

# GMP Services

Onyx Scientific is the CDMO division of Ipca Laboratories and since our formation in 2000 has offered phase appropriate small molecule GMP manufacture.

## Phase-appropriate API Manufacturing

Our phase I-III small molecule API manufacturing and development services mean we can support your molecule throughout its clinical journey. Our chemists adopt a phase-appropriate approach to ensure fit-for-purpose development at each stage.

### Chemistry front and centre. Phase-appropriate small molecule API manufacturing.

Our team of chemists are specialists in small-scale drug substance manufacturing and work hand-in-hand with you to establish the most strategic pathway for your project. We have a strong track record of catering to the unique requirements of clinical phase projects and offer a flexible approach that is suited to today's increasingly complex APIs.

Our laboratories support all phases of clinical trials. From quality assurance to GMP manufacture and analytical chemistry support to stability testing, we are here to optimise your drug substance supply with a focus on minimising risk and expediting timelines.

## GMP Contract Manufacturing

Our Wayfarer site in Sunderland, UK is home to the following:

- Six MHRA-accredited Class 100,000 API production suites for GMP manufacture of Phase I to III clinical trial materials
- Dedicated GMP warehouse
- Raw material sampling
- API dispensing unit
- Home Office schedule 1 licence

Each production suite is designed for flexibility of scale, enabling production of low gram to multi kilo quantities.

This flexibility also means other less standard activities can be carried out in the same area (e.g. solvent evaporation, chromatography, distillation etc).

To support GMP production, our Wayfarer site also houses our GMP analytical laboratory alongside our stability testing facilities all fully supported by Onyx's quality assurance (QA) team that maintains the highest level of quality standards.



*Flexible laboratory design, allowing for less standard activities to be carried out in the same area*

## Equipment

The following equipment are examples of what can be utilized in our GMP production suites:

- Range of Huber controlled jacketed vessels from 250mL up to 10L (for lower quantity requirements)
- Up to two Huber controlled 50L or 100L jacketed vessels
- Up to two 20L rotary evaporators
- 12kg chromatography capability
- Drying ovens
- Distillation equipment
- Wiped Film Evaporator
- Milling

## Regulatory Support

Onyx offers a full CMC technical writing service and application support for internal and external regulatory teams.

## Contact us

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Your molecule, our people - it's good chemistry

