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, including Qualified Persons (QPs), Pharmacists, Pharmacy Technicians, Production Managers, GMP QC Managers, QA Systems Managers, and many other key clinical study roles.

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**
- **In-House Pharmacy**
- **Global Clinical Supplies**
- **Qualified Persons (QP) & QP Services**
- **Investigational Medicinal Product (IMP) Management & Distribution**
- **Controlled Drug Services**
- **Laboratory Services & Chemistry Activities**

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-designed and commissioned in 2016. MAC is licenced by the MHRA to manufacture both sterile and non-sterile investigational medicinal products (IMPs).

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 facility delivers bespoke clinical studies, from single-dose to batch production.

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
- Microbiological, laminar-flow safety cabinets (in Grade-C monitoring)
- Good Manufacturing Practice (GMP), Grade-B, EN ISO 14644-1-compliant clean rooms

Our temperature-controlled suites and storage areas are serviced quarterly, to stringent microbiological performance test standards (DOP testing, monthly SDA and weekly TSA settle and contact-plates) to ensure that room functionality conforms with GMP Grade-B limits, specifications, and other industry standards.

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

In-House Pharmacy

Our in-house pharmacy dispenses accurately dosed patient medications. Our pharmacist leads 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.

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.

QP Release

Our QP release service is 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; it provides alerts before temperatures go out of specification so that we can ensure corrective actions are taken. The system also sends alerts via email and to a dedicated phone application to designated personnel, to ensure full and consistent system monitoring. We can store items from -80°C all the way up to room temperature, depending on the product's requirements.

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.

Laboratory Services

At the heart of our clinical research study sites lies our laboratories.

Laboratory Services is housed in a modern facility and is comprised of three laboratories:

- **Sample Reception**
- **Clinical Pathology**
- **Bioanalytical**

Our laboratories are MHRA GLP and UKAS ISO 17025 accredited, demonstrating our dedication to quality, compliance and excellence.

Our laboratories work closely together to fulfil the needs of both internal and external clients.

Having started with a clean sheet the laboratories' equipment and working practices have been designed to ensure:

- ✓ Highest Quality
- ✓ Traceability
- ✓ Compliance to international standards
- ✓ Timely delivery
- ✓ Flexibility to meet customer needs

Having adopted a quality by design approach to the creation of Laboratory Services, it has been built from the ground up with quality management at the core. A bespoke Laboratory Information Management System (LIMS) ensures that all activities are tracked and traceable.

The LIMS provides secure data management which complies to international regulatory standards and enables the remote monitoring of key infrastructure.

Sample Reception and processing

The sample reception is often overlooked but it provides the foundation of the Laboratory Services activities. It acts to schedule and control the sample flows through the other laboratories ensuring their efficient operation.

The Sample Reception Laboratory has responsibility for:

- Sample lifecycle management
- Initial sample reception and quality checks
- Sample maintenance and storage
- Inventory control
- Bespoke sample processing when required

Acting as the primary point of contact for Laboratory Services the Sample Reception team ensure a smooth and efficient transition of samples from the clinics to the analytical facilities.

Clinical Pathology Laboratory

Clinical Pathology is a key part of Laboratory Services, working to the highest internationally recognised standards.

Investments have been made in state-of-the-art technology to achieve the highest quality results whilst still being able to meet the required turnaround times. Supporting clinical trials with a broad range of assays in several key areas. This is a major part of ensuring the safety and wellbeing of clinical trial participants.

Haematology

Full Blood Count measuring:

- ✓ Haemoglobin
- ✓ Erythrocytes
- ✓ Mean Corpuscular Volume
- ✓ Platelets
- ✓ Reticulocytes
- ✓ Leukocytes
- ✓ Differential:
  - › Eosinophils
  - › Basophils
  - › Neutrophils
  - › Lymphocytes
  - › Monocytes

Digital Morphology

Morphological analysis allows the identification of haematological diseases.

Haemostasis analysis

A broad clotting screen is offered including clotting, chromogenic, immunologic and aggregation.

Clinical Chemistry

Offering an extensive chemistry profile including:

- ✓ General Chemistry
- ✓ Hepatic Profile
- ✓ Bone Profile
- ✓ Cardiac Profile
- ✓ Lipid Profile
- ✓ Renal Function
- ✓ Cancer Markers
- ✓ HIV
- ✓ Hepatitis Testing
- ✓ Fertility Hormones
- ✓ Drugs of Abuse

Urinalysis with a combined analyser

Allowing the early detection of kidney damage/disease.

Measuring the following factors in urine:

- ✓ Leukocyte Esterase
- ✓ Nitrite
- ✓ Urobilinogen
- ✓ Protein
- ✓ pH
- ✓ Blood
- ✓ Specific Gravity
- ✓ Ketones
- ✓ Bilirubin
- ✓ Glucose

Bioanalytical Services

A core component of MAC's Laboratory Service is our state-of-the-art bioanalytical laboratory. Our modern instrumentation and co-location ensure patient safety and facilitate reduced clinical trial timelines, through:

- **Rapid sample turnaround times**
- **High-quality data**
- **Robust quality control**

The laboratory is equipped with the latest Ultra High-Pressure Liquid Chromatography (UHPLC) systems, coupled with Triple Quadrupole (QqQ) Mass Spectrometers (shown, right). Using UHPLC enables rapid, reliable separation of the extracts from complex mixtures that are present in biological samples, such as urine, plasma, CSF, or faeces. Using UHPLC and QqQ together ensures that we can selectively, specifically, and quantitatively detect drug molecules and their metabolites

Additional bioanalytical laboratory features include:

- Secure data storage and transfer
- Pharmacokinetic (PK) analysis
- Metabolite identification

Experienced staff enable the undertaking of project at all readiness levels (concept to mature).

The Bioanalytical Laboratory team can offer:

- ✓ Method Development
- ✓ Technology Transfer
- ✓ Method Verification
- ✓ Method Validation
- ✓ Analytical Service

All carried out in compliance to the highest international standards.

Pharmacokinetic (PK) and Pharmacodynamic (PD) Analysis

Use of liquid chromatography/ mass spectrometry (LC-MS/MS) enables rapid drug level monitoring in the bloodstream following administration.

This data is used to create a pharmacokinetic (PK) profile, allowing our team to determine the appropriate dosing regimen. During a clinical trial, the amount of drug detected in the patient's blood is used to ensure compliance or check for accumulation.

To inform optimal dose determination, adjustment, and monitoring, MAC provides PK/PD analyses, support services, and inhouse statistics and programming as stand-alone or integrated services.

Working with internal and/or external stakeholders and processes to meet high standards, our specialists obtain relevant PK parameters from industry-standard software (Pheonix WinNonlin) to develop individual/ stand-alone outputs and analyses.

Our PK/PD services include:

- End-to-end PK input from protocol development to final CSR
- Non-compartmental and statistical data analyses, including:
  - PK/PD relationship analysis with linear and nonlinear mixed modelling approaches and simulation techniques
  - Bioequivalence, bioavailability, dose-proportionality, and food effect
- Blinded/unblinded interim PK reports to support early phase research
- Measurement of plasma drug level using triple quadruple mass spectrometers

The Special Projects Group

To meet the specific analytical requirements of sponsors, the Special Projects Group offers tailored analyses. This empowers sponsors to incorporate the monitoring of novel biomarkers and companion diagnostics, helping to streamline clinical trials.

Our Pharmaceutical Services Team

In each of our laboratories, our pharmaceutical team use their experience to:

- **Transfer existing methods from clients**
- **Modify methods as needed**
- **Create bespoke methods when required**

Our highly experienced team work collaboratively with sponsors to meet all of their drug development needs.

Watch our Pharmaceutical Services video to learn more

MAC

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

MAC Global Offices

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UKAS TESTING

BRONZE | Top 35%
ecovadis
Sustainability Rating
DEC 2024

CYBER ESSENTIALS
CERTIFIED

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