

# Specialist pharmacy services for clinical trials



- Purpose-built pharmacy
- MHRA Manufacturer's Authorisation
- Royal Pharmaceutical Society registration
- Sterile manufacture
  - 3 isolators
- Radiopharmacy
- 3 QPs

Hammersmith  
Medicines Research

[www.gmp-pharmacy-london.com](http://www.gmp-pharmacy-london.com)

## HMR pharmacy services

Our GMP-compliant, 200 m<sup>2</sup> pharmacy was purpose designed and commissioned in accordance with MHRA best practice, and incorporated into our ISO 9001 quality management system. We manufacture non-sterile, sterile and radioactive IMPs, and have had an MIA (IMP) since 2004.

We:

- import IMPs, non-IMP and challenge agents from outside the EEA;
- collaborate with sponsors to develop, refine, and test small-scale production methods;
- prepare finished sterile and non-sterile products;
- prepare sterile and non-sterile radioactive IMP and radiopharmaceuticals;
- repack, randomise and label IMPs and non-IMP;
- manufacture and assemble hard-shell capsules;
- over-encapsulate other solid dose forms; and
- QP release all doses.

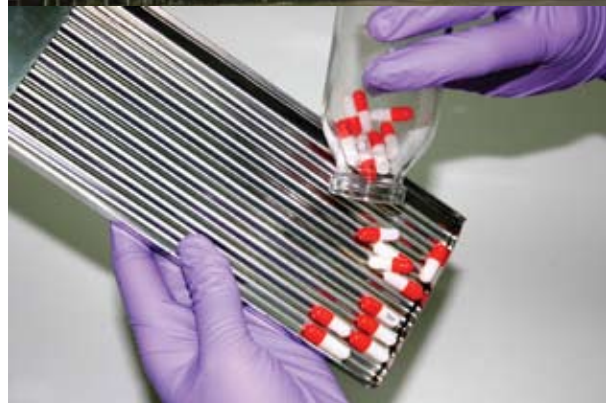
## Non-sterile work

We:

- dispense individual doses from bulk supplies; and
- make solutions, suspensions and capsules.

We have:

- Balances including 2 Oxford G2105D (up to 5 decimal digits);
- Sartorius YWT03 balance table of cast stone;
- Grant ultrasonic bath;
- 2 magnetic stirrers; and
- Chemcap filter cabinet.



## Sterile work

Latest specification sterile areas for IMP manufacture and radiopharmacy

- Constructed to comply with EU GMP
- Electronic environmental control to all areas
- Interlocked doors
- Synchronised clocks
- Intercom to other manufacturing areas
- 'In' and 'out' hatches to all areas for optimum work flow
- Extensive experience of preparing solutions for IV infusion and parenteral injection
- Cherwell surface air sampler
- PMT particle sampler
- 2 warm incubators

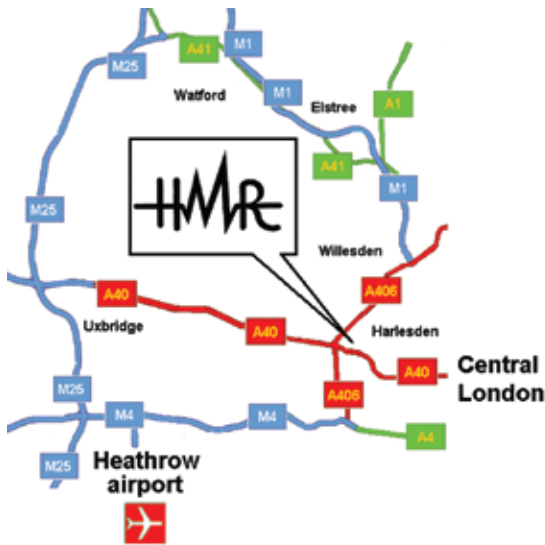
## Isolator rooms

- 2 Envair CDC-F 2-glove isolators (negative pressure)
- 1 Envair CDC-F Technetium isolator (negative pressure)
- > 55 air changes/h
- > 45 Pa above atmospheric pressure

## Radiopharmacy

- Purpose-built radiopharmacy suite, with Envair CDC-F Technetium isolator for manufacture and dispensing of sterile radiolabelled IMP
- Tri-Carb 3100TR liquid scintillation analyzer, for QC, safety monitoring and sample assay
- Experience of manufacturing IMP radiolabelled with radionuclides  $^3\text{H}$ ,  $^{99\text{m}}\text{Tc}$ ,  $^{51}\text{Cr}$  and  $^{131}\text{I}$
- Specialist experience of  $^{14}\text{C}$  radiolabelled IMP, for both microdosing and therapeutic dosing:
  - novel diaminopyrimidine antibiotic
  - gastrin antagonist
  - endothelin receptor antagonist
  - dimethoxime antimicrobial prodrug





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## Staff

- 5 registered pharmacists
- 3 QPs
- 2 pharmacy assistants
- Pharmacy technician
- Radiopharmacy technician
- Radiopharmacy consultant
- Radiation protection supervisor (RPS)
- Radiation protection advisor (RPA)

## First class clinical trials service

- Dedicated champion for each trial
- We prepare trial-specific instructions and documents
- Preliminary work ensures smooth progress of trial
- Wide range of storage facilities for IMP
- IMP reconciliation and destruction at close out
- Central pharmacy for multicentre trials

## Accreditations

- Registered with the Royal Pharmaceutical Society of Great Britain
- MIA(IMP) license May 2004, renewed biannually since
- HM Revenue & Customs authorisation to receive duty-free solvents
- Licence to possess and supply Schedule 2 and 3 Controlled Drugs
- ISO: 9001 (2008)