RCloud Tasking Form – Part B: Statement of Requirement (SoR)

Title of Requirement	Evaluation of a possible dry heat sterilisation mechanism for HI-6 DMS
Requisition No.	As stated in the RCloud Portal
SoR Version	**0.1**

1.	**Statement of Requirements**
1.1	**Summary and Background Information**
	A Contractor is required to provide a proof of principle study evaluating possible dry heat sterilisation exposure times/ temperatures which cause minimal change in the Active Pharmaceutical Ingredient (API) supplied. Dstl is developing a sterile dry powder pharmaceutical product for intravenous administration. Evaluation of gamma irradiation demonstrates a degree of degradation which is undesirable and therefore dry heat sterilisation requires evaluation to determine if it can offer a superior product profile prior to consideration of an aseptic process. The material is a white crystalline solid with a melting point of 170°C with decomposition so standard dry heat sterilisation temperature settings will not be suitable. Evaluation of a suitable cycle should be undertaken in a forced air oven by preference although consideration of a standard laboratory oven will be considered. The composition of primary packaging has not been defined as of this time and therefore any suitable grade of primary packaging is acceptable subject to protecting the material from known degradation routes outlined below.
1.2	**Requirement**
	A Contractor is required to evaluate the conditions required to achieve a dry heat sterilisation cycle (10^6 reduction) suitable for a 1g fill of HI-6 DMS powder in a 10ml type I glass vial with standard stoppers and collars. Vials should be blanketed with a suitably inert gas e.g. Argon or Nitrogen. The cycle should be suitable for compliance with Eudralex Vol 4 Annex I (Sterilisation) but no validation is necessary at this stage.

	The active material is light and moisture sensitive so care should be taken to minimise both potential routes of breakdown where practicable. The Contractor shall evaluate of the impact of a possible cycle on the high level physical characteristics e.g. appearance of the powder and chemical characteristics e.g. Assay/impurity profile (method to be supplied by the Authority for HPLC analysis) in addition to determining that a compliant microbial reduction has been achieved on any down-selected process. Where any analytical method other than the proposed supplied HPLC method is to be used, the Contractor should confirm the ability of the method to discriminate changes in the material which are consistent with the HPLC method offered. This should be considered to be of the order of 0.1% changes in purity/ impurity formation. Initial scoping activity of a number of potential temperatures can be undertaken prior to a down-select of up to three cycles of time/temperature for final confirmatory analysis using appropriate biological indicators. All materials required, with the exception of HI-6 DMS, will be sourced by the Contractor and will be included in the quoted price. Activity shall be planned under a protocol and documented in an associated report, to be delivered to Dstl. The quality standard utilised does not need to be to full GMP as this work will be a proof of principle study only but all materials/ work undertaken should be traceable within the documents provided. Indicative project timeline with quote shall be provided as part of the tender return.
1.3	**Options or follow on work** *(if none, write 'Not applicable')*
	Where necessary the cost of additional cycles being evaluated beyond those anticipated in the core scope of work should be included as options. No more than 3 additional cycles should be anticipated to complete the study satisfactorily. All options may be exercised independently of each other and at the sole discretion of Dstl. The Contractor shall hold it quoted price for the optional work to ensure it is ready to be enacted by Dstl Commercial Services in writing, should it be required. Dstl reserve the right to exercise the Optional work as detailed in the Contractor's tender response. Dstl may wish to evoke up to 3 cycles of Options independently of each other. Dstl will give the Supplier 1 month calendar notice before evoking an option.

1.4	**Contract Management Activities**
	Fortnightly meeting to discuss activities undertaken and next steps. Opportunity to also discuss any issues and discuss deliverables/timelines.
1.5	**Health & Safety, Environmental, Social, Ethical, Regulatory or Legislative aspects of the requirement**
	A material safety data sheet shall be provided with the provision of the HI-6 DMS.

1.6	Deliverables & Intellectual Property Rights (IPR)					
Ref.	**Title**	**Due by**	**Format**	**Expected classification (subject to change)**	**What information is required in the deliverable**	**IPR Condition**
D-1	Protocol		MS Word for review and signed PDF for approval	Official	Protocol outlining the experimental methodology to meet the requirement	Default RCloud Agreement Terms and Conditions shall apply
D-2	Report		MS Word for review and signed PDF for approval	Official	Report detailing the data generated and conclusions of the experiment	Default RCloud Agreement Terms and Conditions shall apply

1.7	**Deliverable Acceptance Criteria**
	Deliverables will undergo technical review and approval prior to acceptance within 30 days of receipt.

2	**Evaluation Criteria**
2.1	Method Explanation

Technical 70% Available Marks
Price 30% Available Marks

<u>For Technical Scores</u>

Each question is individually weighted.

The marks are individually indicated.

Worked Example for Technical Evaluation

The technical competence of the proposal is worth 70%

Question 1 – this question has 20 marks available

Question 2 – this question has 30 marks available

Question 3 – this question has 20 marks available

The total marks for the technical criteria is 70

Calculation of the overall total score

Each supplier's total score for each section shall be summed to give the final score. The winning supplier is the one with the highest total score. **In the event of a tie-break between suppliers for the highest score, the tie supplier with the highest technical mark will be awarded the**

	contract. In the unlikely event that the tied suppliers have identical technical scores also, at this point, the supplier with the cheapest proposal will be awarded the contract. For example: A Supplier's scores were: • 45 out of 70 for technical competence • 15 out of 20 for price Their total weighted score is 60% out of 100% The weighted scores will be rounded to two decimal places where necessary to give a final total score. It is understood that Dstl Reserve the right to not award a Contract as a result of this Competition as detailed in the Framework Agreement and the competition may be stopped at this point.
2.2	Technical Evaluation Criteria
	HI-6 DMS Sterility Assessment Award Technical Questions **Project Overview (20 marks available in total)** **1. Please provide a project plan that identifies timelines, tasks, workflow, and relevant decision points.** Required Response: Dstl is seeking for all work to be completed by no later than 31 January 2023 but it is preferred that the tenderer can complete sooner. A scope of work with a clear timeline for activities should be provided with methodology and any dependencies. Scoring: **15-20 marks** will be awarded for project plans, which are well developed, defining all stages of activity, interdependencies and timelines which significantly improve on the date provided for completion of work. **8-14 marks** will be awarded for organisation which set out a clear vision for high level activities and timelines which meet the completion date provided but which may not demonstrate a granular plan for achieving the activity.

1-7 marks will be awarded for companies with only a high-level timeline containing little evidence of understanding the packages of work required to meet the requirement and/or those whose timelines do not achieve the work within the time constraints stated.

Validation status of equipment/facilities intended for use: (30 marks available)

2. **Please identify any in-house/external facilities and equipment and validation status of those to be utilised.**

Required Response:

Dstl is seeking for all work to be conducted in-house with a description of required GLP or GMP facilities and equipment available that is suitably validated/calibrated.

Scoring:

21-30 marks will be awarded to organisations who can evidence that equipment to be used in the execution of the program of work has been validated to a high standard which supports the generation of key data and conclusions.

11-20 marks will be awarded to organisations who provide evidence of partial validation and/or routine monitoring of equipment e.g. the use of temperature probes/monitors for temperature critical equipment or pre-use calibration checks.

0-10 marks will be awarded to organisations who offer no evidence of validation/ re-validation or any in-use mechanisms for ensuring the correct functioning/accuracy of data generated from equipment.

Site GxP (20 marks available)

3. **Can the tenderer provide a copy of any relevant certification in this response?**

Required Response:

Dstl is seeking a Contractor that has, and can provide evidence of, either GLP or GMP licence and/or ISO accreditation, or be able to achieve it before contract let.

15-20 marks will be awarded for organisations who can demonstrate that facilities to be used are compliant with GxP relevant to the activity i.e. GMP or GLP.

8-14 marks will be awarded to organisations who can demonstrate accreditation to a globally recognised quality management system standard e.g. ISO 9001.

	0-7 marks will be awarded to organisations with no evidence of globally recognised quality standards.
2.3	Commercial Evaluation Criteria
	Price Evaluation Criteria (30%) *To score the price, the cheapest quote will be divided by each suppliers quote.* **Example:** •Supplier A's quote is £15,000 •Supplier B's quote is £10,000 •Supplier C's quote is £30,000 To calculate a score for supplier A, divide 10,000 by 15,000. Supplier A scores 0.667 To calculate a score for supplier B, divide 10,000 by 10,000. Supplier B scores 1 To calculate a score for supplier C, divide 10,000 by 30,000. Supplier A scores 0.333 Each score will then be multiplied by 30 to achieve the commercial percentage score.