

Pharmacists role in ASPIRE

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OUTLINE

- Regulatory
- SOP's
- Staff training
- QA/QC
- Contraception and primary care
- Study product destruction

Regulatory

- Compile application for clinical trial approval and submission to DRA (MCAZ)
- Follow up the application
- Compile responses to queries raised
- This role is a process which continues throughout the study:
 1. Quarterly and annual progress reports
 2. Protocol updates (version changes)
 3. LoA's
 4. Investigator's Brochures and PI updates

SOP development

- Pharmacists assist clinic staff in development of all SOP's that relate to study product:
 1. Study product accountability SOP
 2. Chain of custody SOP
 3. Communication SOP
 4. Study product destruction SOP
- Update these SOP's as need arises due to changes in protocol, LoAs , etc...

Staff training

- Staff training on protocol, SOP's and SSP requirements on study product components of the protocol:
 1. Study product accountability
 2. Chain of custody
 3. Study product destruction
 4. Mechanism of Action, side effects, pharmacokinetics

QA/QC

- Active role in daily QC of clinic binders and regulatory files for all study product documentation:
 1. chart notes
 2. clinic study product accountability logs
 3. Study product destruction cover sheets
 4. Destruction certificates
- Active participation in the clinic quarterly QA processes in preparation for monitoring visits

Contraception and primary care

- This is the only time we are getting for 1 on 1 interaction with ASPIRE participants!
- Provide counselling on participant's chosen contraception when they come to collect
- Provide drug information for prescribed medicines: dosage instructions, warnings and precautions, side effects,
- Maintaining condom supplies

Destruction of used rings



- Toolbox was chosen
- Dimensions- 395x235x175mm
- Lined with plastic
- Slit on top for dropping the used rings
- Pharmacists will verify accuracy of all entries on the accountability log daily and destruction cover sheet during the destruction process.

Overall the pharmacists can be contacted by the clinic on ALL issues that relate to study product and primary care drugs that they may need guidance or training on – WE ARE DRUG EXPERTS

THANK YOU



from the Zim pharmacy team