|  |  |  |
| --- | --- | --- |
| 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). ***Sources of information may include SmPC, Pharmacy Manual, Stem Cell Lab Manual***: |
|  | Risk Factors | Individual Risks | Tick if applicable | Score if ticked |
| 1.1 | Therapeutic Risk | Where there is a significant risk of patient harm or therapeutic failure if the ATMP is not handled or used as intended.**NOTE: All ATMPs are considered to have a high Therapeutic Risk, therefore this will always score 1** | ✓ | 1 |
| 1.2 | High risk route of administration | Examples include intracerebral etc. |  | 10 |
| 2.1 | Conditioning Regime | Patients are required to be pre-conditioned prior to treatment e.g., patient has undergone lymphodepletion prior to treatment |  | 1 |
| 2.2 | Pre-conditioning timings, where the specific timing of a particular chemotherapy may affect the product engraftment and viability post infusion. |  | 1 |
| 3.1 | Preparation: Method | Thaw |  | 1 |
| 3.2 | Sequential thaw of multiple bags (where they cannot all be thawed at the same time) |  | 2 |
| 3.3 | Incubation |  | 1 |
| 3.4 | Centrifugation |  | 1 |
| 3.5 | Any aseptic non-touch manipulations |  | 10 |
| 3.6 | More than five non-touch manipulations |  | 10 |
| 3.7 | Open system manipulations are required for preparation of the dose |  | 25 |
| 3.8 | Where further dilution (after thaw) is required before use. |  | 3 |
| 3.9 | Where only part of a vial or ampoule is required. I.e., 5ml from a 10ml vial.  |  | 1 |
| 3.10 | Where multiple units are required, I.e., four x 5ml ampoules for a single dose. |  | 1 |
| 3.11 | Where partial administration of an IV bag is required to deliver the required dose |  | 10 |
| 4 | Storage and Handling | Handling restrictions following preparation (e.g. transportation limits) |  | 1 |
| 5 | 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 |
| 6.1 | Atypical labelling requirements | Blinding of dose for preparation,  |  | 1 |
| 6.2 | Labelling of frozen containers |  | 1 |
| 7.1 | Administration | Specific infusion time or rate is stipulated. |  | 1 |
| 7.2 | Specialist equipment required for administration (e.g. syringe driver or pump) |  | 1 |
| 7.3 | Specialist consumables required (e.g. giving set, filters) |  | 1 |
| 7.4 | Product must be given within a short timeframe from thaw |  | 1 |
| 7.5 | Sequential administration of multiple infusions required to make up dose |  | 1 |
| 7.6 | Specific spill kits required during administration |  | 1 |
| 8 | Personalised Medicines | The ATMP is linked to the patient as an autologous cellular product, or is HLA matched, and administration to the incorrect patient would be detrimental. |  | 2 |
| 9 | Training  | Where all or part of the preparation process is unfamiliar to the operator e.g., prepared by individual fewer than 6 times in 12 months (however due to use of ATMPs in rare diseases it may be appropriate to aggregate experience in similar products/procedures). |  | 2 |
| Add all risk scores together to determine total risk rating | Total (A) |   |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Preparation Controls | Different preparation arrangements present varying degrees of risk reduction | Tick if applicable | Risk Multiplier |
| 1 | Prepared at patient bedside\* following SmPC instructions |  | 3 |
| 2 | Prepared at patient bedside following locally approved preparation worksheet based on SmPC |  | 2.5 |
| 3 | Prepared in a side (treatment) room following SmPC instructions |  | 2.5 |
| 4 | Prepared in a side (treatment) room following locally approved preparation worksheet based on SmPC |  | 2 |
| 5 | Thawed in pharmacy or stem cell lab and supplied ready-to-administer to clinical area |  | 1 |
| 6 | Third party provider prepared ready-to-administer dose which is labelled on receipt by pharmacy |  | 1.5 |
| 7 | Aseptically prepared in aseptic unit or stem cell lab\*\* |  | 1 |
| Determine the risk multiplier from the proposed preparation location above | Risk Multiplier (B) |  |
| \* Where manipulation in clinical areas is proposed, administration must be immediately following preparation.Where the product will need to be prepared at the bedside. E.g. Where the expiry of the ATMP is <4 hours for cell-based products, sponsor specified requirements, where preparation requires use of clinical apparatus.\*\* Where a product has a post-preparation expiry of >4 hours the preference should always be to prepare this in a suitable aseptic unit e.g. stem cell lab or suitable third party provider.NB: Some genetically modified products are not suitable for preparation in clinical area due to class and containment requirements (see SPS guidance on Requirements for Governance and Preparation of Gene Therapy) |

|  |
| --- |
| **Overall Residual Risk considering proposed location of preparation and the inherent risks of the preparation process** |
| Preparation Risk Score (A) | x | Preparation Risk Multiplier (B) | = | Overall Preparation Risk |
|  | x |  | = |  |
| Risk Score < 30 | Low Risk: Proposed arrangements have controlled the risks to acceptable levels and preparation can proceed as assessed once assigned actions are complete. | 🞎 |
| Risk Score 31 to 55 | 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. | 🞎 |
| Risk Score > 55 | 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. | 🞎 |
| **Risk assessment undertaken by:** Minimally, a Pharmacist with Clinical Practitioner or Specialist |
| **Pharmacist Name** |  | **Clinician Name:** |  |
| **Signature:** |  | **Signature:** |  |