Jacobs

Vaccine Task Force - Build Stream

Antibody Production Facility

8 July 2020

Contents

1. Project Understanding

The UK Government Department for Business, Energy and Industrial Strategy (BEIS) Vaccine Task Force is considering procurement of antibody production capability via two discrete options, namely Buy or Build for which workstreams are in progress. The capability is defined as a facility able to produce up to 1 million doses per year of an antibody based vaccine. This will be a pharmaceutical manufacturing facility that will need to meet the regulatory constraints of the industry.

BEIS intend to issue a formal Request for Proposal (RFP) comprising sufficient contract, procurement, technical and performance information to enable vendors to understand the User Requirements and make proposals for a turnkey Design, Build and Operate (DBO) solution. The objective of the Build workstream is to secure an option for production facilities starting on site in January 2021 at the latest with completion and commence of operations (beneficial GMP production) by January 2022. To achieve this, it is proposed to issue the RFP at circa end of July 2020 with negotiation, selection and appointment of a turnkey Design, Build and Operate (DBO) vendor by October 2020. The facility site location is not being fixed by BEIS and is therefore a function of the vendor technical and commercial proposals which may include offers for use of pre-existing construction or new build arrangements on existing or new sites.

In support of this RFP, BEIS requires a technical specification that describes the technical and pharmaceutical regulatory requirements of the product, the production process, associated environmental considerations and anticipated supporting infrastructure. Whilst stating the minimum process requirements and expected outputs, BEIS requires that the RFP integrates the opportunity for innovation in process, project delivery and operation by the specialist providers.

The RFP process will request detailed technical and commercial proposals for the process design, construction and operation. In the event that a vendor is not able to offer a site and building in its proposals, the vendor will be asked to identify requirements for supporting infrastructure (power, water etc) and state assumptions for the related site and civil engineering (building enclosure etc) including all interfaces which may be used by BEIS as a basis for site and building selection.

BEIS has requested proposals for the provision of the technical specification element of the RFP and for technical support during the review of vendor submissions.

This document sets out Jacobs proposals for immediate mobilisation of a highly experienced team which will be able to efficiently engage with stakeholder and translate critical BEIS requirements into a high level User Requirement Brief (URB) for procurement purposes. We confirm that the proposed team can meet the target delivery date for the URB and will be made available to support the procurement process.

2. Solution / Methodology

2.1 Scope

The scope of work includes:

- User Requirements Brief

  Engagement with the Users and relevant stakeholders required to inform and develop the User Requirements element of the RFP which will include a statement of the process objective/output, indicative process engineering solution and anticipated general arrangement of the supporting infrastructure and facilities as described in the following sections. It will include an outline of the pharmaceutical regulatory requirements.

- Vendor Technical Review

  Review of vendor proposals to report on compliance of process and facility engineering with the User Requirements

Jacobs has not included within this scope for the provision or evaluation of contract terms, performance, operational or commercial aspects of the DBO contract.

2.2 Basis of User Requirement Brief (URB)

The antibody platform will be mammalian cell culture in single-use bioreactors with a standard purification process. The facility will be designed to produce bulk drug substance only.

In the absence of any process specific requirements and based on recent project experience in this area, Jacobs will make a series of assumptions that will allow the User Requirements to be defined. Additional process detail will be required for the bidders to generate their proposals.

2.3 Tasks/Methodology

It is proposed that the RFP process will be executed in 3 phases with Jacobs contribution as follows:

Phase 1 Preparation of URB by Jacobs

Phase 2 Procurement technical support to BEIS

Phase 3 Technical Compliance Review

Phase 1 Preparation of URB

Jacobs will provide biopharmaceutical process engineering expertise to define the functional scope of the facility. Our engineers will, either using specific process information or using their historical experience and judgement, estimate the process scale for the proposed facility. This will allow an indicative outline design to be developed in terms of the process equipment train, supporting process infrastructure and utilities. These will be important for the potential bidders to understand the proposed scale of operations and the scope. Our process engineers will also support the layout development and the overall project scope definition.

Our process architects will work with the process engineers to develop an indicative facility block plan layout that meets the requirements of the process and the pharmaceutical regulatory constraints. The layout will be site agnostic and will act as a guide to the bidders, who will be expected to generate their own designs.

We have included an allowance for process controls, automation, instrumentation, building services, electrical and civil/structural to provide input to the user requirements to ensure all the pharmaceutical and equipment aspects of the design are captured.

The User Requirements will include the following information:

- Equipment sizing basis;
- Process flow diagram;
- Facility scoping diagram;
- Process description;
- Outline process scope;
- Process utilities;
- Pharmaceutical regulatory requirements.

BEIS will advertise this opportunity on the UK Government web site. Jacobs will issue the URB to BEIS for compilation into the RFP documentation and circulation to interested parties.

Phase 2 Procurement Technical Support to BEIS

Jacobs propose to be on standby during the procurement process (following BEIS issue of RFP) to provide technical support to Vendor queries. A notional allowance has been made in our proposal for this service.

Phase 3 Technical Compliance Review

Following submission of proposals by the Vendors, Jacobs engineering team will provide technical review support to BEIS. Jacobs has made an allowance for resource and time to carry out:

- Initial first round review of five proposals
- Second round review of two shortlisted proposals

It is noted that the submissions may require detailed discussions with shortlisted vendors the scope of which will depend on the technical and commercial proposals including inter alia, process technology, approach to site selection and building requirements, operational strategy and commercial objectives. It has been assumed that all operational and commercial negotiations will be undertaken by BEIS.

2.4 Deliverables

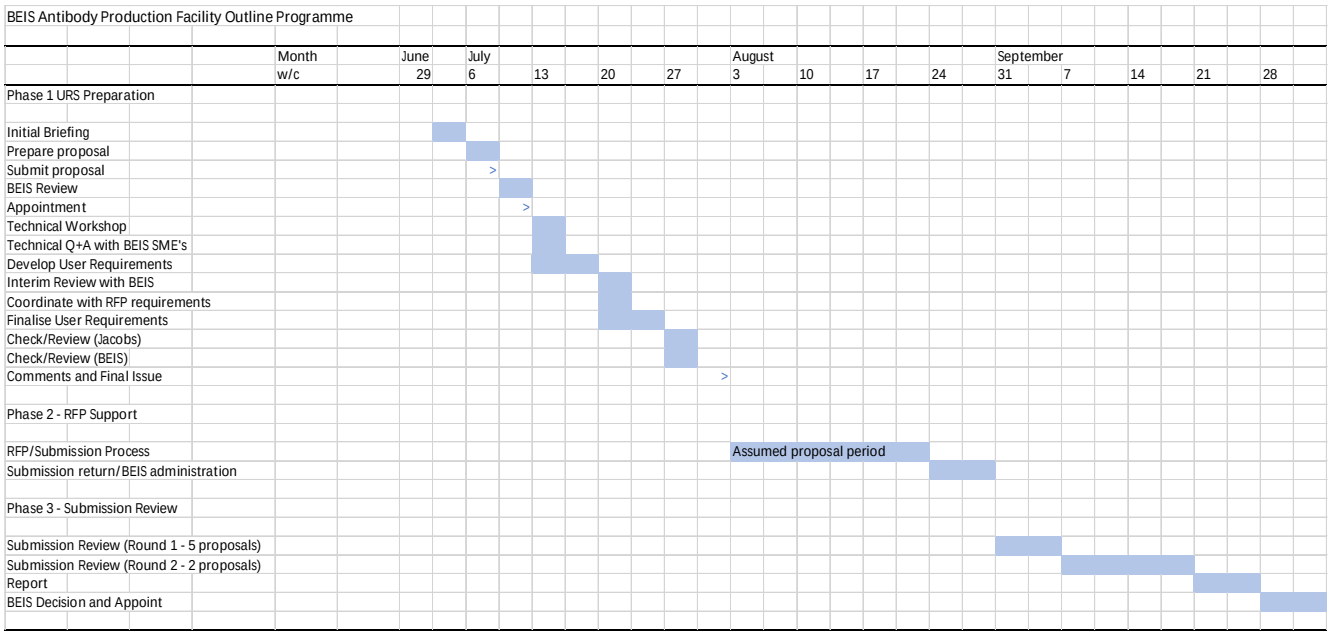
The deliverables to be provided by Jacobs will be:

- High Level Facility User Requirements Brief
- Vendor Technical Compliance Report (Round 1)
- Vendor Technical Compliance Report (Round 2)

The deliverables do not include provision or evaluation of contract terms, performance, operational or commercial aspects of the DBO contract.

2.5 Schedule / Programme

Based on the briefing information provided and initial discussions regarding programme objectives, our understanding of the anticipated timeline for Phases 1, 2 and 3 is shown below. This timeline has been used as a basis for our assessment of requirements and associated resources for delivery.



3. Team

Our core team are highly motivated, collaborative design professionals, with a proven track record of delivering cost effective, flexible and innovative design solutions within Ireland and UK as well as across Europe.

Please find below short biographies of our team members. Full CV's can be made available if required.

[redacted]

[redacted]

[redacted]

[redacted]

4. Commercial Offer

Our proposal is made based on a time charge/reimbursable appointment with the estimate of cost based on the scope of work and programme identified in this proposal. CCS Lot 7 Infrastructure ceiling rates have been applied to the projected resource levels.

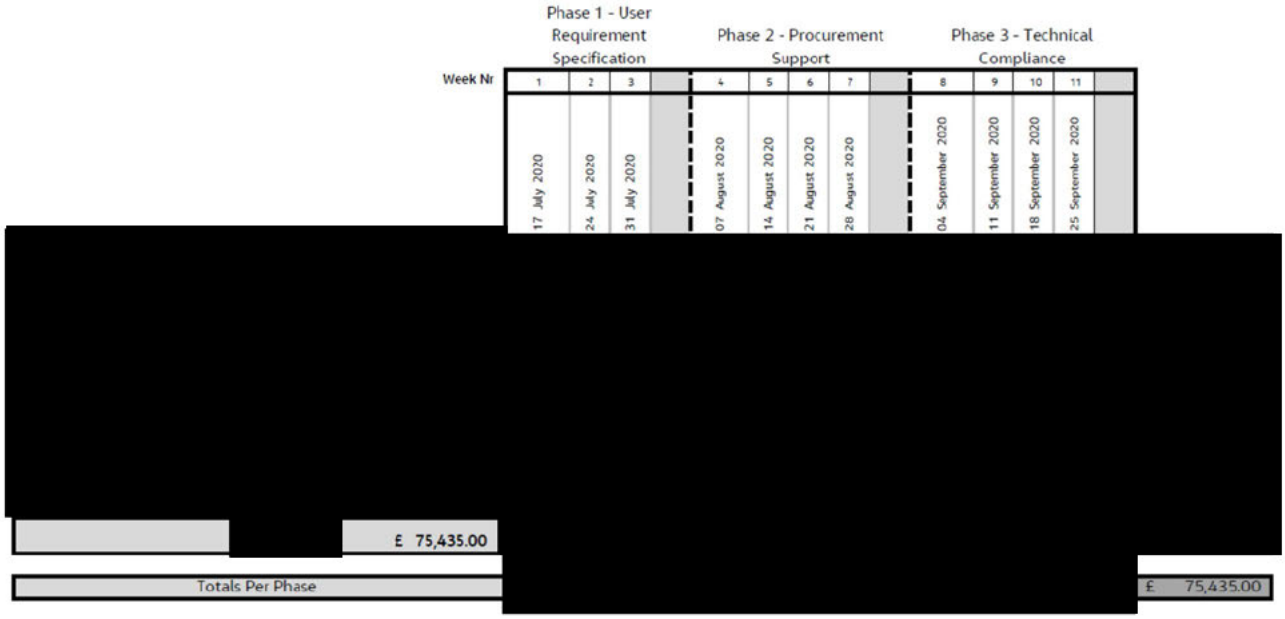
The estimated total cost per stage, overall total cost, and resource levels are shown in the following tables.

It is noted that we have been able to make accurate assessment of the projected resource levels for Phase 1 (URB) as shown in the table. Our approach to Phase 3 (Technical Review) has been on the basis of an anticipated number of responses in two rounds of evaluation and we would therefore consider there is scope to refine the resource applied to this stage to account for actual proposal numbers when known.

Summary of Estimated Fee

Phase/Scope of Work	Estimated Fee Cost £
Phase 1 User Requirements Brief	[redacted]
Phase 2 Procurement Support	[redacted]
Phase 3 Technical Review	[redacted]
Estimated Total Fee Cost	£75,435.00

Resource Schedule and Cost Build Up



5. Assumptions

The technical proposal and commercial offer should be read in conjunction with the following points:

1. Jacobs proposal is made based on direct award appointment under the CCS (RM3745) Lot 7 - Infrastructure Framework. Contract terms to be negotiated commensurate to the provision of services – namely regards: Total Liability, Standard of Care, and Guarantees.

2. Our fee is based on the programme and resource schedule shown in Section 2.5 applying CCS ceiling rates to arrive at a total estimated stage and total cost for the work required. We will keep you appraised of progress against the estimated fee and will advise where any scope or programme adjustments require recalculation of our fee.

3. Our fee excludes VAT which will be added to invoice amounts at the prevailing rate.

4. Our fee assumes that in the current environment (Covid 19), all meetings associated with briefing, technical review, documentation handover, submission review and the like will be virtual. At this stage, no allowance has been made for travel in connection with meetings.

5. We anticipate reasonable and timely access to BEIS stakeholders to establish all information required immediately following commencement.

6. Our input to the RFP will be limited to the provision of a User Requirements Brief which will refer to operational requirements to be specified by others.

7. Our deliverables will be issued in soft copy native and pdf formats and it is assumed that these will be in standard Jacobs headed format.

8. Our review of the vendor proposals will be limited to the technical and pharmaceutical regulatory aspects of the submissions. We have assumed one iteration of our comments to allow for BEIS review. Review of the vendor proposals against contract, performance and operational requirements will be by others.

9. We would anticipate that the detailed technical negotiations with shortlisted vendors may entail technical and commercial interviews, and potentially visits to proposed site locations or facilities. At this stage we have not made allowance for these visits and any reporting arising from same. We will advise the time and cost of such visits when the extent and locations are known.

10. It is noted that whilst BEIS consider a standard platform process as the basis for the RFP, invitations to submit innovative approaches may lead to attractive alternative solutions. Our proposal makes allowance for preparation of the URB on this basis and should alternative technical solutions require additional specialist resources or time, we will advise accordingly.

11. Notwithstanding the need to develop the User Requirements for the purposes of RFP and in the absence of any information on the proposed contract terms Jacobs would wish to discuss our potential involvement with the design and delivery of any successful proposal for construction of this facility.