biopharma group

Diagnostics Services & Solutions: From Research & Development to Manufacture

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Do you need...

- **An expert diagnostics partner for contract R&D and manufacturing?**
- **Flexibility and agility to suit the requirements of your project?**
- **Ownership of the products, processes and intellectual property (IP)?**
- **A supplier that is ISO accredited for 'Medical Devices' and 'Quality Management'?**
- **Access to state-of-the-art facilities and equipment?**
- **Competitive pricing?**



How we help...

30+ countries supported	**4000+** projects completed	**15+** dedicated in-house scientists	**35+** years of freeze drying expertise
40% average reduction in length of lyo cycle after R&D support	**65%** average increase in productivity after R&D support	**80%** average reduction in cost of storage after R&D support	**60%** average reduction in cost of production after R&D support



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Research and Development

Biopharma Group can assist at their cutting-edge Lyophilisation Centre in Winchester, UK, or remotely. No matter whether you are new to lyophilisation or an expert, if you work with diagnostic reagents, Biopharma Group can help as little or as much as you prefer with an end-to-end solution that covers R&D, consultancy, and manufacturing services.

ISO 9001 QUALITY MANAGEMENT

UKAS MANAGEMENT SYSTEMS 0015

ISO 13485 MEDICAL DEVICES

Product & process assessment

- Commercial assessment for return on investment
- Material characterisation
- Data review
- Lyophilisation cycle audit and risk assessment

Proof of concept study

- Trial lyophilisation cycle
- Material characterisation

Formulation development

- Quality by Design
- Design of Experiments
- Material characterisation
- Screening of formulations
- Stability studies

Cycle development

- Quality by Design
- Material characterisation
- Construct process design space
- Stability studies

Scale up and technical transfer

- Tech transfer
- Method development and transfer

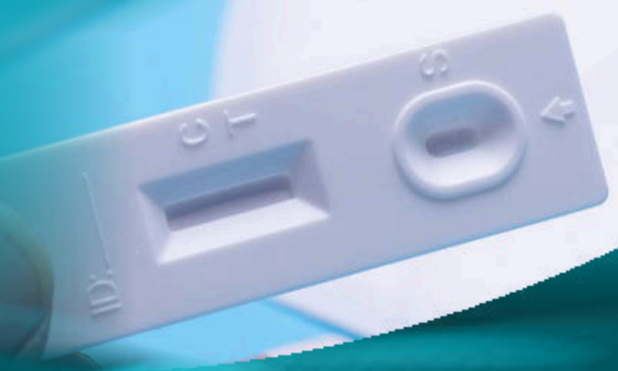
Troubleshooting

- Remote formulation and process development
- Root cause analysis
- Consultancy
- Risk assessment

Technical transfer to our production facilities

- Master batch record
- Feasibility lyophilisation cycle





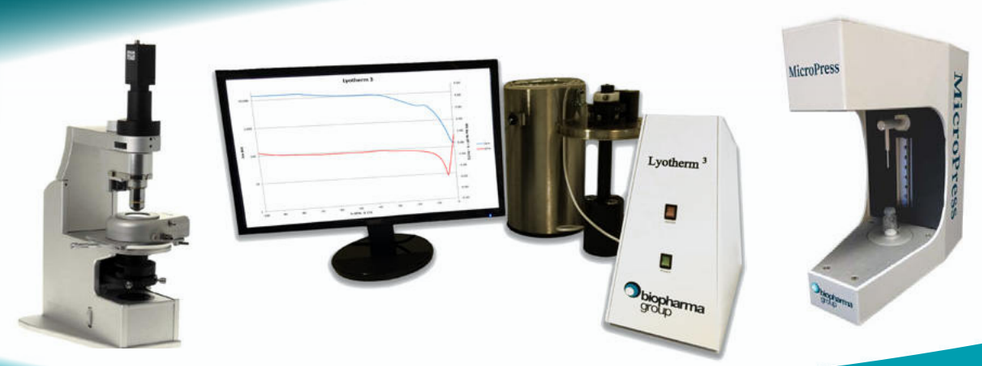
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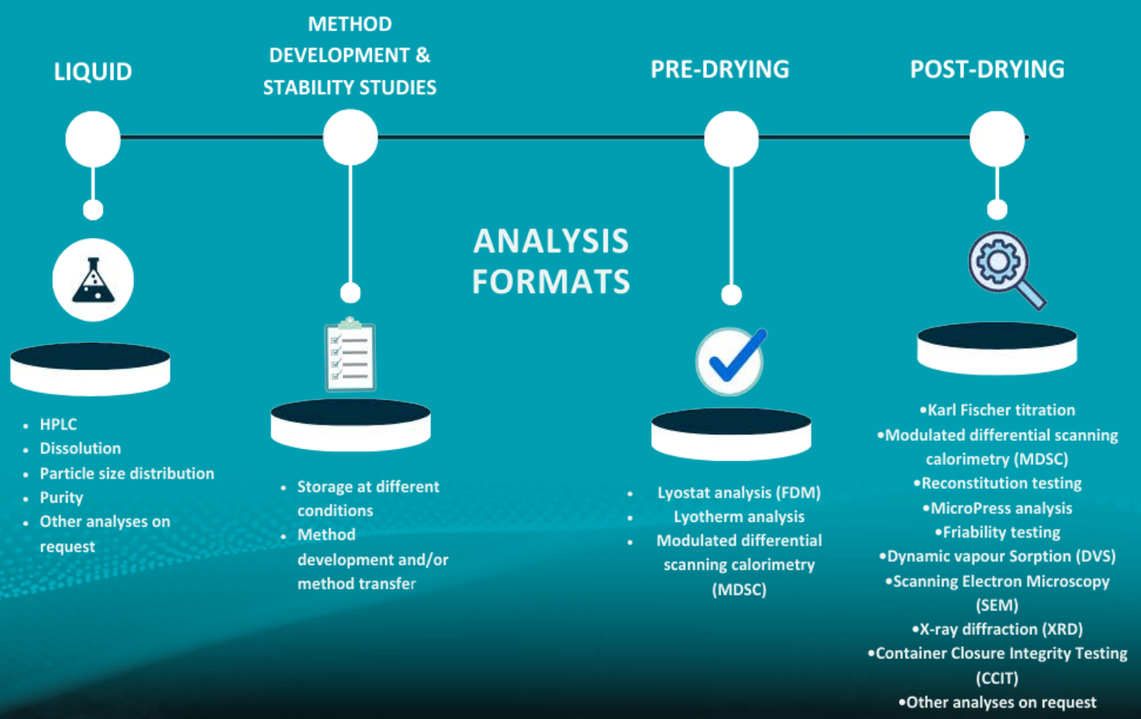
Analytical Services

Use our analytical services for diagnostics ranging from reconstitution to friability. Gain clear insights into the robustness, stability, and integrity of your formulations.

Using an array of techniques, acquire comprehensive data to guide development of your liquid and dried formulations . Receive expert insight to ascertain appropriate quality control processes for your product.

You'll receive invaluable support throughout the critical phases of product development and ownership of the IP, formulations and cycle recipes at the end of the process, giving you ultimate control of your diagnostic products.





Lyostat

Biopharma Group's freeze-drying microscope has been developed to enable precise identification and recording of critical events and collapse temperatures.

mDSC

Measure glass transition, eutectic, and melting temperatures before freeze-drying. The integration of mDSC further enhances the understanding of thermal properties throughout the process.

MicroPress

Determine the quantitative mechanical properties of lyocakes and lyobeads using a linear actuator to understand strength and robustness, during post-lyophilisation analysis.

Karl Fischer Titration

Quality control is ensured by measuring residual moisture content post freeze-drying, while DVS offers insights into a material's moisture sorption properties.



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Diagnostics Manufacturing

Three ‘Category D’ clean rooms are available to fast-track production of your sterile formulations. Have dried or liquid formulations stored within the ideal receptacle, from vials to 96 well plates, to bespoke tubing and cartridges, to suit your specific needs.

Whatever your scale and volume requirements, access to our 15 freeze dryers, benchtop freeze dryers and spray dryer, makes manufacturing at pace straightforward.

Benefit from an extensive range of manufacturing possibilities available from within our ISO13485 accredited diagnostics production facility.

2.5 Million

Diagnostics tests produced per month 2020 -2022





Contract freeze drying of lyocakes

Freeze dried Lyocakes of partial or complete reagent test mixtures are typically provided flat and circular to fill vials, and are a key offering by Biopharma Group’s diagnostic specialists.

Large scale productive capacity

- ✓ 15 freeze dryers
- ✓ More than 10^2m of shelf space
- ✓ Capacity to run batches from 1 to 150 plates in a single machine in 96 well plate or tube format
- ✓ 96,000 test capacity per day in 96 well or PCR tube format, on a 24 hour cycle basis
- ✓ Capability to work on mastermixes, RNase inhibitors and positive controls
- ✓ A dedicated positive control suite in a separate building

Quality control

Diagnostic manufacturing services at Biopharma Group place the quality control of your formulations at the forefront of processes,designed to guarantee that your liquid or freeze-dried products meet rigorous regulatory standards.

Packing and kitting services

Your formulation’s shipping needs are met by our bespoke kitting and packing services, tailored to cater for shipping worldwide from -80°c to ambient temperature. Whether individual kits or final shipper cartons, you will benefit from the expertise of our dedicated team, who are exceptionally well-informed on regulations for a multitude of formulations. Receive specialised advice and guidance, ensuring the best shipping options are used for your unique requirements.

Packing and service for non-standard products

Have an unconventional product? Our years of expertise have enabled us to provide specialised services for a range of products, including non-standard or difficult to handle formulations.



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Lyobeads Format

Biopharma Group's low bioburden lyobead cleanroom, allows the manufacture of hundreds of thousands of lyobeads at a time.

Anoxic environments provide protection for beads whilst handling and packing.

Convenient Single-Dose Format

- Always have the correct dosage or enzyme concentration

Easily Scaleable

- One freeze dryer can produce tens of thousands of beads

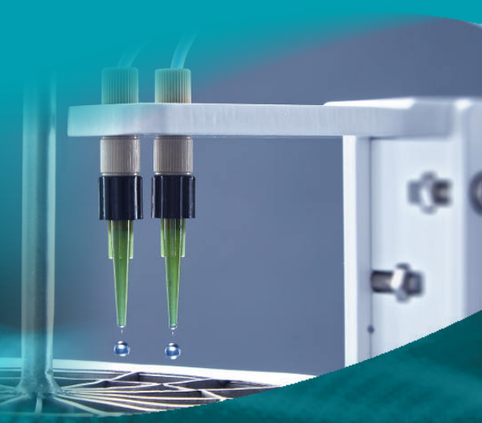
Pick & Place

- Flexibility on containment.
- Complicated buffer/lyobead combinations can be accommodated in cartridges.

Formulation Considerations when Choosing Lyobeads

- Different excipients produce different effects on lyobeads
- An excipient that may be beneficial as a cryoprotectant, can adversely influence bead strength
- Excipients can also impact static properties of beads
- The correct formulation can increase test activity, strength bead robustness and reduce static effects





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Lyobead Generator

The LyobeadPRO™

- ✓ Generates up to 10,000 beads per day.
- ✓ From 5ul to 50ul sizes.
- ✓ Unparalleled ease of use and simplicity of design.
- ✓ For both R&D and Production use.



Containment Types

- ✓ Vials
- ✓ 96 well plates
- ✓ PCR tubes
- ✓ Lyobeads
- ✓ Custom Cartridge

Capping

- ✓ Automated
- ✓ Heat sealed
- ✓ Induction sealed











INDUSTRY CHALLENGES FACED & BIOPHARMA GROUP'S SOLUTIONS

CHALLENGE	DESCRIPTION	SOLUTION FROM BIOPHARMA GROUP
Additional Handling Step	• Worker intensive – may outweigh benefits of producing in volume. • Not yet automatable.	• Custom production tools. • Highly skilled and experienced workforce.
Physical Bead Strength	• Weak beads can reduce yield through breakage. • Adds additional time to pick and place.	• Solvable through formulation. • 35+ years' experience in excipient impact.
Static Build Up	• Can be inherent depending on formulation. • Makes pick and place very difficult.	• Solvable through formulation. • Proprietary anti-static methods available.
Oxygen & Water Vapour Susceptibility	• Needs a dry, anoxic environment to handle and pack.	• Custom enclosures control humidity and oxygen levels. • Allows extended manipulation of lyobeads with no activity loss.

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Additional Services & Solutions From Biopharma Group

Remedial testing

If you have a failing diagnostic product, are experiencing a low Limit of Detection, or suffering from short shelf live, Biopharma Group can help.

Talk to us about our troubleshooting service which includes:

- ✓ Incoming product audit
- ✓ Cycle optimisation
- ✓ Reformulation
- ✓ Revalidation

Proven track record

- ✓ 35+ years freeze drying experience
- ✓ Full production capability from formulation to packing under one roof
- ✓ 100,000 Covid-19 tests produced each day for a sustained period of the pandemic
- ✓ Leading manufacturer of diagnostics supplied to the NHS during the Covid-19 pandemic

Buffer and additional components

- ✓ Automated buffer filling and labelling
- ✓ 25,000 vials per day capacity
- ✓ 200ul – 30ml fill spec

Rigorous quality control

- ✓ Dedicated quality team at all stages of the process
- ✓ Qualified auditors
- ✓ Full batch records
- ✓ Certificate of analysis for all released products



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



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About
Biopharma Group

Biopharma Group has over 35 years of commercial expertise in freeze drying and associated technologies and services, making us an active participant in the industry and a leading CDMO partner. Our qualified team of experts are trusted voices within the diagnostics, biotech and pharma R&D sector and are keen to be supportive contract R&D and manufacturing partners.

We focus on providing high quality and up-to-date freeze-drying R&D, analysis and manufacturing services that are compliant with industry guidelines and regulations.

Why Choose Biopharma Group?

- ✓ Elimination of the cold chain
- ✓ Extension of product stability
- ✓ Efficient storage and transportation
- ✓ Increased productivity
- ✓ Optimised operations
- ✓ Improved batch yield
- ✓ Simplified scale-up and process transfer
- ✓ Ownership of intellectual property rights

Additional Benefits

- ✓ DOE (Design of Experiments)
- ✓ QbD(Quality by Design)
- ✓ Low bioburden and GMP facilities
- ✓ Annex 1-compliance
- ✓ ISO9001 and ISO13485 standards for medical devices

"Through my experience of working with Biopharma Group on various lyo projects, I can happily say that I have always been super impressed with the results that we have received! We will definitely continue to make Biopharma Group our first choice when needing to outsource freeze drying support."

Director of Business Development, UK

"We have had the opportunity to work with Biopharma Group on several projects to optimize and improve processes. Biopharma Group has real expertise that is put to the benefit of its customers. The responsiveness of their teams and the tools used have always been highly appreciated."

Deputy Head of Industrial Development, France

"...fast response to customer requests and provision of a quote. The analysis was conducted immediately and results provided swiftly.

Project Manager, Germany



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