



Medicines & Healthcare products Regulatory Agency

Labman Automation

Seamer Hill
Seamer
North Yorkshire
TS9 5NQ

1st June 2021

Procurement

c/o National Institute for Biological
Standards and Control

Blanche Lane
South Mimms
Potters Bar
Hertfordshire EN6 3QG

www.gov.uk/mhra

Award of contract for the supply of [Automated Infectious Filling Lines and Blood Tube Labeler – Contract Ref. C35385](#)

Following your tender/ proposal for the supply of [Automated Infectious Filling Lines and Blood Tube Labeller](#) to the **Medicines and Healthcare products Regulatory Agency**, we are pleased to award this contract to you.

This letter (Award Letter) and its Annexes set out the terms of the contract between the **Medicines and Healthcare products Regulatory Agency** as the Customer and [Labman Automation](#) as the Supplier for the provision of this requirement Services.

Unless the context otherwise requires, capitalised expressions used in this Award Letter have the same meanings as in the terms and conditions of contract set out in Annex 1 to this Award Letter (the “**Conditions**”). In the event of any conflict between this Award Letter and the Conditions, this Award Letter shall prevail. Please do not attach any Supplier terms and conditions to this Award Letter as they will not be accepted by the Customer and may delay conclusion of the Agreement.

For the purposes of the Agreement, the Customer and the Supplier agree as follows:

- 1) The Goods shall be Delivered to the address set out on the Purchase Order
- 2) The charges for the Services shall be as set out in the tender submission [itt_4447](#) and Annex 2.
- 3) The specification of the Services to be supplied is as set out in the tender submission [itt_4447](#) and Annex 3.
- 4) The Term shall commence on **10th June 2021** and the Expiry Date shall be **9th July 2023** or at the final commissioning of the equipment.
- 5) The address for notices of the Parties are:



Customer

Attention: Procurement

c/o National Institute of Biological
Standards and Control
Blanche Lane
South Mimms
Potters Bar
Hertfordshire
EN6 3QG

Email: purchasin@mhra.gov.uk

Supplier**Labman Automation**

Seamer Hill
Seamer
North Yorkshire
TS9 5NQ

Email: tcumpson@labman.co.uk

- 6) The Customer may require the Supplier to ensure that any person employed in the supply of the Goods has undertaken a Disclosure and Barring Service check. The Supplier shall ensure that no person who discloses that he/she has a conviction that is relevant to the nature of the Agreement, relevant to the work of the Customer, or is of a type otherwise advised by the Customer (each such conviction a “**Relevant Conviction**”), or is found by the Supplier to have a Relevant Conviction (whether as a result of a police check, a Disclosure and Barring Service check or otherwise) is employed or engaged in the provision of any part of the supply of the Goods.

7) **Payment**

All invoices must be sent, quoting a valid purchase order number (PO Number), to:

Accounts Payable
Medicines and Healthcare Products Regulatory Agency
10th Floor
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
Email: accounts.payable@mhra.gov.uk

To avoid delay in payment it is important that the invoice is compliant and that it includes a valid PO Number, PO Number item number (if applicable) and the details (name and telephone number) of your Customer contact (i.e. Contract Manager). Non-compliant invoices will be sent back to you, which may lead to a delay in payment. If you have a query regarding an outstanding payment, please contact our Accounts Payable section between 09:00-17:00 Monday to Friday.

Liaison

For general liaison your contact will be:

Name: [REDACTED]
Position: **Production Manager**
Telephone: **01707 641521**
Email: [REDACTED]

We thank you for your co-operation to date and look forward to forging a successful working relationship resulting in a smooth and successful delivery of the contract. Please confirm your acceptance of the award of this contract by signing and returning the enclosed copy of this letter to Procurement at the above address within 10 days from the date of this letter. No other form of acknowledgement will be accepted. Please remember to quote the reference number above in any future communications relating to this contract.

Yours faithfully,

Signed for and on behalf of the
Medicines and Healthcare Products Regulatory Agency

Name: [REDACTED]
Position: **NIBSC Director**
Date: **29th June 2021**
Signature:

We accept the terms set out in this letter and its Annexes, including the Conditions.

Signed for and on behalf of **Labman Automation**

Name: [REDACTED]
Position: **Senior Project Leader**
Date: **22/06/2021**
Signature:

Annex 1

Terms and Conditions of Contract for Goods

1 Interpretation

1.1 In these terms and conditions:

“Agreement”	means the contract between (i) the Customer acting as part of the Crown and (ii) the Supplier constituted by the Supplier’s countersignature of the Award Letter and includes the Award Letter and Annexes;
“Award Letter”	means the letter from the Customer to the Supplier printed above these terms and conditions;
“Central Government Body”	means a body listed in one of the following sub-categories of the Central Government classification of the Public Sector Classification Guide, as published and amended from time to time by the Office for National Statistics: (a) Government Department; (b) Non-Departmental Public Body or Assembly Sponsored Public Body (advisory, executive, or tribunal); (c) Non-Ministerial Department; or (d) Executive Agency;
“Charges”	means the charges for the Goods as specified in the Award Letter;
“Confidential Information”	means all information, whether written or oral (however recorded), provided by the disclosing Party to the receiving Party and which (i) is known by the receiving Party to be confidential; (ii) is marked as or stated to be confidential; or (iii) ought reasonably to be considered by the receiving Party to be confidential;
“Customer”	means the person identified in the letterhead of the Award Letter;
“Date of Delivery”	means that date by which the Goods must be Delivered to the Customer, as specified in the Award Letter.
“Deliver”	means: the completion of the Customer’s Sign-Off of either of (a) the Design Study (b) the Vesting Certificate, (c) the Document countersigned by Supplier Technical Director (Ian Riley) (d) the satisfactory results of the FAT or (e) the satisfactory results of the SAT in accordance with Annex 3 to the Agreement, together with the hand over the Goods to the Customer at the address and on the date specified in the Award Letter, which shall include unloading and any other specific arrangements agreed in accordance with Clause 6 as applicable. Delivered and Delivery shall be construed accordingly.
“FOIA”	means the Freedom of Information Act 2000;
“GDPR”	the General Data Protection Regulation (Regulation (EU) 2016/679)

GDPR CLAUSE DEFINITIONS

Data Protection Legislation: (i) the GDPR, the LED and any applicable national implementing Laws as amended from time to time (ii) the DPA 2018 [subject to Royal Assent] to the extent that it relates to processing of personal data and privacy; (iii) all applicable Law about the processing of personal data and privacy;

Data Protection Impact Assessment: An assessment by the Controller of the impact of the envisaged processing on the protection of Personal Data.

Controller, Processor, Data Subject, Personal Data, Personal Data Breach, Data Protection Officer: take the meaning given in the GDPR.

Data Loss Event: Any event that results, or may result, in unauthorised access to Personal Data held by the Processor under this Agreement, and/or actual or potential loss and/or destruction of Personal Data in breach of this Agreement, including any Personal Data Breach.

Data Subject Request: A request made by, or on behalf of, a Data Subject in accordance with rights granted pursuant to the Data Protection Legislation to access their Personal Data.

DPA 2018: Data Protection Act 2018

GDPR: the General Data Protection Regulation (Regulation (EU) 2016/679)

Joint Controllers: Where two or more Controllers jointly determine the purposes and means of processing

LED: Law Enforcement Directive (Directive (EU) 2016/680)

Protective Measures: Appropriate technical and organisational measures which may include: pseudonymising and encrypting Personal Data, ensuring confidentiality, integrity, availability and resilience of 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 such measures adopted by it including those outlined in Annex 2 (Security).

Sub-processor: Any third Party appointed to process Personal Data on behalf of that Processor related to this Agreement
means Factory Acceptance Testing

“FAT”

“Goods”

means the Design Study, Vesting Certificate, Document counter signed by Supplier Technical Director (Ian Riley), satisfactory completion of FAT, and satisfactory completion of SAT as set out in Annex 3 to the Agreement and the Filling Machine matching the technical specification set out in Annex 4 to the Agreement;

“Information”

has the meaning given under section 84 of the FOIA;

“Party”	the Supplier or the Customer (as appropriate) and “Parties” shall mean both of them;
“Purchase Order Number”	means the Customer’s unique number relating to the order for Goods to be supplied by the Supplier to the Customer in accordance with the terms of the Agreement;
“Request for Information”	has the meaning set out in the FOIA or the Environmental Information Regulations 2004 as relevant (where the meaning set out for the term “request” shall apply);
“SAT”	means Site Acceptance Testing
“Sign-Off”	means the written approval and signature of an authorised representative of the Customer
“Specification”	means the specification for the Goods to be supplied by the Supplier to the Customer (including as to quantity, description, and quality) as specified in the tender and Award Letter;
“Staff”	means all directors, officers, employees, agents, consultants, and contractors of the Supplier and/or of any sub-contractor of the Supplier engaged in the performance of the Supplier’s obligations under the Agreement;
“Staff Vetting Procedures”	means vetting procedures that accord with good industry practice or, where applicable, the Customer’s procedures for the vetting of personnel as provided to the Supplier from time to time;
“Supplier”	means the person named as Supplier in the Award Letter;
“VAT”	means value added tax in accordance with the provisions of the Value Added Tax Act 1994; and
“Working Day”	means a day (other than a Saturday or Sunday) on which banks are open for business in the City of London.

1.2 In these terms and conditions, unless the context otherwise requires:

- 1.2.1 references to numbered clauses are references to the relevant clause in these terms and conditions;
- 1.2.2 any obligation on any Party not to do or omit to do anything shall include an obligation not to allow that thing to be done or omitted to be done;
- 1.2.3 the headings to the clauses of these terms and conditions are for information only and do not affect the interpretation of the Agreement;
- 1.2.4 any reference to an enactment includes reference to that enactment as amended or replaced from time to time and to any subordinate legislation or byelaw made under that enactment; and
- 1.2.5 the word ‘including’ shall be understood as meaning ‘including without limitation’.

2 Basis of Agreement

- 2.1 The Award Letter constitutes an offer by the Customer to purchase the Goods subject to and in accordance with the terms and conditions of the Agreement.
- 2.2 The offer comprised in the Award Letter shall be deemed to be accepted by the Supplier on receipt by the Customer of a copy of the Award Letter countersigned by the Supplier within [7] days of the date of the Award Letter.

3 Supply of Goods

- 3.1 In consideration of the Customer's agreement to pay the Charges, the Supplier shall supply the Goods to the Customer subject to and in accordance with the terms and conditions of the Agreement.
- 3.2 In supplying the Goods, the Supplier shall co-operate with the Customer in all matters relating to the supply of Goods and comply with all the Customer's instructions.
- 3.3 The Supplier shall supply the Goods in accordance with the Specification. The Supplier warrants, represents, undertakes and guarantees that the Goods supplied under the Agreement shall:
- 3.3.1 be free from defects (manifest or latent), in materials and workmanship and remain so for 12 months after Delivery;
 - 3.3.2 be of satisfactory quality (within the meaning of the Sale of Goods Act 1979) and comply with any applicable statutory and regulatory requirements relating to the manufacture, labelling, packaging, storage, handling and delivery of the Goods;
 - 3.3.3 conform with the specifications (including the Specification), drawings, descriptions given in quotations, estimates, brochures, sales, marketing and technical literature or material (in whatever format made available by the Supplier) supplied by, or on behalf of, the Supplier;
 - 3.3.4 The must be fully CE marked (or UK CA mark) to show that it complies with all European and UK regulations including:
 - BS7671: Requirements for Electrical Installations, 18th edition by the IET
 - Machinery Directive (2006/42/EC)
 - EMC Directive (2014/30/EU)
 - 3.3.5 be compliant with all relevant regulations, guidelines and best practices relevant to the Goods, including but not limited to appropriate and independent testing frameworks.
 - 3.3.6 be fit for any purpose as agreed in the design specification document and subsequently demonstrated and certified (by the Customer) through the Factory Acceptance Test (FAT) and the Site Acceptance Test (SAT) process.

Subsequent to the above, where there is performance discrepancy in the equipment after the completion of certified FAT and SAT, both parties will collaborate to remedy the anomaly. The Supplier will commit to expending reasonable time and efforts to ensure the error is rectified.
 - 3.3.7 and the Supplier itself shall, comply with all applicable laws.

4 Charges, Payment and Recovery of Sums Due

- 4.1 The Charges for the Goods shall be as set out in the Award Letter and shall be the full and exclusive remuneration of the Supplier in respect of the supply of the Goods. Unless otherwise agreed in writing by the Customer, the Charges shall include every cost and expense of the Supplier directly or indirectly incurred in connection with the supply of the Goods, including but not limited to the costs of packaging, insurance, delivery, unloading, stacking and carriage.
- 4.2 All amounts stated are exclusive of VAT which shall be charged at the prevailing rate. The Customer shall, following the receipt of a valid VAT invoice, pay to the Supplier a sum equal to the VAT chargeable in respect of the Goods.
- 4.3 Following Delivery of each of the Goods, the Supplier shall invoice the Customer as specified in Annex 3 to the Agreement. Each invoice shall include such supporting information required by the Customer to verify the accuracy of the invoice, including the relevant Purchase Order Number and a breakdown of the Goods supplied in the invoice period.
- 4.4 In consideration of the supply of each of the Goods by the Supplier, the Customer shall pay the Supplier the invoiced amounts no later than 30 days after verifying that the invoice is valid and undisputed and includes a valid Purchase Order Number.
- 4.5 If the Customer fails to consider and verify an invoice in a timely fashion the invoice shall be regarded as valid and undisputed for the purpose of paragraph 4.4 after a reasonable time has passed.
- 4.6 If there is a dispute between the Parties as to the amount invoiced, the Customer shall pay the undisputed amount. The Supplier shall not suspend the supply of the Goods unless the Supplier is entitled to terminate the Agreement for a failure to pay undisputed sums in accordance with clause 17.3. Any disputed amounts shall be resolved through the dispute resolution procedure detailed in clause 20.
- 4.7 If a payment of an undisputed amount is not made by the Customer by the due date, then the Customer shall pay the Supplier interest at the interest rate specified in the Late Payment of Commercial Debts (Interest) Act 1998.
- 4.8 Where the Supplier enters into a sub-contract, the Supplier shall include in that sub-contract:
 - 4.8.1 provisions having the same effects as clauses 4.3 to 4.7 of this Agreement; and
 - 4.8.2 a provision requiring the counterparty to that sub-contract to include in any sub-contract which it awards provisions having the same effects as 4.3 to 4.8 of this Agreement.
 - 4.8.3 In this clause 4.8, “sub-contract” means a contract between two or more suppliers, at any stage of remoteness from the Authority in a subcontracting chain, made wholly or substantially for the purpose of performing (or contributing to the performance of) the whole or any part of this Agreement.
- 4.9 If any sum of money is recoverable from or payable by the Supplier under the Agreement (including any sum which the Supplier is liable to pay to the Customer in respect of any breach of the Agreement), that sum may be deducted unilaterally by the Customer from any sum then due, or which may come due, to the Supplier under the Agreement or under any other agreement or contract with the Customer. The Supplier shall not be entitled to assert any credit, set-off or counterclaim against the Customer in order to justify withholding payment of any such amount in whole or in part.

5 Cancellation

- 5.1 The Customer shall have the right to cancel the order for the Goods, or any part of the Goods, which have not yet been Delivered to the Customer. The cancellation shall be made in writing. Without prejudice to the generality of the foregoing, the Customer shall pay such Charges or that part of the Charges for Goods which have been Delivered to the Customer or, on the deemed date of service of the notice of cancellation, are already in transit and which cannot be used for other orders or be returned to the supplier of those materials for a refund. For the avoidance of doubt the Customer shall not be liable for any loss of anticipated profits or any consequential loss.

6 Delivery

- 6.1 The Supplier shall Deliver the Goods to the Customer on or by the Date of Delivery. Unless otherwise agreed in writing by the Customer, Delivery shall be on the date and to the address specified in the Award Letter. Delivery of the Goods shall be completed once the completion of unloading the Goods from the transporting vehicle at the Delivery address has taken place and the Customer has signed for the Delivery
- 6.2 Any access to the Customer's premises and any labour and equipment that may be provided by the Customer in connection with Delivery of the Goods shall be provided without acceptance by the Customer or the Crown of any liability in respect of any actions, claims, costs and expenses incurred by third parties for any loss of damages to the extent that such loss or damage is not attributable to the negligence or other wrongful act of the Customer or its servant or agent. The Supplier shall indemnify the Customer and the Crown to a maximum value of £5,000,000.00 in any one claim in respect of any actions, suits, claims, demands, losses, charges, costs and expenses, which the Customer or the Crown may suffer or incur as a result of or in connection with any damage or injury (whether fatal or otherwise) occurring in the course of Delivery or installation to the extent that any such damage or injury is attributable to any act or omission of the Supplier or any of his sub-Suppliers provided that such maximum sum of £5,000,000 shall be separate from and not be computed as part of the Supplier's liability cap as set out in clause 15.
- 6.3 Delivery of the Goods shall be accompanied by a delivery note which shows the Purchase Order Number and the type and quantity of the Goods and, in the case of part Delivery, the outstanding balance remaining to be Delivered.
- 6.4 Unless otherwise stipulated by the Customer in the Award Letter, Deliveries shall only be accepted by the Customer on Working Days and during normal business hours.
- 6.5 Where (i) the Supplier fails to Deliver the Goods or part of the Goods or (ii) the Goods or part of the Goods do not comply with the provisions of clause 3, then without limiting any of its other rights or remedies implied by statute or common law, the Customer shall be entitled:
- 6.5.1 to terminate the Agreement;
 - 6.5.2 to request the Supplier, free of charge, to deliver substitute Goods within the timescales specified by the Customer;
 - 6.5.3 to require the Supplier, free of charge, to repair or replace the rejected Goods, or to provide a full refund of the price of the rejected Goods (if paid);
 - 6.5.4 to reject the Goods (in whole or part) and return them to the Supplier at the Supplier's own risk and expense and the Customer shall be entitled to a full refund on those Goods or part
 - 6.5.5 These clauses (6.5.1 – 6.5.4) shall only be applied after the best efforts of both parties to remedy the failure, and after the supplier has been allowed a reasonable amount of time to

correct any failings.

7 Property and Guarantee of Title

- 7.1 Without prejudice to any other rights or remedies of the Customer, title and risk in the Goods shall pass to the Customer when Delivery of the Goods is complete (including off-loading and stacking) in accordance with clause 6.
- 7.2 The Supplier warrants that:
 - 7.2.1 it has full clear and unencumbered title to all the Goods;
 - 7.2.2 at the date of Delivery of any of the Goods it shall have full and unrestricted right, power and authority to sell, transfer and deliver all of the Goods to the Customer. On Delivery the Customer shall acquire a valid and unencumbered title to the Goods.

8 Staff

- 8.1 If the Customer reasonably believes that any of the Staff are unsuitable to undertake work in respect of the Agreement, it may, by giving written notice to the Supplier:
 - 8.1.1 refuse admission to the relevant person(s) to the Customer's premises;
 - 8.1.2 direct the Supplier to end the involvement in the provision of the Goods of the relevant person(s); and/or
 - 8.1.3 require that the Supplier replace any person removed under this clause with another suitably qualified person and procure that any security pass issued by the Customer to the person removed is surrendered,and the Supplier shall comply with any such notice.
- 8.2 The Supplier shall:
 - 8.2.1 ensure that all Staff are vetted in accordance with the Staff Vetting Procedures and if requested, comply with the Customer's Staff Vetting Procedures as supplied from time to time;
 - 8.2.2 if requested, provide the Customer with a list of the names and addresses (and any other relevant information) of all persons who may require admission to the Customer's premises in connection with the Agreement; and
 - 8.2.3 procure that all Staff comply with any rules, regulations and requirements reasonably specified by the Customer.

9 Assignment and Sub-Contracting

- 9.1 The Supplier shall not without the written consent of the Customer assign, sub-contract, novate or in any way dispose of the benefit and/ or the burden of the Agreement or any part of the Agreement. The Customer may, in the granting of such consent, provide for additional terms and conditions relating to such assignment, sub-contract, novation or disposal. The Supplier shall be responsible for the acts and omissions of its sub-contractors as though those acts and omissions were its own.
- 9.2 Where the Customer has consented to the placing of sub-contracts, the Supplier shall, at the request of the Customer, send copies of each sub-contract, to the Customer as soon as is reasonably practicable.

- 9.3 The Customer may assign, novate, or otherwise dispose of its rights and obligations under the Agreement without the consent of the Supplier provided that such assignment, novation or disposal shall not increase the burden of the Supplier's obligations under the Agreement.

10 Intellectual Property and Indemnity (where applicable)

- 10.1 The Supplier grants the Customer a perpetual, royalty-free, irrevocable, non-exclusive licence (with the right to sub-licence) to use all intellectual property rights in the Goods or in any materials accompanying the Goods to the extent that it is necessary to fulfil its obligations under this Agreement.
- 10.2 The Supplier shall indemnify, and keep indemnified, the Customer in full against all cost, expenses, damages and losses (whether direct or indirect), including any interest, penalties, and reasonable legal and other professional fees awarded against or incurred or paid by the Customer as a result of or in connection with any claim made against the Customer for actual or alleged infringement of a third party's intellectual property arising out of, or in connection with, the supply or use of the Goods, to the extent that the claim is attributable to the acts or omission of the Supplier or any Staff.
- 10.3 The Customer shall promptly notify the Supplier of any infringement claim made against it relating to any Goods and, subject to any statutory obligation requiring the Customer to respond, shall permit the Supplier to have the right, at its sole discretion to assume, defend, settle or otherwise dispose of such claim. The Customer shall give the Supplier such assistance as it may reasonably require to dispose of the claim and shall not make any statement which might be prejudicial to the settlement or defence of the claim.

11 Governance and Records

- 11.1 The Supplier shall:
- 11.1.1 attend progress meetings with the Customer at the frequency and times specified by the Customer and shall ensure that its representatives are suitably qualified to attend such meetings; and
- 11.1.2 submit progress reports to the Customer at the times and in the format specified by the Customer.
- 11.2 The Supplier shall keep and maintain until 6 years after the end of the Agreement, or as long a period as may be agreed between the Parties, full and accurate records of the Agreement including the Goods supplied under it, and all payments made by the Customer. The Supplier shall on request afford the Customer or the Customer's representatives such access to those records as may be reasonably requested by the Customer in connection with the Agreement.

12 Confidentiality, Transparency and Publicity

- 12.1 Subject to clause 12.2, each Party shall:
- 12.1.1 treat all Confidential Information it receives as confidential, safeguard it accordingly and not disclose it to any other person without the prior written permission of the disclosing Party; and
- 12.1.2 not use or exploit the disclosing Party's Confidential Information in any way except for the

purposes anticipated under the Agreement.

12.2 Notwithstanding clause 12.1, a Party may disclose Confidential Information which it receives from the other Party:

- 12.2.1 where disclosure is required by applicable law or by a court of competent jurisdiction;
- 12.2.2 to its auditors or for the purposes of regulatory requirements;
- 12.2.3 on a confidential basis, to its professional advisers;
- 12.2.4 to the Serious Fraud Office where the Party has reasonable grounds to believe that the other Party is involved in activity that may constitute a criminal offence under the Bribery Act 2010;
- 12.2.5 where the receiving Party is the Supplier, to the Staff on a need to know basis to enable performance of the Supplier's obligations under the Agreement provided that the Supplier shall procure that any Staff to whom it discloses Confidential Information pursuant to this clause 12.2.5 shall observe the Supplier's confidentiality obligations under the Agreement; and
- 12.2.6 where the receiving Party is the Customer:
 - (a) on a confidential basis to the employees, agents, consultants and contractors of the Customer;
 - (b) on a confidential basis to any other Central Government Body, any successor body to a Central Government Body or any company to which the Customer transfers or proposes to transfer all or any part of its business;
 - (c) to the extent that the Customer (acting reasonably) deems disclosure necessary or appropriate in the course of carrying out its public functions; or
 - (d) in accordance with clause 13.

and for the purposes of the foregoing, references to disclosure on a confidential basis shall mean disclosure subject to a confidentiality agreement or arrangement containing terms no less stringent than those placed on the Customer under this clause 12.

- 12.3 The Parties acknowledge that, except for any Information which is exempt from disclosure in accordance with the provisions of the FOIA, the content of the Agreement is not Confidential Information and the Supplier hereby gives its consent for the Customer to publish the Agreement in its entirety to the general public (but with any Information that is exempt from disclosure in accordance with the FOIA redacted) including any changes to the Agreement agreed from time to time. The Customer may consult with the Supplier to inform its decision regarding any redactions but shall have the final decision in its absolute discretion whether any of the content of the Agreement is exempt from disclosure in accordance with the provisions of the FOIA.
- 12.4 The Supplier shall not and shall take reasonable steps to ensure that the Staff shall not, make any press announcement or publicise the Agreement or any part of the Agreement in any way, except with the prior written consent of the Customer.

13 Freedom of Information

- 13.1 The Supplier acknowledges that the Customer is subject to the requirements of the FOIA and the Environmental Information Regulations 2004 and shall:
- 13.1.1 provide all necessary assistance and cooperation as reasonably requested by the Customer to

enable the Customer to comply with its obligations under the FOIA and the Environmental Information Regulations 2004;

- 13.1.2 transfer to the Customer all Requests for Information relating to the Agreement that it receives as soon as practicable and in any event within 2 Working Days of receipt;
 - 13.1.3 provide the Customer with a copy of all Information belonging to the Customer requested in the Request for Information which is in its possession or control in the form that the Customer requires within 5 Working Days (or such other period as the Customer may reasonably specify) of the Customer's request for such Information; and
 - 13.1.4 not respond directly to a Request for Information unless authorised in writing to do so by the Customer.
- 13.2 The Supplier acknowledges that the Customer may be required under the FOIA and the Environmental Information Regulations 2004 to disclose Information concerning the Supplier or the Goods (including commercially sensitive information) without consulting or obtaining consent from the Supplier. In these circumstances the Customer shall, in accordance with any relevant guidance issued under the FOIA, take reasonable steps, where appropriate, to give the Supplier advance notice, or failing that, to draw the disclosure to the Supplier's attention after any such disclosure
- 13.3 Notwithstanding any other provision in the Agreement, the Customer shall be responsible for determining in its absolute discretion whether any Information relating to the Supplier or the Goods is exempt from disclosure in accordance with the FOIA and/or the Environmental Information Regulations 2004.

14 DATA PROTECTION

- 14.1 The Parties acknowledge that for the purposes of the Data Protection Legislation, the Customer is the Controller and the Contractor is the Processor unless otherwise specified in Annex 2. The only processing that the Processor is authorised to do is listed in Annex 2 by the Controller and may not be determined by the Processor.
- 14.2 The Processor shall notify the Controller immediately if it considers that any of the Controller's instructions infringe the Data Protection Legislation.
- 14.3 The Processor shall provide all reasonable assistance to the Controller in the preparation of any Data Protection Impact Assessment prior to commencing any processing. Such assistance may, at the discretion of the Controller, include:
- 14.3.1 a systematic description of the envisaged processing operations and the purpose of the processing;
 - 14.3.2 an assessment of the necessity and proportionality of the processing operations in relation to the Services;
 - 14.3.3 an assessment of the risks to the rights and freedoms of Data Subjects; and
 - 14.3.4 the measures envisaged to address the risks, including safeguards, security measures and mechanisms to ensure the protection of Personal Data.

- 14.4 The Processor shall, in relation to any Personal Data processed in connection with its obligations under this Agreement:
- 14.4.1 process that Personal Data only in accordance with Annex 2, unless the Processor is required to do otherwise by Law. If it is so required, the Processor shall promptly notify the Controller before processing the Personal Data unless prohibited by Law;
 - 14.4.2 ensure that it has in place Protective Measures, which are appropriate to protect against a Data Loss Event, which the Controller may reasonably reject (but failure to reject shall not amount to approval by the Controller of the adequacy of the Protective Measures), having taken account of the:
 - 14.4.2.1 nature of the data to be protected;
 - 14.4.2.2 harm that might result from a Data Loss Event;
 - 14.4.2.3 state of technological development; and
 - 14.4.2.4 cost of implementing any measures;
 - 14.4.3 ensure that:
 - 14.4.3.1 the Processor Personnel do not process Personal Data except in accordance with this Agreement (and in particular Annex 2);
 - 14.4.3.2 it takes all reasonable steps to ensure the reliability and integrity of any Processor Personnel who have access to the Personal Data and ensure that they:
 - (a) are aware of and comply with the Processor's duties under this clause;
 - (b) are subject to appropriate confidentiality undertakings with the Processor or any Sub-processor;
 - (c) are informed of the confidential nature of the Personal Data and do not publish, disclose or divulge any of the Personal Data to any third Party unless directed in writing to do so by the Controller or as otherwise permitted by this Agreement; and
 - (d) have undergone adequate training in the use, care, protection and handling of Personal Data; and
 - 14.4.3.3 not transfer Personal Data outside of the EU unless the prior written consent of the Controller has been obtained and the following conditions are fulfilled:
 - (a) the Controller or the Processor has provided appropriate safeguards in relation to the transfer (whether in accordance with GDPR Article 46 or LED Article 37) as determined by the Controller;
 - (b) the Data Subject has enforceable rights and effective legal remedies;
 - (c) the Processor complies with its obligations under the Data Protection Legislation by providing an adequate level of protection to any Personal Data that is transferred (or, if it is not so bound, uses its best endeavours to assist the Controller in meeting its obligations); and
 - (d) the Processor complies with any reasonable instructions notified to it in advance by the Controller with respect to the processing of the Personal Data;
 - 14.4.3.4 at the written direction of the Controller, delete or return Personal Data (and any copies of it) to the Controller on termination of the Agreement unless the Processor is required by Law to retain the Personal Data.
- 14.5 Subject to clause 14.6, the Processor shall notify the Controller immediately if it:
- 14.5.1 receives a Data Subject Request (or purported Data Subject Request);
 - 14.5.2 receives a request to rectify, block or erase any Personal Data;
 - 14.5.3 receives any other request, complaint or communication relating to either Party's obligations under the Data Protection Legislation;

- 14.5.4 receives any communication from the Information Commissioner or any other regulatory authority in connection with Personal Data processed under this Agreement;
 - 14.5.5 receives a request from any third Party for disclosure of Personal Data where compliance with such request is required or purported to be required by Law; or
 - 14.5.6 becomes aware of a Data Loss Event.
- 14.6 The Processor's obligation to notify under clause 14.5 shall include the provision of further information to the Controller in phases, as details become available.
- 14.7 Taking into account the nature of the processing, the Processor shall provide the Controller with full assistance in relation to either Party's obligations under Data Protection Legislation and any complaint, communication or request made under clause 14.5 (and insofar as possible within the timescales reasonably required by the Controller) including by promptly providing:
- 14.7.1 the Controller with full details and copies of the complaint, communication or request;
 - 14.7.2 such assistance as is reasonably requested by the Controller to enable the Controller to comply with a Data Subject Request within the relevant timescales set out in the Data Protection Legislation;
 - 14.7.3 the Controller, at its request, with any Personal Data it holds in relation to a Data Subject;
 - 14.7.4 assistance as requested by the Controller following any Data Loss Event;
 - 14.7.5 assistance as requested by the Controller with respect to any request from the Information Commissioner's Office, or any consultation by the Controller with the Information Commissioner's Office.
- 14.8 The Processor shall maintain complete and accurate records and information to demonstrate its compliance with this clause. This requirement does not apply where the Processor employs fewer than 250 staff, unless:
- 14.8.1 the Controller determines that the processing is not occasional;
 - 14.8.2 the Controller determines the processing includes special categories of data as referred to in Article 9(1) of the GDPR or Personal Data relating to criminal convictions and offences referred to in Article 10 of the GDPR; or
 - 14.8.3 the Controller determines that the processing is likely to result in a risk to the rights and freedoms of Data Subjects.
- 14.9 The Processor shall allow for audits of its Data Processing activity by the Controller or the Controller's designated auditor.
- 14.10 Each Party shall designate its own data protection officer if required by the Data Protection Legislation.
- 14.11 Before allowing any Sub-processor to process any Personal Data related to this Agreement, the Processor must:
- 14.11.1 notify the Controller in writing of the intended Sub-processor and processing;
 - 14.11.2 obtain the written consent of the Controller;
 - 14.11.3 enter into a written agreement with the Sub-processor which give effect to the terms set out in this clause 14.11 such that they apply to the Sub-processor; and
 - 14.11.4 provide the Controller with such information regarding the Sub-processor as the Controller may reasonably require.

- 14.12 The Processor shall remain fully liable for all acts or omissions of any of its Sub-processors.
- 14.13 The Controller may, at any time on not less than 30 Working Days' notice, revise this clause by replacing it with any applicable controller to processor standard clauses or similar terms forming part of an applicable certification scheme (which shall apply when incorporated by attachment to this Agreement).
- 14.14 The Parties agree to take account of any guidance issued by the Information Commissioner's Office. The Controller may on not less than 30 Working Days' notice to the Processor amend this agreement to ensure that it complies with any guidance issued by the Information Commissioner's Office.
- 14.15 Where the Parties include two or more Joint Controllers as identified in Annex 2 in accordance with GDPR Article 26, those Parties shall enter into a Joint Controller Agreement based on the terms outlined in Annex 2 in replacement of Clauses 14.1-14.14 for the Personal Data under Joint Control.

15 Liability

- 15.1 The Supplier shall not be responsible for any injury, loss, damage, cost or expense suffered by the Customer if and to the extent that it is caused by the negligence or wilful misconduct of the Customer or by breach by the Customer of its obligations under the Agreement.
- 15.2 Subject always to clause 15.3
- 15.2.1 the aggregate liability of the Supplier in respect of all defaults, claims, losses or damages howsoever caused, whether arising from breach of the Agreement, the supply or failure to supply of the Goods, misrepresentation (whether tortious or statutory), tort (including negligence), breach of statutory duty or otherwise shall in no event exceed a sum equal to 125% of the Charges paid or payable to the Supplier; and
- 15.2.2 except in the case of claims arising under clauses 10.1.2 and 19.3, in no event shall either Party be liable to the other Party for any:
- (a) loss of profits;
 - (b) loss of business;
 - (c) loss of revenue;
 - (d) loss of or damage to goodwill;
 - (e) loss of savings (whether anticipated or otherwise); and/or
 - (f) any indirect, special or consequential loss or damage.
- 15.3 Nothing in the Agreement shall be construed to limit or exclude either Party's liability for:
- 15.3.1 death or personal injury caused by its negligence or that of its Staff;
 - 15.3.2 fraud or fraudulent misrepresentation by it or that of its Staff;
 - 15.3.3 breach of any obligation as to title implied by section 12 of the Sale of Goods Act 1979 or section 2 of the Supply of Goods and Services Act 1982; or
 - 15.3.4 any other matter which, by law, may not be excluded or limited.

15.4 The Supplier's liability under the indemnity in clauses 10.2 and 19.3 shall be unlimited.

16 Force Majeure

Neither Party shall have any liability under or be deemed to be in breach of the Agreement for any delays or failures in performance of the Agreement which result from circumstances beyond the reasonable control of the Party affected. Each Party shall promptly notify the other Party in writing when such circumstances cause a delay or failure in performance and when they cease to do so. If such circumstances continue for a continuous period of more than 30 days, either Party may terminate the Agreement by written notice to the other Party.

17 Termination

- 17.1 Without prejudice to any other right or remedy it might have, the Customer may terminate the Agreement in whole or in part before Delivery or after Delivery (where only part of Goods have been Delivered) by written notice to the Supplier with immediate effect if the Supplier:
- 17.1.1 (without prejudice to clause 17.1.5), is in material breach of any obligation under the Agreement which is not capable of remedy;
 - 17.1.2 repeatedly breaches any of the terms and conditions of the Agreement in such a manner as to reasonably justify the opinion that its conduct is inconsistent with it having the intention or ability to give effect to the terms and conditions of the Agreement;
 - 17.1.3 is in material breach of any obligation which is capable of remedy, and that breach is not remedied within 30 days of the Supplier receiving notice specifying the breach and requiring it to be remedied;
 - 17.1.4 undergoes a change of control within the meaning of section 416 of the Income and Corporation Taxes Act 1988;
 - 17.1.5 breaches the provisions of clauses 8.2, 12, 13, **Error! Reference source not found.** and 18;
 - 17.1.6 becomes insolvent, or if an order is made or a resolution is passed for the winding up of the Supplier (other than voluntarily for the purpose of solvent amalgamation or reconstruction), or if an administrator or administrative receiver is appointed in respect of the whole or any part of the Supplier's assets or business, or if the Supplier makes any composition with its creditors or takes or suffers any similar or analogous action (to any of the actions detailed in this clause 17.1.6) in consequence of debt in any jurisdiction; or
 - 17.1.7 fails to comply with legal obligations in the fields of environmental, social or labour law.
- 17.2 The Supplier shall notify the Customer as soon as practicable of any change of control as referred to in clause 17.1.4 or any potential such change of control.
- 17.3 In addition to the Supplier's statutory rights, the Supplier may terminate the Agreement by written notice to the Customer if the Customer has not paid any undisputed amounts within 90 days of them falling due.

- 17.4 Termination or expiry of the Agreement shall be without prejudice to the rights of either Party accrued prior to termination or expiry and shall not affect the continuing rights of the Parties under clauses 2, 3.2, 3.3, 8, 10, 11.2, 12, 13, **Error! Reference source not found.**, 15, 17.5, 18.4, 19.3, 20 and 21.7 and any other term or condition of the Agreement that either expressly or by implication has effect after termination.
- 17.5 Upon termination or expiry of the Agreement, the Supplier shall:
- 17.5.1 give all reasonable assistance to the Customer and any incoming supplier of Goods; and
 - 17.5.2 return all requested documents, information and data to the Customer as soon as reasonably practicable.

18 Compliance

- 18.1 The Supplier shall promptly notify the Customer of any health and safety hazards which may arise in connection with the performance of its obligations under the Agreement. The Customer shall promptly notify the Supplier of any health and safety hazards which may exist or arise at the Customer's premises and which may affect the Supplier in the performance of its obligations under the Agreement.
- 18.2 The Supplier shall:
- 18.2.1 comply with the reasonable requirements of the Customer's security arrangements;
 - 18.2.2 comply with all the Customer's health and safety measures;
 - 18.2.3 notify the Customer immediately in the event of any incident occurring in the performance of its obligations under the Agreement on the Customer's premises where that incident causes any personal injury or damage to property which could give rise to personal injury;
 - 18.2.4 perform its obligations under the Agreement in accordance with all applicable equality Law and the Customer's equality and diversity policy as provided to the Supplier from time to time;
 - 18.2.5 take all reasonable steps to secure the observance of clause 18.2.4 by all Staff; and
 - 18.2.6 supply the Goods and any packaging in accordance with the Customer's environmental policy as provided from time to time.
- 18.3 The Goods shall be packed and marked in a proper manner and in accordance with any instructions specified in the Award Letter, any statutory requirements, and any requirements of the carriers. All packaging materials shall be considered non-returnable. The Supplier shall indemnify the Customer against all actions, suits, claims, demands, losses, charges, costs, and expenses which the Customer may suffer or incur as a result of, or in connection with, any breach of this clause 18.3.
- 18.4 The Supplier shall comply with, and shall ensure that its Staff shall comply with, the provisions of:
- 18.4.1 the Official Secrets Acts 1911 to 1989; and
 - 18.4.2 section 182 of the Finance Act 1989.

19 Prevention of Fraud and Corruption

- 19.1 The Supplier shall not offer, give, or agree to give anything, to any person an inducement or reward for doing, refraining from doing, or for having done or refrained from doing, any act in relation to the obtaining or execution of the Agreement or for showing or refraining from showing favour or

disfavour to any person in relation to the Agreement.

- 19.2 The Supplier shall take all reasonable steps, in accordance with good industry practice, to prevent fraud by the Staff and the Supplier (including its shareholders, members, and directors) in connection with the Agreement and shall notify the Customer immediately if it has reason to suspect that any fraud has occurred or is occurring or is likely to occur.
- 19.3 If the Supplier or the Staff engages in conduct prohibited by clause 19.1 or commits fraud in relation to the Agreement or any other contract with the Crown (including the Customer) the Customer may:
 - 19.3.1 terminate the Agreement and recover from the Supplier the amount of any loss suffered by the Customer resulting from the termination, including the cost reasonably incurred by the Customer of making other arrangements for the supply of the Goods and any additional expenditure incurred by the Customer throughout the remainder of the Agreement; or
 - 19.3.2 recover in full from the Supplier any other loss sustained by the Customer in consequence of any breach of this clause.

20 Dispute Resolution

- 20.1 The Parties shall attempt in good faith to negotiate a settlement to any dispute between them arising out of or in connection with the Agreement and such efforts shall involve the escalation of the dispute to an appropriately senior representative of each Party.
- 20.2 If the dispute cannot be resolved by the Parties within one month of being escalated as referred to in clause 20.1, the dispute may by agreement between the Parties be referred to a neutral adviser or mediator (the “**Mediator**”) chosen by agreement between the Parties. All negotiations connected with the dispute shall be conducted in confidence and without prejudice to the rights of the Parties in any further proceedings.
- 20.3 If the Parties fail to appoint a Mediator within one month or fail to enter into a written agreement resolving the dispute within one month of the Mediator being appointed, either Party may exercise any remedy it has under applicable law.

21 General

- 21.1 Each of the Parties represents and warrants to the other that it has full capacity and authority, and all necessary consents, licences and permissions to enter into and perform its obligations under the Agreement, and that the Agreement is executed by its duly authorised representative.
- 21.2 A person who is not a party to the Agreement shall have no right to enforce any of its provisions which, expressly or by implication, confer a benefit on him, without the prior written agreement of the Parties.
- 21.3 The Agreement cannot be varied except in writing signed by a duly authorised representative of both the Parties.
- 21.4 The Agreement contains the whole agreement between the Parties and supersedes and replaces any prior written or oral agreements, representations or understandings between them. The Parties confirm that they have not entered into the Agreement on the basis of any representation that is not expressly incorporated into the Agreement. Nothing in this clause shall exclude liability for fraud or fraudulent misrepresentation.

- 21.5 Any waiver or relaxation either partly, or wholly of any of the terms and conditions of the Agreement shall be valid only if it is communicated to the other Party in writing and expressly stated to be a waiver. A waiver of any right or remedy arising from a breach of contract shall not constitute a waiver of any right or remedy arising from any other breach of the Agreement.
- 21.6 The Agreement shall not constitute or imply any partnership, joint venture, agency, fiduciary relationship or other relationship between the Parties other than the contractual relationship expressly provided for in the Agreement. Neither Party shall have, nor represent that it has, any authority to make any commitments on the other Party's behalf.
- 21.7 Except as otherwise expressly provided by the Agreement, all remedies available to either Party for breach of the Agreement (whether under the Agreement, statute or common law) are cumulative and may be exercised concurrently or separately, and the exercise of one remedy shall not be deemed an election of such remedy to the exclusion of other remedies.
- 21.8 If any provision of the Agreement is prohibited by law or judged by a court to be unlawful, void or unenforceable, the provision shall, to the extent required, be severed from the Agreement and rendered ineffective as far as possible without modifying the remaining provisions of the Agreement, and shall not in any way affect any other circumstances of or the validity or enforcement of the Agreement.

22 Notices

- 22.1 Any notice to be given under the Agreement shall be in writing and may be served by personal delivery, first class recorded or, subject to clause 22.3, e-mail to the address of the relevant Party set out in the Award Letter, or such other address as that Party may from time to time notify to the other Party in accordance with this clause.
- 22.2 Notices served as above shall be deemed served on the Working Day of delivery provided delivery is before 5.00pm on a Working Day. Otherwise delivery shall be deemed to occur on the next Working Day. An email shall be deemed delivered when sent unless an error message is received.
- 22.3 Notices under clauses 16 (Force Majeure) and 17 (Termination) may be served by email only if the original notice is then sent to the recipient by personal delivery or recorded delivery in the manner set out in clause 22.1.

23 Governing Law and Jurisdiction

- 23.1 The validity, construction and performance of the Agreement, and all contractual and non-contractual matters arising out of it, shall be governed by English law and shall be subject to the exclusive jurisdiction of the English courts to which the Parties submit.

Annex 2

Schedule of Processing, Personal Data and Data Subjects

Description	Details
Identity of the Controller and Processor	The Parties acknowledge that for the purposes of the Data Protection Legislation, the Customer is the Controller and the Contractor (Supplier) is the Processor in accordance with Clause 1.1.
Subject matter of the processing	The processing is needed in order to ensure that the Processor can effectively deliver the contract to provide a service to the agency.
Duration of the processing	The duration is for the life of the contract.
Nature and purposes of the processing	Recording and storage of work contact details and names.
Type of Personal Data being Processed	Staff name and department, address of Agency, work telephone numbers and emails.
Categories of Data Subject	Staff
Plan for return and destruction of the data once the processing is complete UNLESS requirement under union or member state law to preserve that type of data	Data does not need to be returned. Staff lists need to be deleted from Processor database at end of contract.

Annex 3

Charges

Labman Revised Payment Agreement

Phase	Timeline	Provisional Cost	Agreement
Design Study	8- weeks		<ul style="list-style-type: none"> Due in 4 weeks from now. <ul style="list-style-type: none"> Invoice 100% payable following the Customer's Sign-Off of (a) the Design Study and (b) the Supplier's fixed price quote for the main build After Design study completion, Labman will give a fixed price for the main build MHRA Design Study sign off period – 2 weeks.
Automated Filler Line & Labelling System Build	28 weeks	15% (finalised at completion of DS) 15% (finalised at completion of DS)	<ul style="list-style-type: none"> Main build order (Due in 2 weeks from design study sign off) <ul style="list-style-type: none"> Invoice 40% payable following the Customer's Sign-Off on: <ul style="list-style-type: none"> Labman to supply a Vesting Certificate that details orders have been placed with suppliers for major equipment (Typically 3 weeks from order) Document counter signed by Labman Technical Director (Ian Riley) Satisfactory FAT completed at the conclusion of the build phase. Invoice 20% payable following Delivery of equipment to NIBSC and the Customer's Sign-Off of the satisfactory FAT 40% payable following the Customer's Sign-Off of the satisfactory completion of SAT
New Project Timeline			<ul style="list-style-type: none"> Design study - estimated 8 weeks Design study sign off period – 2 weeks Main build – estimated 28 weeks This equates to a 38 weeks project timeline, if a PO is transmitted on the week commencing 28 June 2021, that takes us to the early April 2022 for SAT (Includes Labman shutdown, 2 week at Christmas) Labman will not charge NIBSC for storage of the equipment if it was needed to be held until the summer 2022 shutdown.

Annex 4

Specification

TECHNICAL SPECIFICATION

Automated Infectious Filling Line and Blood Tube Labeller

Filling Machine:

The filling machine needs to:

- Accurately deliver biological solutions into 7ml Blood Tubes meeting specification ISO 6710:2017; Single-use containers for human venous blood specimen collection with a CV of 3%
- Have the ability to 'uncap' the tubes if required
- Handle a range of biological media / fluids including Plasma, Blood, Non-viscous Sodium Chloride (NaCl 0.9 %) with a similar viscosity to these fluids
- Fill volumes between 0.25ml – 5ml and recap with a torque 0.5Nm-1.0Nm
- To accommodate a 15L of bulk solution at room temperature 18-22°C
- To stir the bulk solution- or accommodate magnetic stirrer
- To fill between 3,000 and 5,000 blood tubes in 6 hours
- Reject any tube that has no cap, a cap screwed on the wrong way, with the wrong torque or if the liquid fill is missing or incorrect
- Give a yield of 98% acceptable vials compared to the total number presented to the machine
- The machine must be validated to ISO 13485
- Have a counter within the logic control to count the number of vials / tubes processed during a batch. At the end of the batch, the counter will be reset for the start of the next batch. A total counter is also to be provided that counts the number processed since commissioning which will not be re-settable.
- A peristaltic pump/ positive displacement syringe dosing system with disposable feed tubes with a short length to the filling point to minimise loss of product. All parts or tubing that have product contact should be able to withstand sterilisation in an autoclave at 121°C for 20 minutes either for sterilisation before the fill or decontamination after the fill. Disposable systems would be acceptable.
- Dosing Needles, if required, should be removable and able to withstand sterilisation in an autoclave at 121°C for 20 mins. There are to be 3 sets of needles for each size that covers the filling range, disposable systems would be acceptable.
- Dead volumes to be kept to a minimum to avoid wastage of product at the end of a fill. A max of 50 ml hold-up volume is desirable.
- A printable production report should be produced at the end of each production run detailing the date, batch code (input by operator at beginning of run- up to 20 digits and or numbers with forward slash and – options i.e 20/420-002 or QCRURUBlgMQC1), number of tubes filled, number of rejects, start time and end time.
- Fit within the current Class 1 Microbiological Safety Cabinet (MSC) with dimensions 2190mm long and 810mm high with a width of 700mm narrowing to 480mm at the top of the cabinet. The cabinet is housed within room 3.22 in CBRM which is a CL 3 laboratory. A drawing of the existing MSC is provided in **Appendix B** and a drawing showing its position within room 3.22 is provided in **Appendix C**.
- If a replacement MSC is necessary it should fit in the position shown on the plans so that one window and the camera systems must remain unobscured, details to be checked by the contractor. The position of room 3.22 within CBRM is provided in **Appendix D**.
- The filling line is to fit within the existing room without any modifications. If modifications are required then these will need to be discussed with the client and included in the cost of the works.
- Automated decontamination of filled vials / tubes prior to removal from cabinet

- Be able to be fumigated with formaldehyde at room temperature and relative humidity of 80% and will need to be IP 55 rated as a minimum.
- The base of the machine must be flat easy to clean without any holes or crevasses where the biological solutions can enter. The material must be compatible with aggressive sterilisation disinfectants using the following:
 - Formaldehyde
 - Neat Microsol
 - 70% Alcohol
 - Hydrogen Peroxide (H₂O₂)
- The system shall be compliant with Windows 10 and future operating system upgrades
- The system shall be fully updatable and allow for security patches / updates and future releases
- The system shall be encrypted to guard against hacking, could be via SSL secure connection
- The system shall be compatible with Multi Functional Devices (as printers), the site currently uses Canon MFD's -
- Please indicate how the database is stored e.g. servers, cloud etc.
- The PLC/PC is to have open code that can be reprogrammed or adjusted by any PLC/PC technician, a backup of any PLC/PC or logic programs are to be provided.

Spares & Disposal

- Remove and dispose of the present filling line.
- A set of critical spares are to be provided together with a list of critical/ non-critical spares and suppliers details.

Commissioning

FAT to be undertaken using a non-hazardous trehalose solution with the required production rate, yields and tolerance of 4,000 sarstedt blood tubes on at least 3 runs.

Tubes and caps will be supplied FOC to enable machine commissioning and FAT.

SAT to be undertaken using a non-hazardous trehalose solution with the required production rate, yields and tolerance of: 4,000 sarstedt blood tubes on at least 3 runs.

Tubes and caps will be supplied FOC to enable machine commissioning and SAT.

Full training is to be provided to a maximum of 4 operators & 2 maintenance technicians during both FAT & SAT together with a full set of manuals both electronically (Microsoft Word) and in paper form plus parts catalogues.

CE Marking Directive 93/68/EEC

The machine must be fully CE marked to show that it complies with all European and UK regulations including:

- BS7671: Requirements for Electrical Installations, 18th edition by The IET
- Machinery Directive (2006/42/EC)
- Low Voltage Directive (2014/35/EU)
- EMC Directive (2014/30/EU)

Note: the list is not exhaustive and there may be other directives that apply to this project. It is the responsibility of the Manufacturer to identify all regulations and directives that are relevant to this project and ensure full compliance.

In order to show that compliance to all relevant regulations, a Technical File is to be provided with all the appropriate information. If the Vendor resides outside the EEC, they must have an authorised representative within the EEC who acts on behalf of the vendor and may be addressed by authorities and bodies in the Community instead of the Manufacturer with regards to the Directives.

If the Vendor resides within the EEC, then a Technical file must be supplied with machine with the above information that meets UK and EU requirements post Jan 01 2021

Automatic Labelling Machine:

A labelling machine is required to automatically label blood tubes ISO ISO 6710:2017 and will be situated in room 3.27. The labeller needs to be able to accommodate:

- pre-printed and wound onto a roll with an internal diameter of 45mm.
- Labels 60mm x 40mm wound wide side facing
- A labelling speed of at least 4,000 tubes in 6 hours

Annex 5

Key Performance Indicators/Milestones

Phase	Timeline	Agreement	Responsible Person
Design Study	8- weeks	<ul style="list-style-type: none"> • Due in 4 weeks from now. <ol style="list-style-type: none"> 1. Invoice 100% payable following the Customer's Sign-Off of (a) the Design Study and (b) the Supplier's fixed price quote for the main build 2. After Design study completion, Labman will give a fixed price for the main build 3. MHRA Design Study sign off period – 2 weeks. 	<div style="background-color: black; width: 100px; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 100px; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 100px; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 100px; height: 15px; margin-bottom: 5px;"></div>
Automated Filler Line & Labelling System Build	28 weeks	<ul style="list-style-type: none"> • Main build order (Due in 2 weeks from design study sign off) <ol style="list-style-type: none"> a. Invoice 40% payable following the Customer's Sign-Off on: <ol style="list-style-type: none"> i. Labman to supply a **Vesting Certificate that details orders have been placed with suppliers for major equipment (Typically 3 weeks from order) ii. Document counter signed by Labman Technical Director (Ian Riley) iii. Satisfactory FAT completed at the conclusion of the build phase. b. Invoice 20% payable following Delivery of equipment to NIBSC and the Customer's Sign-Off of the satisfactory FAT c. 40% payable following the Customer's Sign-Off of the satisfactory completion of SAT 	<div style="background-color: black; width: 100px; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 100px; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 100px; height: 15px; margin-bottom: 5px;"></div>
Project Conditionalities		<ul style="list-style-type: none"> ○ Design study - estimated 8 weeks ○ Design study sign off period – 2 weeks ○ Main build – estimated 28 weeks ○ This equates to a 38 weeks project timeline, if a PO is transmitted on the week commencing 28 June 2021, that takes us to the early April 2022 for SAT (Includes Labman shutdown, 2 week at Christmas) ○ Labman will not charge NIBSC for storage of the equipment if it was needed to be held until the summer 2022 shutdown. 	