MAC

MAC CLINICAL RESEARCH

Pharmaceutical Services

macplc.com

MAC's Comprehensive Pharmaceutical Services

MAC offers a comprehensive range of fully in-house pharmaceutical services to support our sponsors' drug asset development and clinical trial programmes.

MAC's Pharmaceutical Services department offers global logistical pharmaceutical coverage.

Our team brings years of pharmaceutical research experience with Qualified Persons (QP), Clinical Trials Pharmacists, Quality Assurance and Quality Control.

Our in-house experts hail from many industries, ensuring that we offer high-quality study support services to meet your pharmaceutical research needs, including:

- **Good Manufacturing Practice (GMP) Facilities**
- **Qualified Persons (QP) & QP Services**
- **In-House Pharmacy**
- **Investigational Medicinal Product (IMP) Management & Distribution**
- **Global Clinical Supplies**
- **Controlled Drug Services**

MAC's enhanced Pharmaceutical Services offering allows us to support your compound across all phases of drug development, from pre-clinical in our Bioanalytical Laboratory through to later phases with our Clinical Pathology and Manufacturing solutions.

MAC's experience in conducting complex, scientifically challenging research includes all study phases, from first-in-human/patient through late-phase studies.

Our team of in-house experts, with diverse industry experience and backgrounds, delivers high-quality clinical trial services to help you successfully achieve your research goals.

GMP Manufacturing

MAC's Good Manufacturing Practice (GMP)-compliant, aseptic facilities were purpose-built and commissioned in 2016, across two sites; one dedicated to First-In-Human (FIH) studies located at our early phase unit, and a larger facility dedicated to complex manufacturing processes, distributing to clinics globally. MAC is licensed by the MHRA to manufacture both sterile and non-sterile investigational medicinal products (IMPs).

Driven by our first-in-human (FIH) capabilities and expertise, we can rapidly adapt to evolving study requirements.

GMP Production, Facilities & Resources

Production is facilitated by a range of specialised equipment and services, including a dedicated aseptic manufacturing facility.

Our suites can be used to prepare an extensive range of sterile products (e.g., intravenous injections from syringes or bags).

We have:

- **Grade-A Positive Pressure Isolators**
- **Grade-A Negative Pressure Isolators designed to handle cytotoxic products**
- **Microbiological, laminar-flow safety cabinets (in Grade-C monitoring)**
- **Good Manufacturing Practice (GMP), Grade-B, EN ISO 14644-1-compliant clean rooms**
- **Grade D for non-sterile manufacturing, with dedicated powder handling units and balances for all required processes**

We have invested heavily in resources over the past 5 years to ensure that diverse service capabilities are underpinned by the highest quality. Our teams of clean-room staff are trained in aseptic techniques and ensure that all IMP is prepared accurately and in accordance with SOPs, IMPDs, protocols, and study-specific pharmacy manuals. This ensures that all products are safely controlled, produced, reconstituted, manufactured, manipulated, and dispensed.

Additional Manufacturing Resources

Other manufacturing activities occur within separate, dedicated manufacturing areas, consisting of two Grade D facilities and multiple unclassified areas complemented with an array of equipment for non-sterile activities to ensure safety, quality, efficiency, product segregation, and line clearance, including:

- **Non-sterile, hard-shell capsules and other solid dosage forms, including packaging**
- **Filtration sterilisation of active substances/excipients/finished products**
- **Non-sterile IMP, including liquids for internal use**
- **Routine randomisation, blinding, product packing, and labelling**
- **Licenses for Specials Manufacturing Authorisation**

Global Clinical Supplies

Our effective logistical solution for product import and distribution ensures that clinical supplies and product including controlled substances at varying temperatures are available when and where they are needed.

In-House Pharmacy

Our in-house pharmacy dispenses accurately dosed patient medications.

Our pharmacists lead this service to ensure a safe and effective medicines system. We also manage our on-site pharmacies to ensure correct drug reconciliation, accountability, and safe usage.

QP Services

Our QP release services are provided by experienced team members who have worked in the industry for several years.

They ensure that each batch of product manufactured follows current industry regulations. This team has overall responsibility for product quality, and is legally responsible for certifying batching before products are used in clinical trials.

IMP Management & Distribution

IMPs are managed by expertly trained staff who understand the importance of maintaining quality, integrity and safety.

We have a 24-hour environmental monitoring system that alerts for any temperature excursions. We can store items from -80°C all the way up to room temperature, depending on the product's requirements.

In-House Courier Service

Our MAC in-house courier service allows us to quickly deliver IMP and lab samples across the UK.

We also have controlled drug transport capabilities ensuring full chain of custody.

IMP Importation

We have in-house QPs and a Quality Assurance (QA) team to perform IMP Importation (including IMP QP Declarations) for importation of IMP from countries outside of the UK or EU.

For IMPs sourced from specified countries, we provide full oversight of the importation process through our in-house QPs and QA team.

Investigational Medicinal Product Dossier (IMPD) Writing and Review

Our experienced QPs and QA team are highly skilled in preparing and reviewing IMPDs.

Whether you require a new IMPD or updates to an existing submission, we provide tailored support to meet specific needs.

Controlled Drug Services

Our controlled drug-licensed sites can possess Schedule 1 to 5 controlled drugs through our Home Office licences.

The licences indicate our ability to possess, supply, produce and administer these products at each of our sites. We also have the appropriate controlled storage facilities for these products.

The GMP Team

Our GMP manufacturing team is led by registered QP pharmacists, production managers, and GMP quality control managers.

Each of these team members brings over a decade of experience across the pharmaceutical and healthcare spectrum, including extensive practical knowledge from working in MHRA-licensed manufacturing facilities. Our facilities deliver bespoke clinical studies, from single-dose to batch production.

MAC Clinical Research

Your dedicated partner in clinical research

Strong track record and reputation with over 30 years of experience

Access to a wide reach of patients and volunteers

- Specialist in-house recruitment
- Multiple points of contact and engagement
- Access to almost 35 million people within 20 minutes of our facilities
- 7 million people and 27 universities within 1 hour of MAC EPU

High-performing recruitment deliverables

- Consistently outperforming other sites and countries
- We're often used as a rescue site for other studies

Quality data

- Expert team of statisticians and analysts
- Purpose-built software platform

Expertise

- Accurate feasibility and patient delivery
- Study execution delivered within time, quality, and budget expectations

MAC Clinical Research is one of Europe's largest contract research organisations (CRO), taking a science-based approach to clinical research.

Science at the heart *of everything we do*

Our experienced clinical and medical teams are capable of managing even the most complex studies, with Early Phase and Late Phase capabilities, and providing the best quality data for your research.

Headquartered in the UK with offices globally, we conduct studies both through our fully-owned network of dedicated research sites in the UK and through contracting with sites across the globe. We offer the global clinical study management you need to meet your clinical outcome goals.

MAC

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SILVER | Top 15% ecovadis Sustainability Rating JUN 2026

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