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

Title of Requirement	Determination of optimal particle size for dissolution of 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**
	Dstl is developing a multi-active auto injector for the emergency administration of a therapy to treat nerve agent intoxication.
1.2	**Requirement**
	Using an aliquot of supplied active pharmaceutical HI-6 DMS, the Contractor shall create individual aliquots of the material in a range of particle sizes. The aliquots will then be used to determine the optimal particle size for dissolution of the active material into an aqueous medium. One of the actives in the therapy is required to be kept dry until needed, to maintain efficacy. Given the time-critical nature of the administration of the therapy, the combination of the wet and dry components, resulting in a purely liquid therapy, relies on optimal dissolution characteristics for the powdered Active Pharmaceutical Ingredient (API). To perform this requirement, the Contractor shall: • Receive the active HI-6 DMS and store it refrigerated. • As reasonably practicable, design a process to evaluate the forced introduction of a 2ml aqueous citrate buffer into a chamber containing 700mg of HI-6 DMS such that it models the behaviour of a two chamber pre-filled syringe or cartridge and define that process within a protocol, to be mutually agreed with Dstl. • Create a suitable number of aliquots from the material supplied. The material is supplied in 500g bags and is sealed to prevent exposure to light and moisture. Whilst care should be taken to limit light and moisture once the bag is opened, there is no anticipated issue with using the material in a laboratory setting within a working day. Unused material should be stored with dessicant and light protection for longer periods.

	• Determine a mechanism to assess the dissolution rate of the aliquot noting that the expected dissolution time for an optimal particle size will be less than 5 seconds. • Subject each aliquot to the designed process evaluate data to determine the optimal particle size for quick dissolution. • Due the speed with which dissolution is anticipated to occur, no chemical testing on the final reconstituted material is required. • Document all experimental work in an associated report.
1.3	**Options or follow on work** *(if none, write 'Not applicable')*
	Possible follow on work to create material of the defined particle size for early work at both the PFS and AI contractors
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	19th September 2022	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	17th October 2022	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

For Technical Scores

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 20 marks available

Question 3 – this question has 20 marks available

Question 4 – this question has 10 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 Suppliers 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
	<u>HI-6 DMS Sterility Assessment Award Technical Questions</u> **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: (20 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:

15-20 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.

8-14 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.

0-7 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.

4. **Please provide at least two examples in the last 5 years of work you have developed in this field. (10 marks)**

	Required Response to include: • The development of particle sizing methodology • Research work that has demonstrated, from first principles, the development of validatable particle sizing processes **5-10 marks will be awarded** **1-4 marks will be awarded** **0 marks will be awarded**
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.