biopharma group

GMP Clinical Manufacturing

Supporting Early-Phase Clinical Manufacture

www.Biopharmagroupcdmo.com

Introducing Biopharma Group

Dedicated to providing our customers with a transparent and streamlined Clinical Development and Manufacturing service supporting projects from Research and Development through to small-scale GMP clinical manufacture.

- Provider of flexible CDMO services to the pharmaceutical industry since 1997
- World Leading Lyophilisation Research and Development experts
- Expert trainers in the fundamentals of freeze drying
- Leading supplier of capital equipment for lyophilisation and bioprosessing.

35 +
Years of freeze Drying Expertise

4000 +
Projects Completed

30+
Countries Supported

Our Services

Our Capabilities

- Product development program
- Lyophilised product clinical manufacture
- Sterile aseptic fill and finish
- In-process and finished product analysis
- Clinical labelling and packaging
- Qualified Person product certification
- Regulatory Support

Our Capacity

- SP S10 GMP Freeze Drying Capacities (Per batch)
  2mL Vial Type: 3,200 vials
  10mLVial Type: 1,320 vials
  20mL Vial Type: 858 vials
  10L Bulk Lyophilisation
  Manufacturing Campaigns available
- Formulation of up to 5L batches of Drug/Excipient Solutions
- Flexicon PF7 peristaltic semi-automated dispensing.

Clinical Manufacturing Facility

- Designed for cytotoxic and high potency manufacture up to OEL 5
- Facility built to meet Annex 1 v. 22.8.2022 requirements
- Uni-flow manufacturing process to prevent cross-contamination
- Secure monitored storage
- In-house GMP analytical lab for in-process and final testing
- No Minimum Batch Size

UK Based Facility

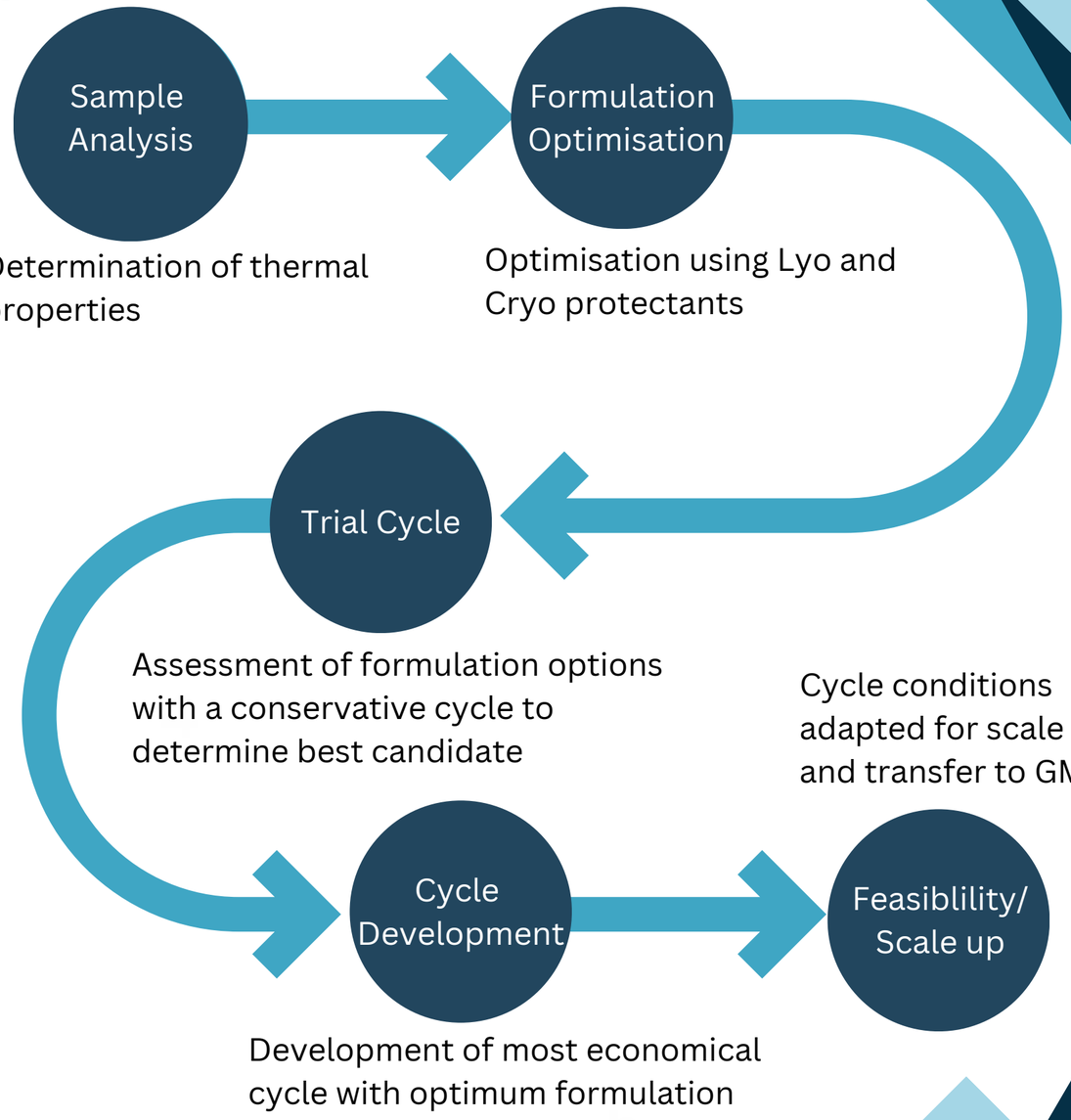
Development Programs

Tailored programs:

- Full development programs for formulation and lyo cycle determination following QbD approach.
- Optimisation of existing formulations and lyo cycles for scalable clinical manufacture.

GMP Transfer Benefits:

- Reduce time and cost by keeping R&D and GMP under one roof and gain fast direct access to engineering runs.



The Route to Clinic

1 Feasibility Batch

Process audit
and optimisation prior
to scale up and transfer.

2 Technical Transfer

Transfer of final approved process
and batch record development.

3 Engineering Run

1st manufacture under GMP sterile conditions.
Assessment of documented process against defined specifications.
Product may be used for stability/toxicology assessments.

4 Clinical Batch

Production of product for
human trials.

5 QP Certification

QP batch certification
followed by Sponsor led
regulatory release.

The Biopharma Benefit

Reduced time to clinic
Fast access manufacturing slots available to get your candidate into clinic on time.

Reduced Vendor Management
Keep your research and development and early phase clinical manufacture in one place to streamline and reduce project life cycles.

Flexible Manufacturing
Agile semi-automated manufacturing solutions that can be tailored to suit project needs.

Small scale
No minimum order quantity for lyophilised or liquid products.

Reduced Cost
Facility designed to suit small scale production allowing competitive pricing.

On-hand development experts
Experts in Lyo and formulation development onsite to support technical transfer and troubleshooting activities.

In-house Qualified Person
Full QP batch oversight and certification allowing fast release to clinic.

Full project management
Dedicated project manager to ensure swift on-boarding and controlled project progress utilising a fully developed delivery plan.

Working with us

Hear from our customers...

Who can we help:

- Companies requiring support with process development
- Sponsors with developed processes looking to start GMP clinical manufacture
- Companies that require process optimisation prior to clinical manufacture

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

- Head of R&D (Consumer Healthcare Development)

★★★★★

"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 (Global leader in plasma protein bio-therapeutics industry)

★★★★★

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

- Director (Oxford MediStress)

★★★★★

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Contact us to discuss a project or to arrange a site visit

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