**Pharmacy Site Assessment Questionnaire**

***[NOTE TO SRA/RM-ATMP: this form is to be used as part of a site assessment process when assessing suitability of the Pharmacy Site participation in the conduct of non-commercial clinical trials that use a medicinal product and that fall under the UK Regulations SI 2004/ 1031 and amendments thereafter.***

***Prior to ending to site:***

***1. Send template to Regulatory Manager – Pharmaceuticals (RMP) to adapt questions for trial***

***2. Send trial specific form to site***

***3. RMP to review completed form and follow-up with pharmacy/trial team if required.***

***PLEASE ENSURE THE RED TEXT IS DELETED BEFORE SENDING IT TO SITES.]***

*Please complete this Pharmacy Site Assessment questionnaire and return it to the JRO Sponsor Regulatory Advisor / Regulatory Manager - ATMP*

*at your earliest convenience.*

**Sponsor ID:**

**Title of Study:**

**Name of Site:**

|  |  |  |
| --- | --- | --- |
| **Contact Details** | | |
| **Name of Pharmacy Hospital with address** | Name: |  |
| Address: |  |
| **Main point of contact for clinical trials pharmacy** | Name: |  |
| Contact Number: |  |
| Email: |  |

|  |  |  |
| --- | --- | --- |
| **Pharmacy Staff** | | |
| 1. Does your Pharmacy unit have a permanent designated member of staff who has overall responsibility for the pharmacy clinical trial service? | Yes No | |
| 1. Are all designated Pharmacy staff providing clinical trial services adequately qualified, trained and experienced in GCP and GMP (if applicable) to assume clinical trial responsibilities? | Yes No | |
| 1. Does your Pharmacy unit hold training records and signature logs for all staff involved in clinical trial activity? | Yes No | |
| **Pharmacy Facilities** | | |
| 1. Which of the following temperature controlled storage facility types do you have? |  | *Comments:* |
| a. Room Temperature (15-25°C) | Yes No |
| b. Refrigerated (2-8°C) | Yes No |
| c. Freezer (approx. -18°C) | Yes No |
| d. Freezer (approx. -80°C) | Yes No |
| 1. Are the storage areas secured with restricted access to personnel authorised to handle IMPs? |  | *Comments:* |
| a. Room Temperature (15-25°C) | Yes No |
| b. Refrigerated (2-8°C) | Yes No |
| c. Freezer (approx. -18°C) | Yes No |
| d. Freezer (approx. -80°C) | Yes No |
| 1. Can IMPs and products used in clinical trials be segregated (i.e. physically separated at identifiable location such as a separate cabinet) within the storage areas for items recently received, in quarantine, returned products and those approved for use? |  | *Comments:* |
| a. Room Temperature (15-25°C) | Yes No |
| b. Refrigerated (2-8°C) | Yes No |
| c. Freezer (approx. -18°C) | Yes No |
| d. Freezer (approx. -80°C) | Yes No |
| 1. Are the storage areas temperature monitored? |  | *Comments:* |
| a. Room Temperature (15-25°C) | Yes No |
| b. Refrigerated (2-8°C) | Yes No |
| c. Freezer (approx. -18°C) | Yes No |
| d. Freezer (approx. -80°C) | Yes No |
| 1. If you have answered yes to the above question, is it monitored continuously or daily? | Continuously Daily | |
| 1. Is there documentation to show evidence of temperature monitoring? |  | *Comments:* |
| a. Room Temperature (15-25°C) | Yes No |
| b. Refrigerated (2-8°C) | Yes No |
| c. Freezer (approx. -18°C) | Yes No |
| d. Freezer (approx. -80°C) | Yes No |
| 1. If electronic monitoring is done, does the system alarm if it is outside temperature range? |  | *Comments:* |
| a. Room Temperature (15-25°C) | Yes No |
| b. Refrigerated (2-8°C) | Yes No |
| c. Freezer (approx. -18°C) | Yes No |
| d. Freezer (approx. -80°C) | Yes No |
| 1. If you have answered yes to the above question, does the system alert outside of normal hours? | Yes No | |
| 1. Does your Pharmacy unit have a written procedure for temperature excursions? | Yes No | *Comments:* |
| 1. Do you have a pest control program? | Yes No | *Comments:* |
| 1. Do you have the following facilities/capabilities as part of IMP assembly operation? |  | |
| a. Primary packaging, e.g. filling bottles with tablets, filling of fluids | Yes No | |
| b. Secondary packaging e.g. compiling bottles into cartons | Yes No | |
| c. Annex 13 Labelling | Yes No | |
| 1. Do you have standard operating procedures (SOPs) detailing the process and controls for the above activities (in Q14)? |  | *Comments:* |
| a. Primary packaging | Yes No |
| b. Secondary packaging | Yes No |
| c. Labelling | Yes No |
| 1. Do you have the capability of carrying out additional labelling of primary and secondary packs e.g. expiry extension labelling? | Yes No | *Comments:* |
| 1. Does your Pharmacy unit have aseptic facilities that allow the reconstitution/dilution of IMP? | Yes No | *Comments:* |
| 1. Can your Pharmacy unit handle Gene-Therapy products? | Yes No | *Comments:* |
| 1. Can your Pharmacy unit handle and prepare Radiopharmaceuticals? | Yes No | *Comments:* |
| 1. Does your Pharmacy unit operate a 7 day service for clinical trials? | Yes No | *Comments:* |
| 1. Can your Pharmacy unit operate out-of-hours? | Yes No | *Comments:* |
| 1. Are you able to destroy IMP at a facility approved for pharmaceutical product destruction? | Yes No | *Comments:* |
| 1. Does your Pharmacy unit have suitable archiving facilities for pharmacy trial files? (trial files include files for non-study documentation e.g. SOPs and study specific files) | Yes No | *Comments:* |
| **IMP Management** | | |
| 1. Does your Pharmacy unit have a procedure in place to record the safe receipt of IMPs, including IMPs which are used from hospital stock? | Yes No | *Comments:* |
| 1. Does your Pharmacy unit collect and store each shipment record with temperature trails (when applicable) for each delivery? | Yes No | *Comments:* |
| 1. Does your Pharmacy unit have a system in place to carry out full accountability per IMP per trial subject? | Yes No | *Comments:* |
| 1. Does your Pharmacy unit have a procedure in place for the reconciliation of IMPs? | Yes No | *Comments:* |
| 1. Does your Pharmacy unit have a system in place that allows the recall of IMPs from all clinical trial subjects in situations where there is product recall? | Yes No | *Comments:* |
| 1. Is your Pharmacy unit familiar with handling requests for Study Product shipments via IxRS (Interactive Voice/Web Response System)? | Yes No | *Comments:* |
| **Quality Systems** | | |
| 1. Does your Pharmacy unit have a GMP/Quality Standards QA department? | Yes No | *Comments:* |
| 1. Are your SOPs for all clinical trials activities reviewed and updated accordingly? | Yes No | *Comments:* |
| 1. Do you have a training programme in place? (please provide details in comments section) | Yes No | *Comments:* |
| 1. Do you keep all trial Pharmacy files in a secure and protected area? | Yes No | *Comments:* |
| **Communication** | | |
| 1. Do you have a system in place to record and maintain a list of all the clinical trials your pharmacy unit provide a service for? | Yes No | *Comments:* |
| 1. Does your Pharmacy unit have links with the R&D department to ensure an effective working relationship with the site principal investigator? | Yes No | *Comments:* |
| 1. Does your Pharmacy unit have a procedure to ensure that all documents relating to communications and other business in relation to a trial are part of the pharmacy trial file? | Yes No | *Comments:* |
| 41. Are all prescriptions used for IMPs, identifiable as prescriptions for “clinical trial use” only? |  | |
| **Set-Up** | | |
| 1. Does your Pharmacy unit have a system in place to review a trial and assess the feasibility of its conduct at your site? | Yes No | *Comments:* |
| 1. Does your Pharmacy unit write a summary for each trial protocol? | Yes No | *Comments:* |
| 1. If you have answered yes to the above question, does anyone review and sign off the summary protocol? | Yes No | *Comments:* |
| 1. Does your Pharmacy unit have a system in place to ensure that prior to the commencement of the trial and the dispensing of any IMP there are all the appropriate approvals in place? E.g. a letter from the Sponsor’s R&D department. | Yes No | *Comments:* |
| **MHRA Inspection** | | |
| 1. Has your Pharmacy unit had a MHRA GCP and/or GMP inspection? | Yes No | |
| 1. If you have answered yes please provide any relevant details which help us as a Sponsor determine the risks associated with the conduct and management of a trial at your site (this information is not obligatory, but it is useful in the assessment of suitability of the site for conducting trials). |  | |
| **Other** | | |
| 1. Please provide us with any extra relevant information that you feel would impact on the management and conduct of a trial at your site. |  | |
| **Additional Trial Specific Questions *[adapt as appropriate]*** | | |
|  |  | |
|  |  | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Completed by:** | | | | | |
| **Name:** |  | **Position:** |  | **Date:** |  |

Please do not hesitate to contact us should you require any further information about the trial.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| ***JRO Use Only*** | | | | | | |
| ***Reviewed by:*** | | | | | | |
| ***Name:*** |  | | ***Position:*** |  | ***Date:*** |  |
| ***Comments:*** | | | | | | |
| ***Actions/Escalation Required:*** | | | | | | |
| ***Responses to Actions/Escalations Required:*** | | | | | | |
| ***Date Actions/Escalations Resolved (if applicable):*** | |  | | | | |
| ***Signature and Date (SRA/RM-ATMP/RMP):*** | |  | | | | |