**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):*** |  |