General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: MAC Clinical Research Finance Ltd, Room 3.011, Floor 3, Citylabs 1.0, Nelson Street, Manchester, Greater Manchester, M13 9NQ

Pharmacy reference: 9012303

Type of pharmacy: Closed

Date of inspection: 15/10/2024

Pharmacy context

This pharmacy is located within an office building, which is not open to the public. It registered with the General Pharmaceutical Council (GPhC) to enable supplies of adjunct medicines for patients on clinical trial studies. Since it started to operate in April 2024, the pharmacy has not made any supplies. Therefore, a full inspection was not carried out.

Overall inspection outcome

✔ **Standards met**

Required Action: None

Follow this link to find out what the inspections possible outcomes mean

Summary of notable practice for each principle

Principle	Principle finding	Exception standard reference	Notable practice	Why
1. Governance	Standards met	N/A	N/A	N/A
2. Staff	Standards met	N/A	N/A	N/A
3. Premises	Standards met	N/A	N/A	N/A
4. Services, including medicines management	Standards met	N/A	N/A	N/A
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance ✔ Standards met

Summary findings

The pharmacy has systems and procedures to make sure it operates safely, protects people's personal information and safeguards individuals who are vulnerable. It has basic procedures in place relevant to GPhC regulated activity should this occur.

Inspector's evidence

The pharmacy was part of a company that provided a clinical trial service on behalf of external clients. It had registered intending to supply medicines against prescriptions issued by employed GMC registered doctors for patients on the company's clinical trials. These were medicines that the patient might need if they experienced acute symptoms or side effects. The pharmacy had not supplied any prescriptions medication to individual clinical trial patients since registering with the GPhC. And there was no clear date when the pharmacy would start supplying medicines directly to patients. Instead, supplies of stock medicines were made against written requisitions to clinical trial sites.

The pharmacy team worked with other teams across the company. This included the clinical trials and quality assurance (QA) teams. The clinical trials teams were based at the same site as the pharmacy and across the UK. The pharmacy used external national courier services to deliver people's treatments and associated products to clinical trial sites.

The pharmacy had a range of procedures covering its operational activities, which the QA team had approved. The procedures included safe dispensing and the responsible pharmacist (RP) regulations. They were scheduled for review in two years. Records indicated that pharmacy team members had read the procedures relevant to their roles and responsibilities. The superintendent pharmacist explained that team members were informally tested on their understanding of these procedures, but no records that supported this were kept.

The pharmacy had professional indemnity insurance for the services it provided. A responsible pharmacist (RP) notice was displayed, and a paper RP log was appropriately maintained. The pharmacy kept a paper-based audit trail that summarised the team members who had prepared and checked each medication it had supplied, which assisted with investigating and managing mistakes. The pharmacy had written procedures for handling mistakes.

A pharmacist from the pharmacy and relevant clinical trial team held meetings each week during and at the end of each trial study. This included reviewing stock availability and the medicines delivery process to trial sites.

The pharmacy kept records that summarised the medication, quantity, date, and clinical trial site that it had supplied. The team also had a prescription only medicine register for recording supplies. The pharmacy did not have a data storage system for individual patients, such as a patient medication record (PMR), that identified the medication supplied to each of them.

The pharmacy had a standard prescription form template for the clinical trial prescribers to complete. The prescription form template included sections for the clinical trial site, the lead doctor in charge of the trial, study reference number, patient's details and date the prescription was issued. A paper-based audit trail, which accompanied the prescription, identified the pharmacy team member who had

prepared and checked the medication, and confirmed the patient's details had been checked and the date of supply.

Pharmacy team members had signed a confidentiality agreement regarding patients on clinical trials. They had completed data protection training, which included General Data Protection Regulation (GDPR). Team members demonstrated how they would securely store people's information and dispose of confidential waste appropriately. Computer systems that had access to patient information were password protected and restricted to pharmacy team members.

All pharmacy team members had completed level two safeguarding training. Patients had to confirm that they understood their participation in the trial and were not diagnosed or under investigation for any mental health condition. They had to provide their full medical history and GP records to the clinical trials team.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy's services are provided by team members who work as part of a wider clinical team. Pharmacy team members complete training that is relevant to their specialised role. New team members receive support to help them develop their skills and knowledge.

Inspector's evidence

The pharmacy team consisted of the superintendent pharmacist, a pharmacist who also worked in the clinical trials team at the same site, one dispenser and five trainee dispensers. They mostly worked as part of the clinical trials team based at the same site as the pharmacy. The pharmacy had an automated system that planned each team members tasks, which included medicines preparation and housekeeping activities. The workload was easily manageable, and team members were not working under pressure. The team usually supplied medicine requisitions to clinical trial sites the same day that it received these orders. Team members could seek support and advice from the clinical trial teams if needed.

The team met weekly to discuss matters such as reviewing procedures and general progress of staff training. The clinical trials pharmacist, who tutored all the trainees, explained that their training was progressing well. They held weekly performance reviews with each trainee. Their training included reviewing prescriptions that the clinical trial prescribers had issued to other pharmacies, good manufacturing practice, aseptic dispensing, and handling medicine recalls. Trainees had protected study time to help make sure they completed their training on time.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy is bright, clean and professional in appearance. It provides a suitable space for the delivery of healthcare services.

Inspector's evidence

The pharmacy was in a room situated in the company’s offices that included one of its clinical trials facilities. It was clean, organised, and a suitable size for the workload undertaken. It had a desk, enough storage units for the stock held and a sink. Fixtures and fittings were in good order. Records indicated that different sections of the pharmacy were regularly cleaned, and the premises was included in the company’s building pest control monitoring programme. The pharmacy was well lit and air conditioning controlled the room temperature. Access to the room was limited to pharmacy team members, who could secure it to prevent unauthorised access, and they kept it locked when not in use.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy has appropriate systems in places. It sources, stores and manages medicines safely.

Inspector's evidence

The pharmacy only operated when it received a request for medication between 8am to 5pm Monday to Friday. It was not accessible to the public. No GPhC registrable activity had taken place since the pharmacy first registered.

During the pre-clinical trial study meeting the trial client gave the pharmacy the list of permitted adjunct medicines to supply during the study, and the medication that was being trialled. The pharmacy checked whether the adjunct medicines were safe and appropriate for the proposed patients. The pharmacy checked GP medical records to make sure that patients on a phase one study were not prescribed any other medication, as required under these studies.

The pharmacy obtained its medicines from a range of MHRA licensed pharmaceutical wholesalers two working days after it had ordered them. Stock was stored in an organised manner. Clinical trials were not started until the pharmacy had stock of each adjunct medicine and these had been supplied to the trial clinic. Most adjunct medicines were for treating acute mild anxiety and mild pain.

Records indicated that the pharmacy team regularly checked stock expiry dates. The pharmacy monitored real-time electronic medication stock refrigerator temperatures, and it kept corresponding records that supported this.

The pharmacy had written procedures for packaging and delivering treatments to clinical trial sites. These packages were labelled with the clinic's address. The supplying pharmacist and dispenser who packaged each medication for delivery initialled the clinic address label.

The pharmacy used one main external courier who delivered medication to trial clinic sites, plus a second courier if needed. The main courier delivered medication to trial units the same day it received them, and there was no cut-off time for dispatching medicines via this courier.

Pharmacy team members signed the courier's and the pharmacy's records when they handed medication over to the delivery driver. Couriers emailed the pharmacy to confirm that it had collected and delivered packages. The trial clinic that received the delivery signed the courier's records and emailed a scan of it to the pharmacy, which verified the supply had been completed. Pharmacy team members bagged and directly delivered medicines to the onsite clinic trials unit. They obtained the signature of the trial staff member to who they handed the medication.

The pharmacy team used insulated packaging and a temperature monitoring device for transporting refrigerated products. The device showed an alert to the trial clinic if there had been a temperature excursion during transit, which the clinic immediately communicated to the pharmacy. The pharmacy had validated via its own testing that refrigerated packages remained below the maximum temperature allowed for at least three days during transit

The pharmacy team took appropriate action when it received alerts for medicines suspected of not being fit for purpose and it kept corresponding records that supported this. It had a process for the

disposal of obsolete medicines in waste bins kept away from its medicines stock, which reduced the risk of these becoming mixed with stock or supplying medicines that might be unsuitable.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy team has the equipment and facilities that it needs to supply medication. The equipment is appropriately maintained and used in a way that protects people's privacy.

Inspector's evidence

The pharmacy was suitably equipped with medical fridges for storing medicines. Pharmacy team members had access to hand and equipment washing facilities, which included running hot water. Water facilities were tested for microbes every six months. Equipment for preparing medicines was available, including a range of liquid measures. The team members had access to the British National Formulary (BNF) online, electronic medicines compendium and each trial study-specific protocol which included clinically relevant information.

The team had facilities that protected people's confidentiality. It viewed people's electronic information on screens in the pharmacy which were not visible from public areas. Patient information was stored and backed up regularly on independent servers that the company's internal IT team maintained. So, people's electronic information was secured and could be retrieved if their data if the system failed. The pharmacy had facilities to store people's medicines and their prescriptions away from public view.

What do the summary findings for each principle mean?

Finding	Meaning
✔ Excellent practice	The pharmacy demonstrates innovation in the way it delivers pharmacy services which benefit the health needs of the local community, as well as performing well against the standards.
✔ Good practice	The pharmacy performs well against most of the standards and can demonstrate positive outcomes for patients from the way it delivers pharmacy services.
✔ Standards met	The pharmacy meets all the standards.
Standards not all met	The pharmacy has not met one or more standards.