

# Statement of Requirement (SoR)

For: Business consultancy ☐ Corporate Procurement ☒

Reference Number	RQ0000046291
Version Number	0.1
Date	14/02/2024

1.	Requirement
1.1	Title
	GXP/Regulatory Training
1.2	Summary
	<p>This requirement is for specialist regulatory training to provide appropriate knowledge to Dstl staff within the pharmaceutical development teams who oversee external Contract Development and Manufacturing Organisations (CDMOs) manufacturing and testing pharmaceuticals on Dstl's behalf. Dstl staff include Project Managers, technical SMEs, clinicians, Quality Assurance and commercial representatives.</p>
1.3	Background
	<p>Pharmaceutical development projects at Dstl require the staff to have specific regulatory knowledge and understand a range of regulatory requirements and guidance's including the GxPs; Good Laboratory Practice (GLP), Good Clinical Practice (GCP) and Good Manufacturing Practice (GMP).</p>
1.4	Requirement

There are 3 total training packages required: **GMP/GCP/GLP**. These will be split into 3 separate lots, please could you confirm in your bid which Lot/Lots you wish to be submit a bid for.

There are 3 training packages required:

1. This is a specific requirement is for GMP training: **LOT 1**

The core requirement is for 3 levels of training

- Basic level introductory GMP training – high level introduction / awareness training to introduce staff to what GMP is and how it applies to the work they are involved with.
- Advanced level GMP training to cover specific roles or tasks i.e. training for project managers. Building on the foundation provided above this training is to develop the individuals understanding of GMP, how it applies to their role and the work they do and the steps they need to take to ensure compliance with the GMP regulations. The training can be delivered by a blend of off the shelf courses or via tailored material to Dstl when required – the ability of a supplier to offer Dstl specific courses is a key requirement.
- Refresher training for the above.

We also require GMP auditor training

Courses to be delivered either face to face or virtually eg.via teams.

Numbers attending courses will range from 1 to 15 participants.

2. This is a specific requirement if for GCP training: **LOT 2**

The core requirement is for 3 levels of training

- Basic level introductory GCP training – high level introduction / awareness type training to introduce staff to what GCP is and how it applies to the work they are involved with.
- Advanced level GCP training to cover specific roles or tasks i.e training for project managers etc. Building on the foundation provided above this training is to develop the individuals understanding of GCP, how it applies to their role and the work they do and the steps they need to take / are taken to ensure compliance with the GCP regulations. This can be done either via off the shelf courses or via tailored to Dstl

material when required – the ability of a supplier to offer Dstl specific courses is a key requirement.

- Refresher training for the above.

We also require GCP auditor training and inspection readiness training.

### 3. This requirement is for GLP training: **LOT 3**

The core requirement is for 3 levels of training

- Basic level introductory GLP training – high level introduction / awareness type training to introduce staff to what GLP is and how it applies to the work they are involved with.
- Advanced level GLP training to cover specific roles or tasks i.e training for project managers etc. Building on the foundation provided above this training is to develop the individuals understanding of GLP, how it applies to their role and the work they do and the steps they need to take / are taken to ensure compliance with the GLP regulations. This can be done either via off the shelf courses or via tailored to Dstl material when required – the ability of a supplier to offer Dstl specific courses is a key requirement.
- Refresher training for the above.

We also require GLP auditor training and inspection readiness training.

If the suppliers can offer any other regulatory training as part of their tender this would be considered (please provide details and pricing of the available courses)

[REDACTED] 43. Commercial interests.

[REDACTED] 43. Commercial interests.

<b>1.7</b>	<b>Deliverable Acceptance Criteria</b>
	Delegate feedback will be used to ensure Dstl requirements are being met.

<b>2.</b>	<b>Quality Control and Assurance</b>
<b>2.1</b>	<b>Quality Control and Quality Assurance processes and standards that must be met by the contractor</b>
	<input type="checkbox"/> <b>ISO9001</b> (Quality Management Systems) <input type="checkbox"/> <b>ISO14001</b> (Environment Management Systems) <input type="checkbox"/> <b>ISO12207</b> (Systems and software engineering — software life cycle) <input type="checkbox"/> <b>TickITPlus</b> (Integrated approach to software and IT development) <input checked="" type="checkbox"/> <b>Other:</b> (Please specify below) GMP
<b>2.2</b>	<b>Safety, Environmental, Social, Ethical, Regulatory or Legislative aspects of the requirement</b>
	[REDACTED] 43. Commercial interests.

<b>3.</b>	<b>Security</b>				
<b>3.1</b>	<b>Highest security classification</b>				
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<b>Of the work</b>	Official				
<b>Of the Deliverables/ Output</b>	Official				
<b>3.2</b>	<b>Security Aspects Letter (SAL)</b>				
	Not applicable				

3.3	Cyber Risk Level
	Not applicable
3.4	Cyber Risk Assessment (RA) Reference
	RAR-240513B02

4.	Government Furnished Assets (GFA)
GFA to be Issued - No	

5.	Proposal Evaluation criteria
5.1	Technical Evaluation Criteria
	<div>[REDACTED] 43. Commercial interests.</div>
	GCP Training (Lot 2)

[REDACTED] 43. Commercial interests.

[REDACTED] 43. Commercial interests.

5.2

Commercial Evaluation Criteria



6.	Defcons
DEFCON:	Covering:
76	<i>Contractors are required to work at MOD premises</i>
703	<i>Intellectual Property Rights - Vesting In The Authority</i>
539	<i>Transparency</i>
532B	<i>Protection Of Personal Data (Where Personal Data is being processed on behalf of the Authority)</i>
DEFFORM:	
532	<i>Personal Data Particulars</i>