IP Management Script # 3

Inspector: What was your role as Pharmacist of Record (PoR)?

Responder: I am responsible for executing the required site pharmacy activities including oversight of the ordering, receiving, storing, dispensing, and accounting for all study products. The pharmacy team consists of back-up PoR and two technicians. The back-up PoR undertakes my responsibilities in case I am not available. The technicians are responsible for drug storage, temperature monitoring, reporting all temperature excursions, drug accountability and reconciliation.(volunteering Information about study team set-up)

Correct answers in red: I am responsible for executing the required site pharmacy activities including oversight of the ordering, receiving, storing, dispensing, and accounting for all study products.

Inspector: What guidelines did you follow for ASPIRE study?

Responder: ASPIRE Pharmacist Study Product Management Procedures Manual

Inspector: What training did Sponsor/CRO provide at study start? How did the Sponsor/CRO provide information on the protocol and study drug?

Responder: We were trained on the protocol, ASPIRE Pharmacist Study Product Management Procedures Manual, Pharmacy Standard Operating Procedures (SOPs).

Inspector: Was this training documented?

Responder: Yes.

Inspector: Do you have SOPs covering your activities?

Responder: Yes.

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IP Management Script # 3

Inspector: Who is responsible for writing SOPs/updates?

Responder: I am responsible.

Inspector: Did you have a contact person at Client/CRO to discuss pharmacy related issues?

Responder: Yes, MTN Pharmacist but in practice this person has never visited the site/contacted us during the course of the study. There was no such need.(volunteering Information, providing information that could trigger additional questions/concerns)

Yes, MTN Pharmacist.

Inspector: When IP arrived at the site, what was checked and what was documented? Talk me through the process.

Responder: The receipt of the product was documented using the Study Product Accountability Record (more detailed description of the process should be provided)

Upon receiving the shipment the temperature monitoring device was stopped. The content of the shipment was cross-checked versus shipment documentation and the rings were moved to appropriate storage area. The Temperature Monitoring Device Form was completed and faxed/e-mailed to Penn. The receipt of the product was documented using the Study Product Accountability Record.

Inspector: What will happen in the case of temperature excursions during the transportation?

Responder: I do not know. (Pharmacist must know the process or at least make a reference to appropriate manual)

The product must be placed in quarantine until MTN pharmacist determines that the excursion data supports the use of the product. Once the temperature data is reviewed the PoR will be notified via email by the MTN pharmacist. This notice must be stored in the site pharmacy study file.

IP Management Script # 3

Inspector: How was Investigational Product (IP) dispensed? Talk me through the process.

Responder: Study prescriptions are completed by site clinic staff and provided to pharmacy. Each prescription has a pre-printed randomization number on it, and it is this number that links the prescription with the Participant-Specific Pharmacy Dispensing Record that will be used for that participant.

Inspector: How did you know the prescription was signed by authorised prescriber?

Responder: I trust that what I received was correct. (inappropriate answer, assuming)

A copy of the most recent 1572 form must be kept in the pharmacy study file.

Inspector: Did you check if study had all necessary approvals in place?

Responder: Yes. A copy of the current IRB approval letter is kept in the pharmacy study file.

Inspector: Did you check if subject signed ICF?

Responder: No. This is checked by clinic staff. (inappropriate answer, should be noted on prescription)

The pharmacist always verifies that the participant has signed the informed consent. This is noted on the prescription.

Inspector: How do you check if the proper IP number is dispensed?

Responder: I am trying to check the numbers carefully (it must be demonstrated that good process is in place to avoid mistakes)

Dispensing product for ASPIRE always involves 2 members of the pharmacy staff.

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Inspector: Has it ever happened that incorrect VR was dispensed?

Responder: Yes. On two occasions, incorrect ring was dispensed at the pharmacy. On another two occasions, the correct ring was dispensed at the pharmacy but the study nurse dispensed incorrect rings. (volunteering information)

Yes.

Inspector: What kind of corrective actions were implemented at the pharmacy?

Responder: The clinic staff were immediately alerted that incorrect rings were dispensed at the pharmacy. The participants were contacted and asked to remove the rings and visit the clinic as soon as possible. The root cause analysis of the events was completed. The pharmacy staff was re-trained on study product dispensing procedures. Emphasis was placed on adherence to pharmacy dispensing workflow especially QC process and second check that must be completed in real time. In addition, third check by study nurse was added to the IP dispensing process.

Inspector: How were the changes to the process documented?

Responder: The Note to File was created. The Note to File includes the description of the event, root case analysis and the implemented corrective and preventative actions. The re-training was documented using the training logs. The IP dispensing logs were revised, the column for the third QC by the nurse was added.