3.	Security	
3.1	**Highest security classification**	
	Of the work	REDACTED
	Of the Deliverables/ Output	REDACTED
3.2	**Security Aspects Letter (SAL)**	
	Not applicable If yes, please see SAL reference- *Enter iCAS requisition number once obtained*	
3.3	**Cyber Risk Level**	
	REDACTED	
3.4	**Cyber Risk Assessment (RA) Reference**	
	REDACTED If stated, this must be completed by the contractor before a contract can be awarded. In accordance with the Supplier Cyber Protection Risk Assessment (RA) Workflow please complete the Cyber Risk Assessment available at https://www.gov.uk/guidance/supplier-cyber-protection-service	

4.	Government Furnished Assets (GFA)				
GFA to be Issued - Yes					
GFA No.	**Unique Identifier/ Serial No**	**Description:**	**Available Date**	**Issued by**	**Return Date or Disposal Date (T0+)**
GFI	TBD	Antibody/antibody gene sequences		Dstl	End of contract

1.5 Standard Deliverable Acceptance Criteria
As advised on tasking forms
1.6 Specific Deliverable Acceptance Criteria
See requirements section (1.4).

2.	Quality Control and Assurance
2.1	**Quality Control and Quality Assurance processes and standards that must be met by the contractor**
	☒ **ISO9001** (Quality Management Systems) ☐ **ISO14001** (Environment Management Systems) ☐ **ISO12207** (Systems and software engineering — software life cycle) ☐ **TickITPlus** (Integrated approach to software and IT development) ☐ **Other:** (Please specify below)
2.2	**Safety, Environmental, Social, Ethical, Regulatory or Legislative aspects of the requirement**
	Standard for antibody production.

1.4	Deliverables & Intellectual Property Rights (IPR)					
Ref.	**Title**	**Due by**	**Format**	**TRL***	**Expected classification (subject to change)**	**What requir delive**
D – 1	Material outputs	See requirements section (1.4)	See requirements section (1.4)	n/a	REDACTED	See re sectio
D - 2	Certificates of analysis	See requirements section (1.4)	See requirements section (1.4)	n/a	REDACTED	See re sectio
D - 3	Progress reports	See requirements section (1.4)	See requirements section (1.4)	n/a	REDACTED	See re sectio
D - 4	Annual reports	See requirements section (1.4)	.pptx file	n/a	REDACTED	See re sectio

***Technology Readiness Level required**

Annual Review The Authority requires an annual review to be held in the March/April of every contract year. The review shall be primarily technical in nature, be administered by the Contractor and located at the Contractor's facility. The Contractor shall deliver a series of technical presentations (totalling no more than 1 day) in order for the Authority to review the technical delivery of taskings for the contract year to date. The review shall be attended by the Authority and the Contractor; but may include sub-contractors (at their own expense) and the Authority's stakeholders at the discretion of the Authority.
1.3 Options or follow on work
As this work/competition is for a tasking contract, all requirements will be requested on an ad hoc basis

the best technique for achieving this requirement. The expression plasmid should perform equal to or better than pcDNA3.4 for the expression of antibody in the ExpiCHO system.

The Authority subsequently requires the high-throughput transient expression of antibody in a high yielding (typically 100 to 1000 mg/L) mammalian expression system. The Contractor shall use their knowledge and expertise to propose the best system for achieving this requirement, with the chosen expression system performing equal to or better than the ExpiCHO system. The Contractor shall deliver a minimum of 2 mL of mammalian cell culture supernatant per antibody. It is desirable that this supernatant be filtered, however as a minimum the supernatant will be delivered to the Authority frozen with an appropriate preservative (e.g. NaN3 to a final concentration of 0.05% w/v) to ensure cell death.

Certificates of analysis are required as part of this type of deliverable.

It is anticipated that the Authority will wish to use this service in each year of the contract for the high throughput transient expression of in the region of 2 batches of 100 antibody sequences (i.e. each batch consisting of 100 heavy chain variable domain genes and 100 light chain variable domain genes). An alternative source of sequences (e.g. antibody display libraries) may result in batch sizes of a minimum of 10 antibody sequences.

Delivery of All Aspects

All reports (e.g. technical reports or certificates of analysis) shall be delivered electronically (preferably by e-mail where size permits, or via courier on a CD/DVD-ROM when greater than or equal to 10 Mb in size) to the Demander for the work package, as well as to the Primary Contact REDACTED

All material output (e.g. protein, plasmid, etc.) shall be delivered for the attention of the Demander, unless otherwise directed at the point of tasking, at:

Bldg [TBC on each tasking]
Dstl Porton Down
Salisbury
Wiltshire SP4 0JQ
UK

All shipping costs, import/export Customs costs and paperwork shall be the responsibility of the Contractor.

The Location of the Work

The Authority requires all work to be performed in the UK, Western Europe, North America, Australia or New Zealand. Government Furnished Materials (e.g. GFA or GFI) and data or materials derived from Government Furnished Materials shall not leave the aforementioned geographic areas.

Site Visits

The Authority reserves the right to visit the premises of the Contractor/sub-contractor for the purposes of technical discussions and auditing of Government Furnished Materials. The Authority shall provide at least 48 hours' notice of a visit.

Progress Reviews

The Authority requires informal progress reviews by teleconference at the end of each Quarter of the UK Financial Year. The Authority requires ad hoc progress discussions when deemed necessary in order to remain up to date on progress, risks and opportunities.

Statement of Requirement (SoR)

1.	Requirement
1.1 Title	
Production of recombinant antibodies and associated materials	
1.2 Requirement	
Recombinant Antibody Production and Purification from Transient Transfection of Mammalian Cell Lines The Authority has a requirement for production and purification of recombinant antibody (specifically IgG) in mammalian cell lines. To enable this, the Authority requires the synthesis of complete variable domain antibody genes, cloning into appropriate mammalian expression vectors and subsequent production and purification of recombinant protein from a high throughput mammalian expression system as described above. The Authority will provide the Contractor with GFE sequences as text files. It is anticipated that the Authority will require small and large scale recombinant antibody production across the contract, with a target of 20 mg and 100 mg respectively of protein A, G or L affinity-purified protein. The purified antibody shall be a minimum of 90% pure as determined by SDS-PAGE analysis and delivered to the Authority as soluble proteins at a concentration 2±1 mg/mL in physiological buffer, such as PBS, in sterile 1 mL aliquots, free from preservatives, or denaturants. The concentration shall not alter by more than 10% following centrifugation at 10,000 x g for 15 minutes at +4 °C. However, if a pilot purification demonstrates incompatibility with the required conditions, the Authority may make concessions to the acceptance criteria in order to facilitate delivery of output in sub-optimal conditions (e.g. lower concentration or purity). The proposal shall describe the approach a Contractor would take to deliver this requirement, including the use of named sub-contractors and the collective experience that can be used to deliver the requirement. It is anticipated that the Authority will wish to use this service during each year of the contract with up to 40 small-scale recombinant antibody production events. It is expected that this will be performed flexibly throughout the year, with a minimum batch size of 5 antibodies. For large-scale recombinant antibody production it is anticipated that the Authority will require 30 events over the duration of the contract, and these are likely to be required simultaneously. A certificate of analysis (as a minimum detailing: antibody name, lot number, summary of production, concentration, buffer, type of purification and isotype, as well as purity including SDS-PAGE image of reduced and non-reduced product), shall be provided ahead of product shipment.	
High-throughput Antibody Gene Synthesis and High Throughput Transient Expression in Mammalian Cells The Authority owns a diverse panel of antibody sequences and has a requirement to verify these as part of this contract. To enable this the Authority requires the synthesis of complete variable domain sequences for both the heavy and light chains into IgG mammalian expression plasmids for evaluation by the Authority. The Authority will provide the Contractor with GFE sequences as text files (expected to be MS Excel or MS Word). The Contractor shall use their knowledge and expertise to propose	