|  |  |  |
| --- | --- | --- |
| Name and strength of prepared ATMP: | Hospital site: | Date of assessment: |
| Diluent:  | Final volume: | Bag, syringe, other (please specify): |
| Pre-preparation storage condition and expiry: | Post preparation storage condition and expiry: |
| Summary of arrangements under assessment (description of preparation process and local arrangements intended to be applied including any risk reduction measures that require implementation prior to ordering the ATMP): |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Risk factors** | **Description** | **Tick if applicable** | **Score if ticked** |
| 1.1 | **Therapeutic risk** | Where there is a significant risk of patient harm if the injectable medicine is not used as intended.**Note: It is anticipated in-vivo gene therapy will always present therapeutic risk therefore this section has been pre-populated.** | **✓** | **1** |
| 1.2 | **High risk route of administration** | Examples include intrathecal, intracerebral, epidural etc. |  | **10** |
| 2 | **Use of a** **concentrate** | Where further dilution (after reconstitution) is required before use, i.e. slow iv bolus not appropriate. |  | **1** |
| 3 | **Complex calculation** | Any calculation with more than one step required for preparation and/or administration, e.g., vg (vector genomes)/kg where the vg is variable between batches. |  | **1** |
| 4.1 | **Complex method** | Complex preparation method including any of the following:  |  |  |
| 4.2 | Syringe-to-syringe transfer |  | **1** |
| 4.3 | Thaw required |  | **1** |
| 4.4 | Any open manipulations |  | **2** |
| 4.5 | Non-standard manipulation |  | **1** |
| 5 | **Reconstitution of powder in a vial**  | Where a dry powder has to be reconstituted with a liquid. |  | **1** |
| 6.1 | **Use of a part vial or ampoule, or use of more than one vial or ampoule**  | Part vial/ampoule |  | **1** |
| 6.2 | 2-4 vials/ampoule |  | **2** |
| 6.3 | 5-10 vials/ampoule |  | **4** |
| 6.4 | 11-20 vials/ampoule |  | **5** |
| 6.5 | >20 vials/ampoule |  | **10** |
| 7 | **Use of a pump or syringe driver** | All pumps and syringe drivers require some element of calculation and therefore have potential for error and should be included in the risk factors. However it is important to note that this potential risk is considered less significant than the risks associated with not using a pump when indicated. |  | **1** |
| 8 | **Use of non-standard giving set/device required**  | Examples: light protected, low adsorption, in-line filter or air inlet. |  | **1** |
| Add all risk scores together and determine if total risk rating | Total |  |
| Risk Score < 6 | Low Risk: Proposed arrangements have controlled the risks to acceptable levels and preparation can proceed as assessed once assigned actions are complete.  | 🞎 |
| Risk Score 6 to 8 | Medium Risk: Proposed actions control some risks, but residual risks remain. Preparation may proceed as assessed after introduction of assigned actions. Additional mitigation should be considered where possible to further reduce these risks. Where points come from multiple starting containers (i.e. vials), these cannot be mitigated in a clinical area, and preparation in pharmacy is recommended. | 🞎 |
| Risk Score > 8 | High Risk: Despite proposed actions, the risk remains high. Preparation may proceed as assessed provided all proposed actions are introduced, and the organisation accepts the residual high risk rating. An entry in the organisational risk register should be made to document this. Regular review of the process is required to identify further risk reduction opportunities. Where points come from multiple starting containers (i.e. vials), these cannot be mitigated in a clinical area, and preparation in pharmacy is recommended. | 🞎 |
| **Risk assessment undertaken by:** Minimally, a Pharmacist with Clinical Practitioner or Specialist |
| **Pharmacist Name** |  | **Clinician Name:** |  |
| **Signature:** |  | **Signature:** |  |