



**biopharma  
group**

# **Pharmaceutical Services & Solutions**

From liquid & lyo R&D through  
to clinical manufacturing

[www.biopharmagroupcdmo.com](http://www.biopharmagroupcdmo.com)

## Do you need...

- An expert partner in contract R&D and manufacturing that delivers top quality results?
- A flexible and agile collaboration?
- Access to state-of-the-art facilities?
- A company that can develop and manufacture cytotoxic products up to OEB6?
- Fast turnaround to develop and/or manufacture your product?
- Competitive pricing?

## How we help...

**30+**  
countries  
supported

**5000+**  
projects  
completed

**15+**  
dedicated  
in-house  
specialists

**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

# Research & Development

Biopharma Group can assist at their cutting-edge Lyophilisation Centre in Winchester, UK, or remotely. No matter if you are new to lyophilisation or an expert, if you work with drug substances or drug products, 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.

## Product & process assessment

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

## Proof of concept study

- Trial lyo 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 to the preferred site
- Method development and transfer

## Troubleshooting & risk prevention

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

## Internal tech transfer to clinical manufacturing

- Master batch record
- Feasibility lyo cycle

# Contract Pharma R&D

For your liquid and lyophilised products

## Applications

- Targeted cancer therapy
- Precision medicine
- Rare diseases
- Immunomodulation
- Gene therapy
- Cell therapy
- Tissue engineering
- Drug delivery
- Vaccine development
- Gut health improvement
- Cosmetics

## Products

- HPAPIs & Cytotoxic compounds up to OEB6
- Antibiotics
- Hormones
- Peptide
- Oligonucleotides
- Proteins
- Monoclonal antibodies
- ADCs
- Nanoparticles
- Viral vectors
- mRNA vaccines
- Cells and stem cells
- Human and animal tissues
- Plasma derivate product
- Microbiome
- Probiotics
- Aerobic and anaerobic bacteria
- Collagen

## R&D services

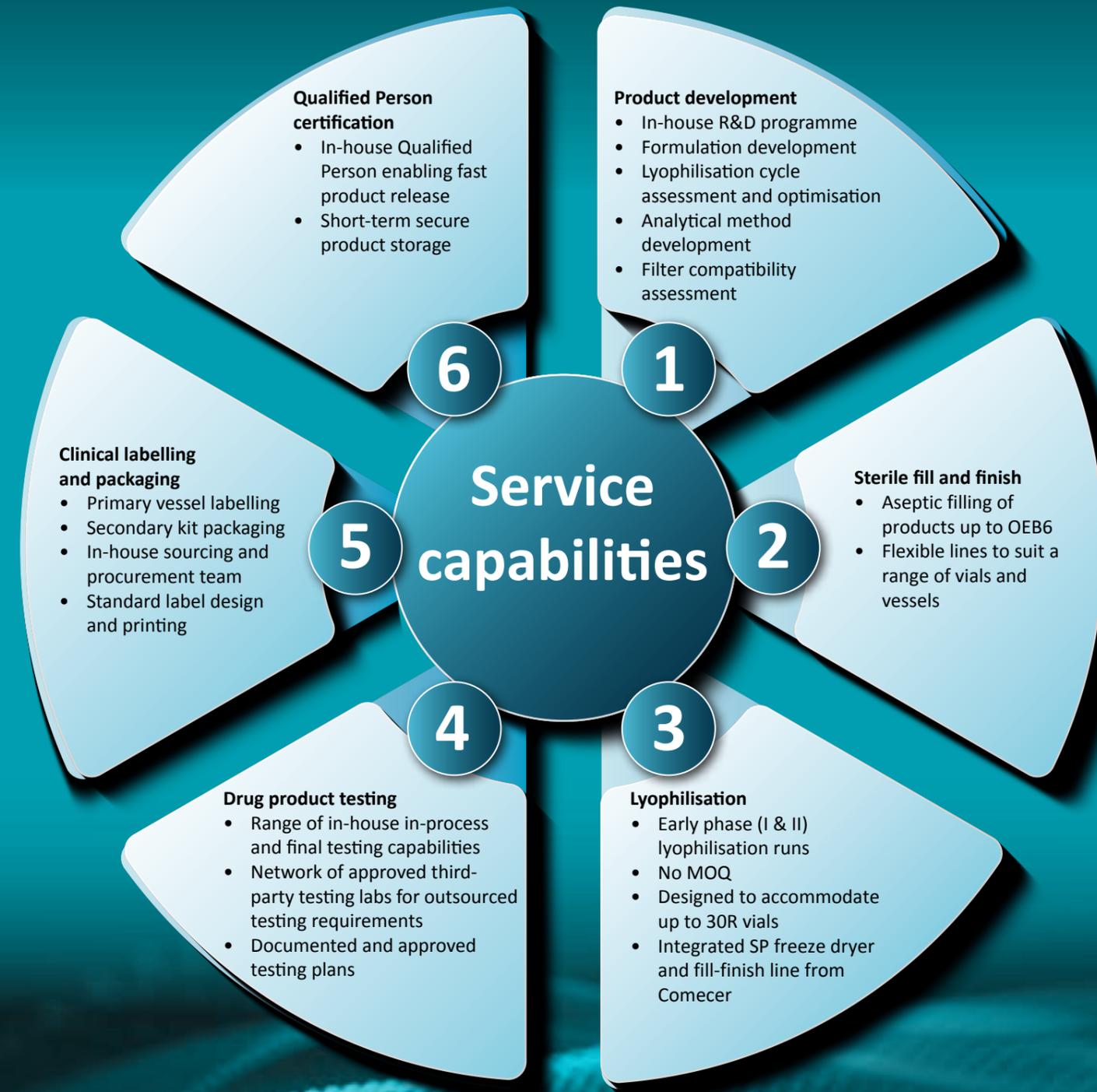
- Material characterisation (including freeze drying microscopy)
- Proof of concept studies
- Formulation development for liquid and dried products
- Process development
- Freeze drying design space
- Stability studies
- Controlled nucleation
- Freeze drying vs spray drying: comparative studies

## Consultancy

- 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

# Clinical Manufacturing

Biopharma Group's clinical manufacturing facility supports sponsors with the transition of drug candidates from R&D into early-stage clinical manufacture. The UK-based facility is designed and validated to accommodate small batch manufacture of both cyto and products of non-specific toxicity in a variety of formats for first-in-human (FIH) trials. Our facility enables access to fast and efficient clinical manufacturing slots, paired with an on-hand dedicated team providing a transparent, streamlined, and tailored service to ensure timelines and expectations are met.



# Clinical Manufacture



# About Biopharma Group

Since 1989, we have consistently placed client needs at the forefront of our operations, supporting a diverse array of global clients ranging from ambitious start-ups to leading industry giants. We specialise in stable liquid formulation and lyophilisation process development, tailored to address your unique challenges and aspirations.

Over 5,000 projects have been successfully completed – a testament to our client-focused approach. Utilising a Quality by Design approach, products have been developed for a variety of product applications, including large molecules, biologics, and advanced therapies.

Services are tailored and managed to suit your unique requirements, both in R&D and aseptic manufacturing.

Get in touch today to discuss your R&D and clinical manufacturing needs with our experts.

## Why use 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

## How we help

- DOE (Design of Experiments)
- QbD (Quality by Design)
- Dedicated labs & facilities - 1 standard R&D lab, 3 x low bioburden labs, 1 x cytotoxic suite and 1 x clinical manufacturing facility
- 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 freeze drying 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. Even though we had delays confirming the order and providing the samples [...], the analysis was conducted immediately and results provided swiftly, which is very helpful for a CMO to keep our customers satisfied.”*

**Project Manager, Germany**



**biopharma  
group**

 [www.biopharmagroupcdmo.com](http://www.biopharmagroupcdmo.com)

 +44 (0)1962 841092

 [btl@biopharma.co.uk](mailto:btl@biopharma.co.uk)

 Biopharma House  
Winnall Valley Road  
Winchester  
Hampshire  
SO23 0LD  
United Kingdom