



SHORT SERVICE DELIVERY AGREEMENT

(NEC PROFESSIONAL SERVICES SHORT CONTRACT)

This is a Short Service Delivery Agreement as defined in the Framework Agreement made between Scape Procure Limited (1) and Perfect Circle JV Ltd (2) dated 29th January 2021 (the 'Agreement'). Except where the context otherwise requires, all terms defined in the Framework Agreement shall have the same meaning in this Short Service Delivery Agreement.

THIS AGREEMEN	IT is made on 1/3	3/2024	
BETWEEN			
	icines and Healthcare lucts Regulatory Agency	2. the Consultant	Perfect Circle JV Limited
of			whose registered office is
communications Car	South Colonnade nary Wharf don I 4PU	Address for communications	Halford House Charles Street Leicester LE1 1HA
Telephone 0170	07 641000	Telephone	
Address for electronic communications		Address for electronic communications	
SERVICES OF for the	project is to deliver a feasibine removal and replacement sequent Agreements will be	medical freeze dryer a	and the same of th
Commission Name			Commission No.

MHRA Freeze Dryer & Ampoule Filling Line Replacement

5882





Introduction

NEC Professional Services Short Contract

This Delivery Agreement incorporates the NEC 4th edition Professional Services Short Contract June 2017 (the NEC Professional Services Short Contract) with January 2019 and October 2020 Amendments.

Any subsequent amendments to the NEC Professional Services Contract shall apply to this Delivery Agreement, if agreed in writing by SCAPE and the Partner, but shall only be incorporated into Delivery Agreements executed after such amendments are published and their inclusion has been agreed accordingly with SCAPE.

The following rules apply to the incorporation of clauses into a Delivery Agreement:

- a) The conditions of contract set out below shall be incorporated unless varied by an incorporated amendment to contract or as otherwise agreed in writing by the Client in this contract and Scape
- b) The Z clauses and amendments to contract clauses set out shall be incorporated within the Delivery Agreement
- c) The Client shall indicate within the Delivery Agreement whether the optional clauses are to be incorporated
- d) The Client has sole discretion to the choice of optional clauses.
- e) Delivery Agreements must be executed and witnesses as a deed, 'under seal', or as an 'agreement' on a Client's request.
- f) Unless a Client specifies otherwise, Short Service Delivery Agreements will be limited to commissions of £500,000.00 or less, based on the initial forecast of services or the offered total of the Prices.

Whereas:

This Delivery Agreement is made pursuant to the Framework Agreement dated 29th January 2021 made between Scape Procure Limited and the Partner (the 'Framework Agreement') and incorporates those provisions of the Model Delivery Agreement set out in the Framework Agreement.

IT IS AGREED as follows:

1. The Consultant's Obligations

The Consultant provides the services and complies with his obligations, acting as the Consultant in accordance with the conditions of contract set out in the Contract Data herein.

The Client's Obligations 2.

The Client pays the amount of money and complies with its obligations in accordance with the conditions.

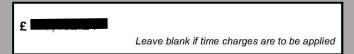




The Consultant's Offer and Client's Acceptance

The Consultant offers to Provide the Services in accordance with the conditions of contract for an amount to be determined in accordance with the conditions of contract.

The offered total of the Prices is



Contract Data and Service Information

Information provided by the Parties

The following details the Contract Data and associated Scope / Service information which is provided by the parties for this Delivery Agreement and Appended for execution.

'The Main Contract Data must be completed in full and uploaded using ONLY the standard template provided by Scape' ...

Main Contract Data:

General Project Information,

Clauses Applicable to Main Options and Secondary options where applicable, Data Pertaining to Optional (X) Clauses,

Y Clauses and Z Clauses where applicable.

Contract Data Provided by the Client:

Contract Data Provided by the Consultant:

Additional Contract Data provided by the parties.

One or more files may be attached in each section of the table below.

Please itemise and upload in the order you wish documents to be appended.

Ref	Item Description	Attach
001	Service Request Proposal	
Doc 1	CBRM Freezeryer Design	

Continues





Contract Data and Service Information

Additional Contract Data provided by the parties.

One or more files may be attached in each section of the table below.

Please itemise and upload in the order you wish documents to be appended.

Ref	Item Description	Attach
App D	CV1	
App D	CV2	





[The execution details for the Client below are an example intended for use with DocuSign and may be amended by the Client to suit their normal practice, if required. If the Client chooses to sign the Agreement on paper, only this page should be returned by upload using the DocuSign Print and Sign function]

Executed as a simple contact (under hand) for and on behalf of)
Medicines and Healthcare Products Regulatory Agency)
by)
	Authorised Signatory
	Full name
	Head of Market Analysis, Manufacturing and Logistics
	Position/title

Executed as a simple contract (under hand) for and on behalf of Perfect Circle JV Ltd

by

Executed as a simple contract (under hand) by as attorney for

Perfect Circle JV Ltd

under a power of attorney dated

)			
)			
)		-	
A 15 - 2 -			
Authoriseu	Signatory		
Full name			
Director			
Position/title)		







Contract Data

The Client's Contract Data

The following details the Contract Data which will be provided by the Client for each Delivery Agreement.

Certain defined terms and information in the Contract Data will be common to all Delivery Agreements, other information included in the Contract Data will be specific to individual commissions.

The *conditions* of *contract* are the NEC4 Professional Services Short Contract June 2017 with January 2019 and October 2020 amendments and the following additional conditions, amendments, alterations, additions and deletions as contained below apply and take priority over the standard form short contract.

The Client is:

Name	Medicines and Healthcare Products Regulatory Agency
Address for communications	10 South Colonnade Canary Wharf London E14 4PU UK
Telephone	01707 641000
Address for electronic communications	
	The Client's delegate ¹ , as defined by Clause 14.5 is:
Name	
Address for communications	10 South Colonnade Canary Wharf London E14 4PU UK
Telephone	01707 641000
Address for electronic communications	

The *Client's delegate* is authorised to perform all duties and responsibilities of the *Client* up to **Completion/Defects date** * excluding the following:

None

*delete as appropriate

The service is

This project is to deliver a feasibility and budget cost estimate proposal to RIBA stage 1 for the removal and replacement medical freeze dryer and ampoule filling line. Subsequent Agreements will be issued to develop the designs required.

¹ The Client's delegate is not the Lead Partner. If applicable, this is the Project Manager appointed by the Client to manage this Delivery Agreement on its behalf.







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	MTP	Oct	1242
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ille Ollelle 3 OC	illiact Data		
	The starting date is	12/02/2024	
	The completion date is	29/03/2024	
The law of	the contract is the law of	England and Wales	
	The period for reply is	2	weeks
	Optional clause	13.3 – electronic communication Does apply. ²	
	The defects date is	26	weeks after Completion
Th	e assessment day is the	7 th day	of each month
Work <u>is / is not</u> *	to be carried out on a time	ne charge basis *(delete as applicable)	
The United Kingdom	Housing Grants, Construc	ction and Regeneration Act (1996) <u>Does</u> apply	
The Adjudicate	or is		
	Name	Not named	
	Address for communications	N/A	
	Telephone	N/A	
	Address for electronic communications	N/A	
The interest rate on late payment is 0.2 % per complete week of delay.			
Insert a rate only if a	a rate less than 0.5% per	week of delay has been agreed	

² See additional conditions of contract below.





Contract Data

The Client's Contract Data

The *Client* provides this insurance

insurance for all existing buildings and property existing within the Site or at the sole discretion of the *Client* he may elect to 'self-insure' such existing buildings and property and in doing so accepts all of the *Client's* associated risks arising out of or in relation to such 'self-insurance'. In accordance with a *Client's* decision to 'self-insure' they do not accept any additional insurance premium/cost from the *Consultant*.

Only enter details here if the Client is to provide insurance

The Consultant provides the following insurance cover:

Insurance against	Minimum amount of cover	Period following Completion or earlier termination
Professional Indemnity Insurance — Liability of the <i>Consultant</i> for claims made against it arising out of the <i>Consultant's</i> failure to use the reasonable skill, care and diligence normally used by competent and appropriately qualified professionals providing services similar to the <i>service</i>		6 years
Loss of or damage to property and liability for bodily injury or death to a person (not an employee of the <i>Consultant</i>) or loss of or damage to property resulting from an action or failure to take action by the <i>Consultant</i>		6 years
Liability for death or bodily injury to employees of the <i>Consultant</i> arising out of and in the course of their employment in connection with this contract		6 years

The Consultant's total liability to the Client which arises under or in connection with the contract for all matters other than Cladding Claims is limited to:

.

The Consultant's liability to the Client for indirect or consequential loss or for any cost of decamping and rehousing in respect of Cladding Claim is excluded³.

Within the total liability limit identified above, the *Consultant's* liability to the *Client* for the provision of the following low risk, low value Services arising under or in connection with this contract is limited to:

N/A at Service	Request stage.
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The amount and basis of professional indemnity insurance provided by the Subconsultant(s).

and such other low risk, low value Services that are instructed by the Client as Compensation Events

The Adjudicator nominating body is the Royal Institution of Chartered Surveyors

³ The Consultant is not liable to the Client for indirect or consequential loss or for any cost of decamping and rehousing in respect of Cladding Claims.



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The tribunal is the Courts of England and Wales





Contract Data

The Client's Contract Data

The conditions of contract are the NEC4 Professional Services Short Contract June 2017 with January 2019 and October 2020 Amendments and the following additional conditions

1	General
11.2(5)	At the end of the first sentence, add:
	'less Disallowed Cost.'
11.2(12)	Insert a new clause 11.2(12):
	'Data Protection Legislation means:
	 the UK GDPR (as that term is defined in the Data Protection Act 2018)) and any applicable national implementing laws as amended from time to time; and
	ii. all applicable law about the processing of personal data and privacy.'
11.2(13)	Insert a new clause 11.2(13):
11.2(13)	
	'Data Subject has the meaning given to it in the Data Protection Legislation.'
11.2(14)	Insert a new clause 11.2(14):
	'Personal Data has the meaning given to it in the Data Protection Legislation.'
11.2(15)	Insert a new clause 11.2(15):
	'Framework Agreement is the framework agreement between Scape Procure Limited and the <i>Consultant</i> dated 29 th January 2021. Terms defined in the Framework Agreement have the same meanings in this Contract unless a contrary intention is apparent.'
11.2(16)	Insert a new clause 11.2(16):
	'Framework Commercial Model as included in the Framework Agreement between Scape Procure Limited and the Consultant dated 29th January 2021.'
11.2(17)	Insert a new clause 11.2(17):
	'Disallowed Cost is cost which;
	 is included within the Commercial Inclusions Tables contained in the Pricing Procedures of the Framework Agreement, unless the <i>Client</i> otherwise agrees, exceed the relevant, regionally adjusted People Rates for the applicable role and seniority stated in the relevant table of the Framework Commercial Model is not justified by the <i>Consultant's</i> accounts and records, should not have been paid to the Subcontractor or supplier in accordance with its contract, was incurred only because the <i>Consultant</i> did not

follow an acceptance or procurement procedure stated in the Scope, give an early warning which the contract required it to give or

give notification to the *Client* of the preparation for and conduct of an adjudication or proceedings of a tribunal between the *Consultant* and a Subcontractor or supplier,





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and the cost of

- activities included under the Client Proposed Appointment Charge of the Framework Agreement,
- correcting Defects after Completion,
- correcting Defects caused by the Consultant not complying with a constraint on how it is to Provide the Service stated in the Scope.
- resources not used to Provide the Service (after allowing for reasonable availability and utilisation),
- preparation for and conduct of an adjudication or proceedings of the tribunal between the Parties.'

11.2 (18) Insert a new clause 11.2(18):

'Cladding Claim shall mean any claim in respect of:

The combustibility of any Aluminium Composite Panels (and associated core/filler and insulation) which failed the BRE testing programme on behalf of The Department for Communities and Local Government in July and August 2017 or fails BS8414 test set out in the current Building Regulations.'

12.4 Insert at the end:

'provided that Clauses 23 (Convictions), 29 (Statutory Requirements), 30 (Competition Law, Corrupt Gifts and Payments), 31 (Modern Slavery), 33 (Confidentiality and Freedom of Information), 35 (Intellectual Property) and 37.11 (Miscellaneous: Whistle Blowing) of the Framework Agreement shall be deemed incorporated into this contract, mutatis mutandis, as if references to 'Scape' were to 'the Client' and references to the 'Agreement' were to 'the contract.'

12.5 Insert a new clause 12.5:

'A reference to any statute, enactment, order, regulation or other similar instrument shall be construed as a reference to the statute, enactment, order, regulation or instrument as amended by any subsequent statute, enactment, order, regulation or instrument or as contained in any subsequent re-enactment of it.'

13.3 Insert a new clause 13.3:

'The following communications shall be deemed to have no effect if made by electronic mail transmission:

- any notification of a wish to terminate this contract or the employment of the Consultant under it;
- any notification by the Consultant of his intention to suspend performance of his obligations under this contract;
- any invoking by either party of the procedures applicable under this contract to the resolution of disputes or differences; and
- any agreement between the parties amending the provisions of this contract.'

(Clause 13.3 may be deleted at the Client's sole discretion).

14.4 Add, after the final sentence:

'Notwithstanding any other provision of this contract, the terms 'acceptance', 'approval' or similar when used in the context of any acceptance or approval to be given by or on behalf of the Client has the meaning 'acceptance of general principles only' and no such acceptance or approval shall diminish or relieve the Consultant from any of the Consultant's obligations or liabilities under this contract.'

14.5 Add, at the end of final sentence:

'unless the delegate's authority is limited in that action by the Contract Data.'



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18.	Insert a new clause 18: 'Data Protection
18.1.	Both Parties will comply with all applicable requirements of the Data Protection Legislation. These clauses are in addition to, and does not relieve, remove or replace, each Party's obligations under the Data Protection Legislation. It is agreed that:
18.2.	Without prejudice to the generality of clause 18.1, both Parties will ensure that it has all necessary appropriate consents and notices in place to enable lawful transfer of any Personal Data to each other for the duration and purposes of this agreement.
18.3.	Without prejudice to the generality of clause 18.1, the <i>Consultant</i> shall, in relation to any Personal Data processed in connection with the performance by the <i>Consultant</i> of its obligations under this agreement:
18.3.1.	Process the Personal Data only on the written instructions of the <i>Client</i> and only as required for the purpose of the performance of this agreement;
18.3.2.	Ensure that it has in place appropriate technical and organisational measures, reviewed and approved by the <i>Client</i> , to protect against unauthorised or unlawful processing of Personal Data and against accidental loss or destruction of, or damage to, Personal Data, appropriate to the harm that might result from the unauthorised or unlawful processing or accidental loss, destruction or damage and the nature of the data to be protected, having regard to the state of technological development and the cost of implementing any measures (those measures may include, where appropriate, pseudonymising and encrypting Personal Data, ensuring confidentiality, integrity, availability and resilience of its systems and services, ensuring that availability of and access to Personal Data can be restored in a timely manner after an incident, and regularly assessing and evaluating the effectiveness of the technical and organisational measures adopted by it);
18.3.3.	Ensure that all personnel who have access to and/or process Personal Data are obliged to keep the Personal Data confidential;
18.3.4.	Not transfer any Personal Data outside of the European Economic Area;
18.3.5.	Assist the <i>Client</i> , at the <i>Consultant's</i> cost, in responding to any request from a Data Subject and in ensuring compliance with its obligations under the Data Protection Legislation with respect to security, breach notifications, impact assessments and consultations with supervisory authorities or regulators;
18.3.6.	Notify the Client without undue delay on becoming aware of a Personal Data breach;
18.3.7.	At the written direction of the Client, delete or return Personal Data and copies thereof to the Client on termination of the agreement; and
18.3.8.	Maintain complete and accurate records and information to demonstrate its compliance with this clause and allow for audits by the <i>Client</i> or the <i>Client</i> 's designated auditor.
18.4.	The Client does not consent to the Consultant appointing any third-party processor of Personal Data under this agreement.'
2	The Consultant's main responsibilities
20.2	Delete and replace with:
	'The Consultant's obligation is to is to use (and warrant that it has used) all the reasonable skill, care and diligence normally used by competent and appropriately qualified professionals experienced in providing services similar to the service.'
20.4	Insert a new clause 20.4:
	'The Consultant checks the Scope provided by the Client and satisfies itself that its own provision of the

service, including any proposals, designs and Scope documents for a subsequent Delivery Agreement



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meet the *Client's* Scope with no discrepancy within and or between the Scope and the *service*. Where there is ambiguity, inconsistency or conflict between these documents the *Client's* Scope will prevail.'

20.5 Insert a new clause 20.5:

'The Consultant performs the Services in accordance with relevant laws and regulations, statutory and other requirements ("Laws") and (to the extent that the Consultant can control the same) such that the product of the Services complies with all relevant Laws.'

21.4 Insert a new clause 21.4:

'The Consultant, in subletting of any part of the service:

- procures that the relevant subcontract contains such obligations as necessary to ensure that it is in all respects compatible with the terms of this contract and, without limitation, steps down the obligation to use the degree of skill, care and diligence specified in this contract and that requires collateral warranties in favour of the *Client* to be provided in the forms specified in Schedule 14 to the Framework Agreement but with any amendments as permitted by Schedule 14 to the Framework Agreement;
- warrants each Subcontractor's compliance with this contract's Modern Slavery Act requirements;
- procures that all relevant subcontracts shall be executed and delivered as a deed; and
- provides to the Client a certified copy of any subcontract (save for particulars of the cost of such subcontract service unless other provisions of this contract or the Framework Agreement oblige the Consultant to disclose them).'
- 21.5 Insert a new clause 21.5:

'The Consultant notifies the Client of the name, contact details and legal representatives of each Subcontractor before appointing the Subcontractor. The Consultant does not appoint a Subcontractor if there are compulsory grounds for excluding the Subcontractor under regulation 57 of The Public Contracts Regulations 2015.'

21.6 Insert a new clause 21.6:

'The Consultant includes in any subcontract awarded by him provisions requiring that:

- payment due to the Subcontractor under the subcontract is made no later than 30 days after receipt
 of a valid and undisputed invoice unless the Framework Agreement required the Consultant to make
 earlier payment to the Subcontractor;
- invoices for payment submitted by the subcontractor are considered and verified by the Consultant in a timely fashion;
- undue delay in considering and verifying invoices is not sufficient justification for failing to regard an
 invoice as valid and undisputed; and
- any contract awarded by the Subcontractor for work included in this contract includes provisions to the same effect as these provisions.'
- 23 Insert a new clause 23:

'The Consultant shall enter a novation agreement in the form specified in the Framework Agreement with the Client's contractor within 14 days of being asked to do so by the Client in writing and shall, within 14 days of being provided with an engrossment, execute and return to the Client the collateral warranty agreement in favour of the Client, but with such amendments as the Consultant, Client and contractor may agree, such agreement not to be unreasonably withheld or delayed.'







3 Time

31.2 Insert a new clause 31.2:

'The first programme is to be submitted to the *Client* two weeks prior to the *starting date*. The programme is to be updated and similarly distributed each month until the date of Completion.'

5 Payment

50.3 Insert at the end of the third bullet point:

'less expenses included in the Commercial Inclusions Tables contained within the Pricing Procedures of the Framework Agreement,'

51.4 Insert a new clause 51.4:

'In addition to any other legal rights and remedies of the *Client*, with the exception of when the *Consultant* is novated to a contractor under the *conditions of contract*, whenever any sum of money is recoverable from or payable by the *Consultant* under this contract that sum may be deducted from any sum then due, or which at any time thereafter becomes due to the *Consultant* under this contract provided that the *Client* notifies the *Consultant* in writing not later than three days before the final date for payment of the amount to be paid and the basis on which it is calculated.'

6 Compensation events

60.1(9) Insert a new clause 60.1(9):

'A change to the guidance issued by the UK Government or a local authority, which affects working practices, solely due to COVID19 or any future pandemic as declared by the UK Government or a local authority, occurring after the *starting date*.'

63.5 After the first sentence add:

'Unless the *Client* otherwise agrees, proposed rates must not exceed the relevant regionally adjusted 'People Rates with expenses' for the applicable role and seniority stated in the relevant table of the Framework Commercial Model. The Peoples Rates will be adjusted annually on 5th January in accordance with the indexation provisions of the Framework Agreement. This is based on the BCIS Labour Cost Index and will be applied annually thereafter until the completion of works under this Delivery Agreement. Any quotations for compensation events will apply the latest People Rates.'

8 Liabilities and insurance

83.3 delete the words 'and care normally used by professionals' in the first insurance of the Insurance Table and replace with:

', care and diligence normally used by competent and appropriately qualified professionals experienced in'

85 Insert a new clause 85:

85.1

'Before the starting date and on each renewal of the insurance policy until the defects date, the Consultant submits to the Client for acceptance certificates which state that the insurance required by the contract is in force. After the defects date and on renewal of the insurance policy until the end of the periods stated in the Contract Data for which insurance is to be maintained, the Consultant submits to the Client for acceptance certificates which state that the insurance required by the contract is in force. The certificates are signed by the Consultant's insurer or insurance broker. The Client accepts the policies and certificates if the insurance complies with the contract and if the insurer's commercial position is strong enough to carry the insured liabilities. The Client's acceptance of an insurance certificate provided by the Consultant does not change the responsibility of the Consultant to provide the insurances stated in the Contract Data.







The Parties comply with the terms and conditions of the insurance policies to which they are a Party.'

9 Termination and dispute resolution

Insert the following section:

90.7 (1) 'The *Client* may terminate the *Consultant's* obligation to Provide the Services if any of the provisions of regulation 73(1) of The Public Contracts Regulations 2015 apply.

If the *Client* terminates under the provisions of regulation 73(1)(b) of the Public Contracts Regulations 2015 as a result of information not disclosed by the *Consultant* at the Contract Date, the procedures and amounts due on termination are the same as for a default by the *Consultant*, (Reason 2).

If the *Client* otherwise terminates under the provisions of regulation 73(1) of the Public Contracts Regulations 2015 the amount due on termination is the same as if the *Client* had terminated for Reason 8.

Insert the following new section:

10 The Contracts (Rights of Third Parties) Act 1999

- 100.1 'A person who is not a party to this contract shall have no rights under the Contracts (Rights of Third Parties)
 Act 1999 to enforce any term of this contract unless it is stated expressly in the Contract Data that an identified third party may enforce such rights and those rights are identified.
- The rights of the Parties to terminate, rescind or agree any variation, waiver or settlement under this Agreement are not subject to the consent of any other person.'



Appendix 1

Contract Data The Consultant's Contract Data

The Consultant is Name Perfect Circle JV Ltd Address for communications Halford House, Charles Street, Leicester, LE1 1HA 0345 045 0050 Telephone Mobile Address for electronic communications The fee percentage is The people rates are category of person: Hourly **Project Management & Quantity Surveying** Rate***(£) **Technical Director** Associate/Principal Consultant **Senior Consultant** Consultant Senior Technician Technician/Graduate **Commercial Surveying Technical Director** Associate/Principal Consultant **Senior Consultant** Consultant Senior Technician Technician/Graduate Architectural Design, Mechanical Engineer, Electrical Engineer, Structural Engineer & **Building Surveying Technical Director** Associate/Principal Consultant **Senior Consultant** Consultant **Senior Technician** Technician/Graduate

The *Client* Proposed £ Appointment Charge is

The Lead Partner is

Management Ltd

Gleeds Cost



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**** [Unless the Client agrees otherwise, the charge must not exceed the rate stated in the Framework Commercial Model.]

The Consultant's Offer and Client's Acceptance

The Consultant offers to Provide the Services in accordance with the conditions of contract for an amount to be determined in accordance with the conditions of contract.

The offered total of the Prices is	
If all work is to be carried out on	a time charge basis, enter 'Not Applicable'.







Price List

A detailed breakdown of the Prices and an invoice drawdown schedule is provided in the Service Request Form annexed to this contract

The method and rules used to compile the Price List are

as described in Schedule 5 (Pricing Procedures) of the Framework Agreement

Scope

1. The Scope provided by the Consultant is detailed in the Service Request Form annexed to this contract

2. Information and other things provided by the Client

Describe what information and other things the *Client* is to provide and by when. Information is that which is not currently available, but will become available during the contract. Other things could include access to a person, place (such as office space or a site) or the *Client's* information technology systems.

ITEM	DATE BY WHICH IT WILL BE PROVIDED
None	







Annex 1 - Service Request Form

Service Request Proposal

Further to recent discussions, please find below a Service Request as defined in the Framework Agreement made between Scape Procure Limited and Perfect Circle JV Ltd dated 29th January 2021

This Service Request Proposal is formed of 4 parts:

Part A: Outline Service Requirements, which captures your service needs and desired approach,

Part B: Pre-Engagement Activity Checklist, identifying any activities required to enable our proposal and price to be presented,
Part C: Detailed Service Requirements, identifying your key value drivers, inc. Social Value and measures of VfMcaptured within our comprehensive service delivery proposal,

hart b. Statement of Key Outputs, setting out the deliverables from the pre-engagement stage.

If you are satisfied that this Service Request represents an accurate record of our pre-engagement discussions, and you would like Perfect Circle to proceed with producing a Delivery Agreement based on this proposal, we should be grateful if you would provide your confirmation.

national supply chain formed of SVEs, micro businesses and larger consultancies, ensuring we provide performance managed services through local businesses. Forming an integrated team across Perfect Circle and our approved suppliers allows the broadest project scope to be offered with value for money through one simple and effective contract, providing maximum efficiencies and contributions to economic, environmental and social benefits to achieve the Perfect Circle is a company jointly owned by Pick Everard, Gleeds and AECOM. Our offer is unique in framework experience, with an unrivalled record of teams providing excellence through collaboration. We deliver with an extensive greatest levels of social value.

Client Name	Medicines and Healthcare Products Regulatory Agency		
Commission No.	5882	Commission Name (Title)	MHRA Freeze Dryer & Ampoule Filling Line Replacement
Commission Description	This project is to deliver a feasibility and budget cost estimate proposal to RIBA stage 1 for the removal and replacement medical freeze dryer and ampoule filling line. Subsequent Agreements will be issued to develop the designs required.	Commission Postcode	E14 4PU
Client Contact Name		Client Contact Email	
Client Contact Position	Senior Scientist	Client Contact Telephone Number	01707 641000
Lead Partner - Company Name	Gleeds Cost Management	Commission Lead Contact Name	
Commission Lead Contact Email		Commission Lead Contact Mbbile	
Nain Contract Type	NEC4 Professional Service Short Contract (PSSC) - Short Service DA	Region	Greater London North
		Lead Partner's Service Manager (or NEC3 PM)	
Client estimated budget for Commission $\boldsymbol{\mathcal{E}}$	19,482.24	Client anticipated end date	29 Mar 2024
Client anticipated start date	12 Feb 2024		
Has a Client's draft/outline programme been No appended?	No		
Other Document Upload 1		Other Document Comments 1	
Other Document Upload 2			

Part B - Pre-Engagement Activity Checklist

2

Has a Scheme Layout been appended?

Has a Client's Project Brief been appended? No

Other Document Upload 3

2

Are there Client Proposed Organisations?

ટ

Are Pre-Engagement Matters required?

Part C - Detailed Service Requirements

1.1 Project Overview/Background

This project is to deliver a feasibility and budget cost estimate proposal to RIBA stage 1 for the removal and replacement medical freeze dryer and ampoule filling line.

The project is located at The Medicines Healthcare products Regulatory Agency (WHRA) site at Blanche Lane, South Mimms, Potters Bar, EN6 3CG. The freeze dryer is located predominately in a

1.2 Objectives/Outcomes

The successful completion of this project will deliver the following outcomes:

1) Produce a feasibility report for the removal and replacement of the freeze dryer and filling line including the enabling costs of relocation, upgrade of services, structural alternations, statutory

requirements and making good.

- 2) Review available as built information including drawings and operation and maintenance manuals
- 3) Prepare schedule of information required for the freeze dryer replacement.
- 4) Review responses from client and resolve any matters arising.
- 5) Prepare feasibility proposals based on information provided, including block plans to confirm spatial fit and coordination of the proposals.
- 6) Site visits to inspect existing installations and confirm feasibility of proposals prior to submitting to dient.

2.0 Health, Welfare, Safety, Environment and None identified

Sustainability Considerations

3.0 Value for Money Statement

Not applicable to commissions under £20k

The client has selected the following Value Drivers that best match its organisation's key objectives for the successful delivery of the commission. These should be referenced by the Client during any subsequent feedback to gauge whether Value for Money has been achieved.

Value for Money Driver (1)

Value for Money Driver (2)

Value for Money Driver (3)

4.0 Project Success Criteria

In addition to the Value Drivers identified in section 3.0 above, we also monitor the following Performance Indicators as standard for each commission:

- Time Predictability
- Cost Predictability
- Local Spend Percentage of total spend within 20 miles of Client office/site
- SIVE Engagement Percentage of appointments with SIVE's compared with total number of Supply Chain appointments
- SNE Spend Percentage spend with SNE's compared with total spend with Supply Chain
- Fair Payment Payment of Supply Chain within Government Fair Payment guidelines
- Client Satisfaction
- Supply Chain Satisfaction
- Achievement of Client Social Value Targets as agreed in section 5.0 below

5.0 Social Value

The Public Services (Social Value) Act 2012 for England and Wales requires all public bodies to consider how the services they commission and procure might improve the economic, social and environmental wellbeing of the area for which they are responsible. We recognise that we have a responsibility to the environment, the communities within which we work, our own people, our supply chain and society. Perfect Circle's business management systems are fully compliant with the Public

Sector (Social Value) Act 2012 and social value is an integral part of Perfect Circle's approach and operations. Perfect Circle collect data in the following areas as part of our business-as-usual activities.

- Local spend on projects, reporting on spend within 20 miles of commissions our target is 45% of the commission value to be within that 20 miles
 Small and Medium (SME) spend, targeting greater engagement of SME's in our supply chain our target is 85% of spend with our supplier chain to be SME suppliers
 Fair payment, ensuring we pay our supply chain within 30 days of receipt of invoices our target is 100% of our invoices to be paid within 30 days

2 Is the Client interested in setting TOWS

targets?

TOMS Outcome No

Having discussed with the client whether they wish us to augment our Social Value offering by setting up to 5 additional metrics against the National Data Set of TOMs (Themes, Opportunities, Measures), we confirm that additional measures are not required on this commission.

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Unit £	Unit £	Unit %	Unit	Unit	Unit	Unit	Unit
Comments (1)	Comments (2)	Comments (3)	Commenis (4)	Comments (5)	Comments (6)	Comments (7)	Comments (8)
NT18 - Total amount (£) spent in Co LOCAL supply chain through the contract	NT19 - Total amount (£) spent through contract with LOCAL micro, small and medium enterprises (NSNEs)	NT61 - Fair Payment - Percentage Co of invoices on the contract paid within 30 days	0	0	0	0	8
NT Ref (1)	NT Ref (2)	NT Ref (3)	NT Ref (4)	NT Ref (5)	NT Ref (6)	NT Ref (7)	NT Ref (8)

6.4 Summary of Services at Each Project Stage

The services and suppliers proposed for this project are summarised below. In addition, we have indicated the procurement route that is intended to be adopted for each service.

DocuSign Envelope ID: 061AA/ Prime Core - RIBA Stages (✔)	DocuSign Envelope ID: 061AAA8C-8992-4D1F-A571-C10D6B4E46F7	1F-A571-C10D6B4E46F 0-1 *	-7	m	4	9	g	7	Procurement Route
Project Wanagement	Gleeds Cost Management	Yes	N _O	ON ON	o _N	No No	ON N	ON.	ту Е
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Core - RIBA Stages (V)	Ž								
Building Surveying Gleeds Cost Management	Gleeds Cost Management	Yes	N _O	o V	9 2	No	<u>0</u>	0 V	£ 8
Architectural Design	C	ON	No	No	No	ON.	No	No	03-70
Mechanical Engineering	Gleeds Cost Management	Yes	ON.	o V	9 2	ο <u>ν</u>	<u>8</u>	0 N	K. 2
Electrical Engineering		δ 0	NO N	o V	9 2	N 0	<u>8</u>	0 N	410000
Structural Engineering		9 2	°N N	O _N	o N	No No	0 N	ON.	511 0
Commercial Surveying		2	ON.	2	ON.	<u>8</u>	9	<u>8</u>	
Non Core Services	Sa								
				There are no	There are no records to display				

* use RIBA stages 0-1 for non-construction projects where only time charges are applicable

Supply Chain Procurement routes available through the framework:

SFR	Scape Framework Rates
AFR	Alternative Framework Rates
CPO	Client Proposed Organisation using rates agreed with the Client
ರ	Competitive tender with 3 or more suppliers
BM	Negotiation with a single provider, using an alternative benchmark mechanism
OB	Adopting an Open book arrangement with a single provider
CPS	Client determines that a Preferred Supplier's fee offers value for money

Clients should be aware that in order for Perfect Circle to engage Client Proposed Organisations you are acknowledging in approving this Service Request that

- You requested that Perfect Circle appoint the proposed organisation(s).
- You are aware that the fees of the proposed organisation(s) are not in line with the Framework Agreement but nonetheless you are content that these offer value for money.
 You have undertaken your own technical, commercial, and legal due diligence for the appointment of the proposed organisation(s).
 The appointment of a Client Proposed Organisation(s) shall only be permitted when other Services are procured through the Partner and/or its Preferred Partner(s). Sole appointment of a Client Proposed Organisation(s) shall only be permitted when other Services are procured through the Partner and/or its Preferred Partner(s). permitted unless otherwise agreed by Scape.
 - Perfect Circle's appointment of a Client Proposed Organisation(s) will be conditional on the supplier.
- Meeting our approval criteria (insurances/ISOs/H&S etc).
- Agreeing to the terms of the SCAPE Consultancy Framework Agreement in all other respects byway of a Consultancy Agreement with Perfect Circle that is back-to-back with the main contract with you Providing a Collateral Warranty to you.
 - If the risks associated with the appointment of any such organisation(s) are considered unacceptable then Perfect Circle may refuse to appoint that organisation.

6.5 Sub-consultant Selection and Competitive No sub-consultants for this task order.

Tender Award Criteria

We await confirmation from the Client of their appointment of the Principal Designer. 6.6 Appointment of Principal Designer

CVs for key staff can be found in AppendixD

7.0 Delivery Team

Delivery Team - document upload

Delivery Programme

Our proposed delivery programme is as follows:

Would you like to upload your own Project

2

Programme

Delivery Programme

There are no records to display.

This comprises of:

- Where the commission relates to a Construction Project; Percentage charges for Prime Core services based on the estimated construction value.
- Where the commission relates to a Construction Project, Percentage charges for Core services based on the estimated construction value. **ҚВ**СОШ
 - Time charge fees covering Prime Core, Core and Non-core services. These are detailed in section 16.2 below.
 - Sub-total (A plus B plus C)
- Prices secured from suppliers procured using 'external' non-framework rates. These are detailed in section 16.3 below. Total of Charges (D plus E)
- Total Commission Value (D plus E plus F)
 - Disbursements & Expenses Ġ

Overall Commission Value (D plus E plus G)

These figures are exclusive of VAT

In preparing our fee we have followed the prescribed rules and tendered rates as defined in the Framework Agreement made between Scape Procure Limited and Perfect Gircle JV Ltd dated 29th January 2021 (the Agreement') and updated by all Deeds of Variation since. Please note that the People Rates are adjusted annually for inflation on the 5th January in accordance with the Indexation Table contained within the 'Agreement'. This is based on the BCIS Labour Cost Index published by the Building Cost Information of the Royal Institute of Chartered Surveyors.

If the Client has elected to include Secondary Option X1 (Price Adjustment for Inflation) in the NEC Delivery Agreement that is executed to progress this Service Request, then those Prices derived from People Rates (identified as 'Time Charges above) will be subject to adjustment in line with the same inflation indexation provisions of the Framework. Your budget should therefore include an allowance for inflation on these Prices.

Alternatively, if the Client has elected not to include Secondary Option X1 in the NEC Delivery Agreement, then an allowance for the risk of inflation will have been incorporated into the above 'Time Charges'

In both the above scenarios, any quotations for compensation events that arise in the future will apply the latest People Rates.

If percentage 'Charges' for Prime Core or Core Services apply, then the Construction Cost Estimate will be reviewed at the end of each RIBA Stage or annually (whichever is the shorter) and should this change (upwards or downwards), the 'Charges' for those RIBA stages yet to be undertaken will be re-calculated accordingly. Any change in the Prices will as a consequence be recognised through a compensation event due to the change in

Our Services are broken down across the RIBA Stages as follows:

a

16.3 External Consultancy Costs

The below table provides a summary of those Suppliers who have been selected to undertake services that have been procured using 'external' non-framework rates, as referenced in section 6.4 above

External Consultancy

There are no records to display.

17 Delivery Agreement Professional Services Contract Model

NEC4 Professional Service Short Contract (PSSC) - Short Service DA

17.0 Delivery Agreement Professional Service Contract Model. A description of the contracting options available to you can be found in Appendix B. We are proposing that this appointment is placed using the following:

Appendix A

Scope of Services Lot 1

Appendix B

NEC Professional Services Contract Options

Introduction

Services provided by Perfect Circle JV Limited (the Consultant) to Clients using the Consultancy Framework shall (unless otherwise directed by Scape) be based on the terms of one of four Model Delivery agreements. Perfect Circle JV Ltd will in turn enter into an agreement with each Supplier providing the services, under which the delivery Agreement obligations are "stepped down".

The four Model Delivery Agreements available are:

- 1:NEC4 Professional Service Short Contract (PSSC) Short Service Delivery Agreement
- 2:NEC4 Professional Service Contract (PSC) Option A Priced Contract with Activity Schedule
- 3:NEC4 Professional Service Contract (PSC) Option C Target Contract
- 4:NEC3 Professional Services Contract Option G Term Service Delivery Agreement

A commission that does not have an engrossed Delivery Agreement between Perfect Gircle JV Ltd and the Client is non-compliant.

1: NEC4 Professional Service Short Contract (PSSC)

The PSSC is simplified version of the Professional Services Contract which is suitable for less complex appointments.

The PSSC is for use on commissions that impose only low risks on both the client and the Consultant.

2: NEC4 Professional Service Contract (PSC) - Option A

Priced Contract with Activity Schedule

A lump sum priced contract, in which the risks of being able to provide the service at the agreed prices in the Activity Schedule are largely borne by the Consultant. The Client carries some risk through the compensation event procedures.

This contract is only used when the scope of work at tender stage is fully known and capable of being priced and programmed.

This option should also be used where the prices are based on the cost of construction (percentage fee). Please note the consultant fees vary in accordance with the construction cost.

3: NEC4 Professional Service Contract (PSC) - Option C

Target Contract

A target fee contract in which the financial risks (savings or over-spend) are shared by the Client and the Consultant.

The Consultant's share percentages and the share ranges are:

Share range	Consultant's Share Percentage
Less than 95%	10%
From 95% to 100%	40%
From 100% to 102.5%	40%
Greater than 102.5%	100%

This contract can only be used when good estimates of scope and price can be made attender stage or where the cost of construction (percentage fee) is used to set the target

Also used when the scope of work is finalised after some initial work is undertaken under through a PSSC time charge arrangement, or similar. The target is adjusted for compensation events other than changes in Scope approved by the Client which are proposed by the Consultant which reduce the total Time Charge. This provides an incentive to Consultants to propose changes to reduce costs.

4: NEC3 Professional Services Contract - Option G

Term Contract

Provides the ability to agree a long-term call-off arrangement using Task Orders.

Option G contains options for time charge and lump sum fee arrangements. The tasks must be defined in the Task Schedule and Delivery Agreement.

This type of contract lends itself to a programme of works where the same contract terms apply for all orders. The Task Schedule should define the projects, the anticipated services required and an outline budget and programme

Summary

For each of the above model contracts, Scape has prescribed through the Framework Agreement several Optional clauses, the inclusion or otherwise is at the discretion of Clients. Other than the above, no other variation to the terms of the Model Delivery Agreements shall be made without the agreement of Scape. In accordance with the Access Agreement, Client's are entitled to obtain and review a copy of the Framework Agreement to assist them in understanding a Delivery Agreement. The Client should advise the Consultant of the Options that are at the Client's discretion prior to preparation of the Delivery Agreement.

Appendix D - CVs for Key Staff

- CV Document Upload (1)
- CV Document Upload (2)
- CV Document Upload (3)
- CV Document Upload (4)
- CV Document Upload (5)

Part D - Statement of Key Outputs

The Client and Perfect Circle have used all reasonable endeavours to capture the following requirements in Part C of the document:

A summary of the Commission including the extent of the Commission with, a statement of values, performance measures/targets and, as appropriate a sketch layout(s), outline budget(s) and programme for the Commission and any subsequent project(s) which includes estimate for the works or services etc.

Where the execution of an element of the Commission is not a settled matter, the strategy for taking the matter forward, including details of client approval processes

The Partner's resourcing proposals and supply-chain Procurement Schedule for provision of most economically advantageous service.

On approval of this Service Request, Perfect Circle will draft a Delivery Agreement ready for execution which includes the following where appropriate to the commission:

- The agreed Scope which shall detail the requirements for the carrying out of the Service including agreed outcomes/deliverables, resources, Quality Policy Statement and Quality Plan requirements including roles and responsibilities for the whole team and covering the whole service.
 - A programme for the Delivery Agreement.
- An activity schedule, Price List or task schedule, as appropriate to the proposed form of contract and the pricing processes of the Agreement.
- A fully completed Tendered Total Model as required by the Framework Agreement including justification and details of any derogations from the Framework Commercial Model.
 - The initial NEC3 PSC Risk Register or NEC4 PSC Early Warning Register.
- Any other documents required by the Delivery Agreement, Collateral Warranties etc A completed and agreed Value for Money Statement (must be offered on projects > £20k, but mandatory over £500k)

SPECIFICATION FOR DESIGN OPTIONS

MHRA freeze dryer and ampoule filling line replacement

Introduction

The Medicines Healthcare products Regulatory Agency (MHRA) are an Executive Agency of the Department for Health and Social Care (DHSC) within the UK government. They are the UK regulatory body responsible for the safety and efficacy of medical products used within the UK.

One of the MHRA's statutory delegated functions is the provision of biological reference materials, these are available to support all stages of the product life cycle and play an essential role in supporting the development of safe and effective biological medicines that underpin patient health.

We play a critical role in developing new standardisation technologies and methodologies and we evolve our NIBSC biological standards to reflect industry innovation. This is crucial to how we bring confidence to complex and rapidly changing areas of medicine and healthcare.

Manufacturing facility

As well as government offices in London, the MHRA also has dedicated laboratory and manufacturing facilities at a site in Hertfordshire.

The manufacturing facility operates on a smaller scale than many pharmaceutical sites and as final products are not for clinical administration does not operate under GMP. Instead, aseptic principles are observed with environmental monitoring performed to inform product bioburden. The facility is certified to ISO 9001 for the delivery of much of the portfolio and ISO 13485 for the delivery of CE marked diagnostic reference materials that must conform the incoming In Vitro Diagnostic Regulation (IVDR).

The facility delivers a broad portfolio of over 1300 different types of material ranging from infectious materials that support blood safety to monoclonal antibodies for new therapies and small proteins that support drug dosing such as insulin. Materials can comprise a variety of excipients both biological and synthetic in nature.

In total the facility delivers in the order of ~ 500,000 units/year.

The facility houses two filling lines for ampoule and vial filling, and batch freeze dryers that support a capacity up to 25,000 ampoules or 15,000 vials in a single run.

The current equipment comprises a Bausch & Stroebel AFV 5090, ampoule filling & sealing with a throughput of up to 6,000/hour. The line operates as a semi-automated feed with manual intervention required for loading glass ampoules and the transfer of filled ampoules to the freeze dryer shelves. Automated check weighing is performed on 3 of every 90 ampoules filled.

This project will deliver improved freeze-drying capacity for the facility. It will see the removal of a small scale 1.0m2 Serail CS15 freezer dryer to be replaced with a medium scale 6.0m2, production, steam sterilizable freeze dryer

The described equipment is approaching end of life and no longer provides business efficiencies both in time and environmental impact. The MHRA have carried out a market evaluation and understand possible solutions for equipment replacement but acknowledge that this will have an impact on infrastructure and dependent plant.

Design Description

We require a design proposal to be able to remove the old freeze dryer from its current position and replace with a new freeze dryer in its location.

Preferably the design must go to RIBA stage 4, so that a Principal contractor can take over the build section of these works using this design.

As part of the design review we would be keen to understand the following:

- Planning or building regulation that needs applying for within your options.
- All disconnections, isolations, and safe removal of the freeze dryer, including building fabric, and structural elements.
- Removal and re-positioning of other plant and equipment in the plantroom, may have to be temporarily taken out to accommodate the new FD. These plant items must be re-instated so that production can continue to operate in adjacent areas. We have itemsed plant and process equipment we feel needs careful considerations and they are:
 - Compressed air (6 Bar).
 - Nitrogen gas via the liquid Nitrogen evaporator at 1.5 bar.
 - Chilled water from the Lyo chillers on the roof.
 - Serail steam generators x 2.
 - Three phase a neutral power including the UPS backup.
 - Drainage requirements.
 - Removal of mezzanine staircase and possible relocation.
 - Process water tank and other items to be removed to gain access to the outside panel doors to allow FD to be moved in.
 - Allow free movement along the highlighted walkway between the Production workshop and the rear external door. Consideration for maintainable space around other plant, equipment, and machinery in the plantroom.

The design must allow for all services required to run the new dryer, and where necessary upgrading the services to suit the new FD.

Design layouts are to be provided in Autocad DWG files, along with your design proposal as part of this package of works.

Installation & Material Costs

Your design option is to provide an indicative breakdown cost for each required element of the install including proposed material costs. This is to allow us to formulate an indicated budget for the entire project. Please provide alternative cost saving ideas or options on how this project can save money or time, and still give us the high quality required.

Additional information:

Site

The site for the works is the existing CBRM Lyo plantroom, located on the Southwest of the building. The freeze dryer chamber will be located behind the production room wall with the door protruding. Into the production room. The condenser is in the freeze dryer plantroom behind where the refrigeration skid, vacuum skid and electrical cabinets are also placed.

Access to this area is via eight large plantroom panel doors. Rear external single door, and off the production workshop. Where the large plantroom doors are located to the outside, there is some concrete hard standing before butting onto a grasscrete roadway. Access to the grasscrete is via the service road that runs around the site on the North and West side.

The Lyo plantroom has a full length and width mezzanine floor with a central cat ladder staircase. A lifting hatch is incorporated into the mezzanine for transfer of maintenance equipment.

Services

The freeze dryer requires, new clean steam generators and associated pipework, processed water, refrigeration plant, compressed gasses, drainage, and electrical connections. The size of these service will form part of the design requirement.

Survey site setup Information

A full survey is to be undertaken to establish and verify actual site dimensions, prior to further design work and the subsequent construction phase.

Removal Works

Freeze dryer to be full removed between the Lab and the plantroom.

Strip out

All services and cables are to be pulled back outside the lab. The vinyl floor will be lifted. The modular wall will be removed around the FD and any wall mounted plant/equipment/services removed to a practical position.

A contractor's skip/s can be located in the local area but must be maintained so no rubbish is left around it, or be blown around by the wind. "Contractors engaging in refurbishment or new works on MHRA sites are required by law to control their waste arising's. If waste skips are being brought onsite these should, where possible, be controlled by the site service provider; ensuring that a 'duty of care' is maintained. If a contractor brings his own skip onsite they should provide details and waste

licenses/permits of the waste contractor and site where the waste will be disposed of as described above."

Electrical

All new electrical work shall be carried out in accordance with IEE Wiring Regulations eighteenth Edition and relevant current revisions.

Isolations will be carried out in accordance with SOP 6373

Electrical and Trend panels within the plant room must be air cooled or fan assisted.

Allowance must be made within your return for correctly sized new distribution board breakers accompanied with cable size and volt drop calculations.

Cpc' (circuit protective conductors) shall either be an incorporated core or a separate cable, for SWA's the armour is for mechanical protection only.

Cable trays shall be perforated and supplied in nominal 2,400mm lengths manufactured from galvanised mild steel complying with BS 1499 (Classification CR4/GP). Cable tray accessories shall be supplied by the Cable Tray Manufacturer; only where these are inadequate to meet special conditions can site-fabricated accessories be accepted with the approval of the Supervising Officer. Holes cut in cable trays for the passage of cable shall be drilled and suitably bushed

Fixing of cable trays shall unless otherwise stated be at intervals not exceeding 1,200mm and at 200mm from bends of intersections. Fixing shall be either by brackets made by the Cable Tray Manufacturer of brackets made from "Unistrut" and/or "Unirax" sections whichever are preferred.

Trays up to but not including 150mm wide shall be 20 SWG thick: all cable trays shall be of the return flange-type.

Unless otherwise required wiring tray and accessories shall be finished in hot dip galvanised after manufacture and sections of wiring trays shall be jointed together with 6mm diameter mushroom headed safety bolts and nuts to comply with BS 1494, Part 1. Adequate copper earthing strips shall be fitted at every joint. A minimum clear space of 25mm shall be left behind all cable trays.

Data/Trend outlets

Trend BMS will be required for a process alarm out port on the machine.

Power sockets

Any twin power outlets are to be re-instated if removed during the install.

Lighting

Additional lighting may be required once size and shape of FD is known, this will enable safe maintenance to be carried out under the mezzanine floor.

Earth Bonding

The bonding of the electrical installation is to be carried out to the requirements to the current IEE Regulations and the Electricity Boards recommendations, special attention to be paid to the bonding of extraneous metalwork.

Inspection & Testing

The installation shall, upon completion, be inspected and tested in accordance with the standard procedure within the IEE Regulations.

The Contractor's attention is drawn to the electronic components within the control system which is disconnected before carrying out any tests.

Upon completion of the project the whole installation shall be inspected and completion and inspection certificate will be submitted in accordance with the IEE Regulations Appendix 1.5

Labels

All items of equipment and sockets, data outlets etc. shall be fully identified with a label showing which distribution board or cabinet they are fed from.

Finishes

Finishes should be impervious and appropriate to an aseptic manufacturing environment, i.e. to prevent bacterial growth and aid washing and disinfecting. Altro 2mm vinyl will be used on the floor, ceiling, and walls, and have a welded joint between sheets.

Penetrations

It is imperative that penetrations of the room fabric for fixings, services etc. are kept to an absolute minimum to provide containment of pathogens.

Equipment re-location

It will be necessary to re-locate existing equipment (plantroom process equipment and plant etc.) to new positions. These will be detailed during discussions when on the site visit.

Air Pressure: The air pressure in the laboratory filler room must be @-60 \pm 5 Pa. The outer lobby is to be -45 Pa. A cascade affect must always be towards the filler room laboratory.

Temperature: 21 °C +/- 2 °C

Air Changes: 20 / hr

Relative Humidity: Ambient

Commissioning

The area must be rebalanced after the works have taken place.

Upon completion of the works, the lab will be tested for integrity using a combination of room pressure testing and smoke tests. These works will be carried out by MYRA staff. The room must pass these tests to be accepted.

Any instruments used, must be UKAS certified with an approved calibration test sheet. These sheets and test results must form part of the electronic O and M file.

Personnel carrying out the test and inspection must be suitably qualified to either BS 2391/2394/2395

Maintenance

All plant and its subsidiary components must be easily accessible for routine servicing and maintenance.

Electronic O and M manuals will be provided at the end of the works, showing as installed drawings, routine service parts and the frequency of maintenance. Electrical certificates along with information etc. on manufacturer's literature must also be included.

Steam Generators

Ideally in discussions with the freeze dryer suppliers, the existing 2 x steam generators, housed on two independent skids, could be housed on one skid to free up space in the plantroom.

Unless you tell us otherwise in accordance with the procedures described herein, we will provide electronically to you through the DocuSign system all required notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you during the course of our relationship with you. To reduce the chance of you inadvertently not receiving any notice or disclosure, we prefer to provide all of the required notices and disclosures to you by the same method and to the same address that you have given us. Thus, you can receive all the disclosures and notices electronically or in paper format through the paper mail delivery system. If you do not agree with this process, please let us know as described below. Please also see the paragraph immediately above that describes the consequences of your electing not to receive delivery of the notices and disclosures electronically from us.

How to contact Scape Group:

You may contact us to let us know of your changes as to how we may contact you electronically, to request paper copies of certain information from us, and to withdraw your prior consent to receive notices and disclosures electronically as follows:

To contact us by email send messages to: chrisc@scapegroup.co.uk

To advise Scape Group of your new email address

To let us know of a change in your email address where we should send notices and disclosures electronically to you, you must send an email message to us at chrisc@scapegroup.co.uk and in the body of such request you must state: your previous email address, your new email address. We do not require any other information from you to change your email address.

If you created a DocuSign account, you may update it with your new email address through your account preferences.

To request paper copies from Scape Group

To request delivery from us of paper copies of the notices and disclosures previously provided by us to you electronically, you must send us an email to chrisc@scapegroup.co.uk and in the body of such request you must state your email address, full name, mailing address, and telephone number. We will bill you for any fees at that time, if any.

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To inform us that you no longer wish to receive future notices and disclosures in electronic format you may:

i. decline to sign a document from within your signing session, and on the subsequent page, select the check-box indicating you wish to withdraw your consent, or you may;

ii. send us an email to chrisc@scapegroup.co.uk and in the body of such request you must state your email, full name, mailing address, and telephone number. We do not need any other information from you to withdraw consent.. The consequences of your withdrawing consent for online documents will be that transactions may take a longer time to process..

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The minimum system requirements for using the DocuSign system may change over time. The current system requirements are found here: https://support.docusign.com/guides/signer-guide-signing-system-requirements.

Acknowledging your access and consent to receive and sign documents electronically

To confirm to us that you can access this information electronically, which will be similar to other electronic notices and disclosures that we will provide to you, please confirm that you have read this ERSD, and (i) that you are able to print on paper or electronically save this ERSD for your future reference and access; or (ii) that you are able to email this ERSD to an email address where you will be able to print on paper or save it for your future reference and access. Further, if you consent to receiving notices and disclosures exclusively in electronic format as described herein, then select the check-box next to 'I agree to use electronic records and signatures' before clicking 'CONTINUE' within the DocuSign system.

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- You can access and read this Electronic Record and Signature Disclosure; and
- You can print on paper this Electronic Record and Signature Disclosure, or save or send this Electronic Record and Disclosure to a location where you can print it, for future reference and access; and
- Until or unless you notify Scape Group as described above, you consent to receive exclusively through electronic means all notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you by Scape Group during the course of your relationship with Scape Group.