle Audit and Regulatory Support ✓
- New Product Development ✓
- Innovative Process Research ✓
- Variable and Phased Scale Production ✓
- Shortcut to Market Access ✓
- Corporate Training Courses ✓
- Design and Development of Proprietary Analytical Technology ✓
- In-house Engineering Service ✓
- End-to-End Process Support ✓



## CUSTOMER SERVICE

- Local Support ✓
- Fast Tracking ✓
- Change Request: Flexibility and Speed ✓
- Dedicated Project and Account Managers ✓

# PEOPLE SAY...



This is the first time we have used Biopharma Group and the support, responses and help was excellent.

**Head of R&D - Consumer Healthcare Develop**



Thank you for being so professional, helpful, innovative and friendly. We were extremely impressed with the quality of your service.

**Director- Oxford MediStress**



We very much look forward to working with you again in the future, and would highly recommend you. You're definitely the best in the business!

**R&D from a global leader in the plasma protein bio-therapeutics industry**

**Contact our Product Specialists today:**

**[bt1@biopharma.co.uk](mailto:bt1@biopharma.co.uk) or visit our website: [biopharma.co.uk](http://biopharma.co.uk)**

# CASE STUDIES



## CASE STUDY 1 (BENEFITS OF THERMAL ANALYSIS):

- The formulation was analysed using Biopharma Group's freeze drying microscope Lyostat5
- The FDM analysis identified a Tc range of  $-18.6^{\circ}\text{C}$  to  $-17.4^{\circ}\text{C}$
- Differential thermal analysis and impedance analysis was carried out using Lyotherm (proprietary technology, DTA / Electrical impedance analyser)
- This identified a softening event in the impedance at  $-25^{\circ}\text{C}$
- A freeze drying cycle was designed to maintain the product temperature below  $-30^{\circ}\text{C}$ , allowing a  $5.0^{\circ}\text{C}$  safety margin below the lowest critical temperature identified
- This new cycle, designed by Biopharma Group, was 45 hours long
- This was 16 hours shorter than the original cycle, resulting in a significant time and energy saving for the manufacturer



## CASE STUDY 2 (BENEFITS OF FORMULATION DEVELOPMENT):

- The customer wanted to develop a freeze drying cycle for a product. However freeze drying microscopy had identified a low collapse temperature of  $-42^{\circ}\text{C}$
- Low collapse temperatures require cycles that are slow and lengthy and energy expensive
- Biopharma Group scientists were able to reformulate to replace some of the sucrose, which has a low collapse temperature, with dextran. Dextran can affect biological products but the small amount used ensured there were no detrimental effects to the active ingredient
- The final formulation had an overall collapse temperature of  $-23^{\circ}\text{C}$ , a significant improvement over the original ( $-42^{\circ}\text{C}$ )



## CASE STUDY 3 (BENEFITS FOR DIAGNOSTIC SECTOR):

- Biopharma Group scientists designed several formulations for pick-and-place applications.
- Several factors were taken into consideration, such as the mechanical properties of the dried material and the interactions with the material of the container.
- After the developmental phase, Biopharma Group supported the customer with a phased scale production. All steps of the manufacturing line were considered, such as procurement of materials, compounding, lyophilisation, kitting and shipping.

**VISIT OUR WEBSITE:**

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