



Medicines & Healthcare products Regulatory Agency

Enbloc Limited

Unit 2
Pale Lane
Hook
Hampshire
RG27 8DH

27th May 2021

Dear Sir,

Award of contract for the supply of [ATD Specialist Cleaning Services - Ref. C35251](#)

Following your tender/ proposal for the supply of Specialist Cleaning Services 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 **Enbloc Limited** 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 the conclusion of the Agreement.

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

- 1) The Services shall be performed at c/o National Institute of Biological Standards and Control, Blanche Lane, South Mimms, Potters Bar, Hertfordshire, EN6 3QG. The customer operates under HTA license number 22502. And as set out in the Purchase Order
- 2) The charges for the Services shall be as set out in your tender submission - [itt_4599](#) and as set out in Annex 2.
- 3) The specification of the Services to be supplied shall be as set out in your tender submission - [itt_4599](#) and as set out in Annex 3.
- 4) The Term shall commence on **2 June 2021** and the Expiry Date shall be **1 June 2023**. The contract may be extended for up to three periods of 12 months at the discretion of the Agency with the agreement of both parties.
- 5) The address for notices of the Parties are:

Procurement

c/o National Institute for Biological Standards and Control

Blanche Lane
South Mimms
Potters Bar
Hertfordshire EN6 3QG

www.gov.uk/mhra

Customer

[REDACTED]

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

[REDACTED]

Supplier

[REDACTED]

Enbloc Limited
Unit 2
Pale Lane
Hook
Hampshire
RG27 8DH

[REDACTED]

Cc
Attention: Procurement

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

E [REDACTED]

6) The following persons are Key Personnel for the purposes of the Agreement:

Customer

[REDACTED]

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

[REDACTED]

Supplier

[REDACTED]

Enbloc Limited
Unit 2
Pale Lane
Hook
Hampshire
RG27 8DH

[REDACTED]

- 7) For the purposes of the Agreement the Staff Vetting Procedures/data security requirements will be applied as stated in section 7 of this document.

8) **Payment**

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

Accounts Payable,
Medicines & Healthcare products Regulatory Agency,
10th floor,
10 south Colonnade
Canary Wharf
London
E14 4PU

[REDACTED]

You must be in receipt of a valid PO Number before submitting an invoice.

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] | [REDACTED] |
| Position | [REDACTED] | [REDACTED] |
| Telephone | [REDACTED] | [REDACTED] |
| Email | [REDACTED] | [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 Services. 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:

Position:

Signature:

Date:

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

Signed for and on behalf of **Enbloc Limited**

Name:

Position:

Signature:

Date:

Annex 1
Terms and Conditions of Contract for Services

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; |
| “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 Services 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 named as Customer in the Award Letter; |
| “Designated Individual (DI)” | means the individual designated on the HTA licence as the person under whose supervision the licensed activity is authorised to be carried on. |
| “DPA” | means the Data Protection Act 1998; |
| “Expiry Date” | means the date for expiry of the Agreement as set out in the Award Letter; |
| “FOIA” | means the Freedom of Information Act 2000; |
| “Information” | has the meaning given under section 84 of the FOIA; |
| “HTA” | means Human Tissue Authority |
| “Key Personnel” | means any persons specified as such in the Award Letter or otherwise notified as such by the Customer to the Supplier in writing; |
| “Party” | means the Supplier or the Customer (as appropriate) and “Parties” shall mean both of them; |
| “Personal Data” | means personal data (as defined in the DPA) which is processed by the Supplier or any Staff on behalf of the Customer pursuant to or in connection with this Agreement; |

| | |
|----------------------------------|---|
| “Purchase Order Number” | means the Customer’s unique number relating to the supply of the Services; |
| “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); |
| “Samples” | means individual items of stem cells that gave their own specific ID |
| “Serious Adverse Event (SAE)” | means any untoward occurrence associated with the procurement, testing, processing, storage and distribution of tissues and cells that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients which might result in, or prolong, hospitalisation or morbidity. |
| “Serious Adverse Reaction (SAR)” | means an unintended response, including communicable disease, in the donor or the recipient associated with the procurement or human application of tissues and cells that is fatal, life-threatening, disabling, incapacitating or which results in, or prolongs, hospitalisation or morbidity. |
| “Services” | means the services to be supplied by the Supplier to the Customer under the Agreement; |
| “Specification” | means the specification for the Services (including as to quantity, description and quality) as specified in the 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; |
| “Supplier” | means the person named as Supplier in the Award Letter; |
| “Term” | means the period from the start date of the Agreement set out in the Award Letter to the Expiry Date as such period may be extended in accordance with clause 4.2 or terminated in accordance with the terms and conditions of the Agreement; |
| “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 Services 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 Services

- 3.1 In consideration of the Customer's agreement to pay the Charges, the Supplier shall supply the Services to the Customer for the Term subject to and in accordance with the terms and conditions of the Agreement.
- 3.2 In supplying the Services, the Supplier shall:
 - 3.2.1 co-operate with the Customer in all matters relating to the Services and comply with all the Customer's instructions;
 - 3.2.2 perform the Services with all reasonable care, skill and diligence in accordance with good industry practice in the Supplier's industry, profession or trade;
 - 3.2.3 use Staff who are suitably skilled and experienced to perform tasks assigned to them, and in sufficient number to ensure that the Supplier's obligations are fulfilled in accordance with the Agreement;
 - 3.2.4 ensure that the Services shall conform with all descriptions and specifications set out in the Specification;
 - 3.2.5 comply with all applicable laws; and
 - 3.2.6 provide all equipment, tools and vehicles and other items as are required to provide the Services.
- 3.3 The Customer may by written notice to the Supplier at any time request a variation to the scope of the Services. In the event that the Supplier agrees to any variation to the scope of the Services, the Charges shall be subject to fair and reasonable adjustment to be agreed in writing between the Customer and the Supplier.

4 Term

- 4.1 The Agreement shall take effect on the date specified in Award Letter and shall expire on the Expiry Date, unless it is otherwise extended in accordance with clause 4.2 or terminated in accordance with the terms and conditions of the Agreement.
- 4.2 The Customer may extend the Agreement for a period of up to 6 months by giving not less than 10 Working Days' notice in writing to the Supplier prior to the Expiry Date. The terms and conditions of the Agreement shall apply throughout any such extended period.

5 Charges, Payment and Recovery of Sums Due

- 5.1 The Charges for the Services 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 Services. 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 performance of the Services.

- 5.2 The Supplier shall invoice the Customer as specified in 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 Services supplied in the invoice period.
- 5.3 In consideration of the supply of the Services by the Supplier, the Customer shall pay the Supplier the invoiced amounts no later than 30 days after receipt of a valid invoice which includes a valid Purchase Order Number. The Customer may, without prejudice to any other rights and remedies under the Agreement, withhold or reduce payments in the event of unsatisfactory performance.
- 5.4 Any invoices for payment submitted by the Supplier will be considered and verified by the Customer in a timely fashion and that undue delay in doing so is not to be sufficient justification for failing to regard an invoice as valid and undisputed.
- 5.5 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 Services.
- 5.6 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 Services unless the Supplier is entitled to terminate the Agreement for a failure to pay undisputed sums in accordance with clause 16.4. Any disputed amounts shall be resolved through the dispute resolution procedure detailed in clause 19.
- 5.7 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.
- 5.8 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.
- 5.9 Any subcontract awarded by the contractor contains suitable provisions to impose, as between the parties to the subcontract—
 - 5.9.1 requirements to the same effect as those which sub-paragraphs 4.3 and 4.4 require to be imposed as between the parties to the public contract; and
 - 5.9.2 a requirement for the subcontractor to include in any subcontract which it in turn awards suitable provisions to impose, as between the parties to that subcontract, requirements to the same effect as those required by this sub-paragraph 5.9.

6 Premises and equipment

- 6.1 If necessary, the Customer shall provide the Supplier with reasonable access at reasonable times to its premises for the purpose of supplying the Services. All equipment, tools and vehicles brought onto the Customer's premises by the Supplier or the Staff shall be at the Supplier's risk.
- 6.2 If the Supplier supplies all or any of the Services at or from the Customer's premises, on completion of the Services or termination or expiry of the Agreement (whichever is the earlier) the

Supplier shall vacate the Customer's premises, remove the Supplier's plant, equipment and unused materials and all rubbish arising out of the provision of the Services and leave the Customer's premises in a clean, safe and tidy condition. The Supplier shall be solely responsible for making good any damage to the Customer's premises or any objects contained on the Customer's premises which is caused by the Supplier or any Staff, other than fair wear and tear.

- 6.3 If the Supplier supplies all or any of the Services at or from its premises or the premises of a third party, the Customer may, during normal business hours and on reasonable notice, inspect and examine the manner in which the relevant Services are supplied at or from the relevant premises.
- 6.4 The Customer shall be responsible for maintaining the security of its premises in accordance with its standard security requirements. While on the Customer's premises the Supplier shall, and shall procure that all Staff shall, comply with all the Customer's security requirements.
- 6.5 Where all or any of the Services are supplied from the Supplier's premises, the Supplier shall, at its own cost, comply with all security requirements specified by the Customer in writing.
- 6.6 Without prejudice to clause 3.2.6, any equipment provided by the Customer for the purposes of the Agreement shall remain the property of the Customer and shall be used by the Supplier and the Staff only for the purpose of carrying out the Agreement. Such equipment shall be returned promptly to the Customer on expiry or termination of the Agreement.
- 6.7 The Supplier shall reimburse the Customer for any loss or damage to the equipment (other than deterioration resulting from normal and proper use) caused by the Supplier or any Staff. Equipment supplied by the Customer shall be deemed to be in a good condition when received by the Supplier or relevant Staff unless the Customer is notified otherwise in writing within 5 Working Days.

7 Staff and Key Personnel

- 7.1 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:
 - 7.1.1 refuse admission to the relevant person(s) to the Customer's premises;
 - 7.1.2 direct the Supplier to end the involvement in the provision of the Services of the relevant person(s); and/or
 - 7.1.3 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.
- 7.2 The Supplier shall:
 - 7.2.1 ensure that all Staff are vetted in accordance with the Staff Vetting Procedures;
 - (i) All contractors working on the South Mimms site must have a Baseline Personal Security Standard (BPSS) check, this must be carried out via NIBSC/MHRA. If the check results in security concerns being raised, NIBSC reserve the right to refuse access and request alternative staff.
 - 7.2.2 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
 - 7.2.3 procure that all Staff comply with any rules, regulations and requirements reasonably specified by the Customer.

- 7.3 Any Key Personnel shall not be released from supplying the Services without the agreement of the Customer, except by reason of long-term sickness, maternity leave, paternity leave, termination of employment or other extenuating circumstances.
- 7.4 Any replacements to the Key Personnel shall be subject to the prior written agreement of the Customer (not to be unreasonably withheld). Such replacements shall be of at least equal status or of equivalent experience and skills to the Key Personnel being replaced and be suitable for the responsibilities of that person in relation to the Services.

8 Assignment and sub-contracting

- 8.1 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.
- 8.2 Where the Supplier enters into a sub-contract for the purpose of performing its obligations under the Agreement, it shall ensure that a provision is included in such sub-contract which requires payment to be made of all sums due by the Supplier to the sub-contractor within a specified period not exceeding 30 days from the receipt of a valid invoice.
- 8.3 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.
- 8.4 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.

9 Intellectual Property Rights

- 9.1 All intellectual property rights in any materials provided by the Customer to the Supplier for the purposes of this Agreement shall remain the property of the Customer but the Customer hereby grants the Supplier a royalty-free, non-exclusive and non-transferable licence to use such materials as required until termination or expiry of the Agreement for the sole purpose of enabling the Supplier to perform its obligations under the Agreement.
- 9.2 All intellectual property rights in any materials created or developed by the Supplier pursuant to the Agreement or arising as a result of the provision of the Services shall vest in the Supplier. If, and to the extent, that any intellectual property rights in such materials vest in the Customer by operation of law, the Customer hereby assigns to the Supplier by way of a present assignment of future rights that shall take place immediately on the coming into existence of any such intellectual property rights all its intellectual property rights in such materials (with full title guarantee and free from all third party rights).
- 9.3 The Supplier hereby grants the Customer:
 - 9.3.1 a perpetual, royalty-free, irrevocable, non-exclusive licence (with a right to sub-license) to use all intellectual property rights in the materials created or developed pursuant to the Agreement and any intellectual property rights arising as a result of the provision of the Services; and

9.3.2 a perpetual, a royalty-free, irrevocable and non-exclusive licence (with a right to sub-license) to use:

- (a) any intellectual property rights vested in or licensed to the Supplier on the date of the Agreement; and
- (b) any intellectual property rights created during the Term but which are neither created or developed pursuant to the Agreement nor arise as a result of the provision of the Services,

(including any modifications to or derivative versions of any such intellectual property rights which the Customer reasonably requires in order to exercise its rights and take the benefit of the Agreement including the Services provided.)

9.4 The Supplier shall indemnify, and keep indemnified, the Customer in full against all costs, 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 Services, to the extent that the claim is attributable to the acts or omission of the Supplier or any Staff.

10 Governance and Records

10.1 The Supplier shall:

- 10.1.1 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
- 10.1.2 submit progress reports to the Customer at the times and in the format specified by the Customer.

10.2 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 Services 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.

11 Confidentiality, Transparency and Publicity

11.1 Subject to clause 11.2, each Party shall:

- 11.1.1 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
- 11.1.2 not use or exploit the disclosing Party's Confidential Information in any way except for the purposes anticipated under the Agreement.

11.2 Notwithstanding clause 11.1, a Party may disclose Confidential Information which it receives from the other Party:

- 11.2.1 where disclosure is required by applicable law or by a court of competent jurisdiction;

- 11.2.2 to its auditors or for the purposes of regulatory requirements;
- 11.2.3 on a confidential basis, to its professional advisers;
- 11.2.4 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;
- 11.2.5 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 11.2.5 shall observe the Supplier's confidentiality obligations under the Agreement; and
- 11.2.6 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 12.

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 11.

- 11.3 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 this 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.
- 11.4 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.

12 Freedom of Information

- 12.1 The Supplier acknowledges that the Customer is subject to the requirements of the FOIA and the Environmental Information Regulations 2004 and shall:
 - 12.1.1 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;
 - 12.1.2 transfer to the Customer all Requests for Information relating to this Agreement that it

receives as soon as practicable and in any event within 2 Working Days of receipt;

- 12.1.3 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
- 12.1.4 not respond directly to a Request for Information unless authorised in writing to do so by the Customer.
- 12.2 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 Services (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.
- 12.3 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 Services is exempt from disclosure in accordance with the FOIA and/or the Environmental Information Regulations 2004.

13 Protection of Personal Data and Security of Data

- 13.1 The Supplier shall, and shall procure that all Staff shall, comply with any notification requirements under the DPA and both Parties shall duly observe all their obligations under the DPA which arise in connection with the Agreement.
- 13.2 Notwithstanding the general obligation in clause 13.1, where the Supplier is processing Personal Data for the Customer as a data processor (as defined by the DPA) the Supplier shall:
 - 13.2.1 ensure that it has in place appropriate technical and organisational measures to ensure the security of the Personal Data (and to guard against unauthorised or unlawful processing of the Personal Data and against accidental loss or destruction of, or damage to, the Personal Data), as required under the Seventh Data Protection Principle in Schedule 1 to the DPA;
 - 13.2.2 provide the Customer with such information as the Customer may reasonably request to satisfy itself that the Supplier is complying with its obligations under the DPA;
 - 13.2.3 promptly notify the Customer of:
 - (a) any breach of the security requirements of the Customer as referred to in clause 13.3; and
 - (b) any request for personal data; and
 - 13.2.4 ensure that it does not knowingly or negligently do or omit to do anything which places the Customer in breach of the Customer's obligations under the DPA.
- 13.3 When handling Customer data (whether or not Personal Data), the Supplier shall ensure the security of the data is maintained in line with the security requirements of the Customer as notified to the Supplier from time to time.

14 Liability

- 14.1 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.
- 14.2 Subject always to clauses 14.3 and 14.4:
- 14.2.1 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 Services, 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
 - 14.2.2 except in the case of claims arising under clauses 9.4 and 18.3, in no event shall the Supplier be liable to the Customer 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.
- 14.3 Nothing in the Agreement shall be construed to limit or exclude either Party's liability for:
- 14.3.1 death or personal injury caused by its negligence or that of its Staff;
 - 14.3.2 fraud or fraudulent misrepresentation by it or that of its Staff; or
 - 14.3.3 any other matter which, by law, may not be excluded or limited.
- 14.4 The Supplier's liability under the indemnity in clause 9.4 and 18.3 shall be unlimited.

15 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 Supplier. 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 two months, either Party may terminate the Agreement by written notice to the other Party.

16 Termination

- 16.1 The Customer may terminate the Agreement at any time by notice in writing to the Supplier to take effect on any date falling at least 1 month (or, if the Agreement is less than 3 months in duration, at least 10 Working Days) later than the date of service of the relevant notice.
- 16.2 Without prejudice to any other right or remedy it might have, the Customer may terminate the Agreement by written notice to the Supplier with immediate effect if the Supplier:
- 16.2.1 (without prejudice to clause 16.2.5), is in material breach of any obligation under the

- Agreement which is not capable of remedy;
- 16.2.2 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;
 - 16.2.3 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;
 - 16.2.4 undergoes a change of control within the meaning of section 416 of the Income and Corporation Taxes Act 1988;
 - 16.2.5 breaches any of the provisions of clauses 7.2, 11, 12, 13 and 17; or
 - 16.2.6 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 16.2.6) in consequence of debt in any jurisdiction.
- 16.3 The Supplier shall notify the Customer as soon as practicable of any change of control as referred to in clause 16.2.4 or any potential such change of control.
- 16.4 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.
- 16.5 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 this clause and clauses 2, 3.2, 6.1, 6.2, 6.6, 6.7, 7, 9, 10.2, 11, 12, 13, 14, 16.6, 17.4, 18.3, 19 and 20.7 or any other provision of the Agreement that either expressly or by implication has effect after termination.
- 16.6 Upon termination or expiry of the Agreement, the Supplier shall:
- 16.6.1 give all reasonable assistance to the Customer and any incoming supplier of the Services; and
 - 16.6.2 return all requested documents, information and data to the Customer as soon as reasonably practicable.

17 Compliance

- 17.1 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.
- 17.2 The Supplier shall:
- 17.2.1 comply with all the Customer's health and safety measures while on the Customer's premises; and
 - 17.2.2 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.

17.3 The Supplier shall:

17.3.1 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; and

17.3.2 take all reasonable steps to secure the observance of clause 17.3.1 by all Staff.

17.4 The Supplier shall supply the Services in accordance with the Customer's environmental policy as provided to the Supplier from time to time.

17.5 The Supplier shall comply with, and shall ensure that its Staff shall comply with, the provisions of:

17.5.1 the Official Secrets Acts 1911 to 1989; and

17.5.2 section 182 of the Finance Act 1989.

18 Prevention of Fraud and Corruption

18.1 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.

18.2 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.

18.3 If the Supplier or the Staff engages in conduct prohibited by clause 18.1 or commits fraud in relation to the Agreement or any other contract with the Crown (including the Customer) the Customer may:

18.3.1 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 Services and any additional expenditure incurred by the Customer throughout the remainder of the Agreement; or

18.3.2 recover in full from the Supplier any other loss sustained by the Customer in consequence of any breach of this clause.

19 Dispute Resolution

19.1 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.

19.2 If the dispute cannot be resolved by the Parties within one month of being escalated as referred to in clause 19.1, 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.

19.3 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.

20 General

- 20.1 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.
- 20.2 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.
- 20.3 The Agreement cannot be varied except in writing signed by a duly authorised representative of both the Parties.
- 20.4 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.
- 20.5 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.
- 20.6 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.
- 20.7 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.
- 20.8 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.

21 Notices

- 21.1 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 21.3, 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:
- 21.2 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.
- 21.3 Notices under clauses 15 (Force Majeure) and 16 (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 21.1.

22 Governing Law and Jurisdiction

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 Charges

| Item | Cost Per Clean | Total Cost for 2 Years |
|-------------------------------|----------------|------------------------|
| Monthly and Bi-Annual Cleans: | | £48,240.00 |



V1837 NIBSC 2 Year
Deep Cleaning Agree

DEEP CLEANING

Enbloc Ltd will provide NIBSC with fully trained deep cleaning technicians and supervisory staff, responsible for the following deep cleaning processes in line with the Proposed Deep Cleaning Schedule in Appendix 1:

Table 1a – Cleaning Requirements 2021 and 2022

| Cleaning Type | Number of Cleans P.A | Cleaning Process | Step | Areas |
|---|----------------------|---|------|--|
| Weekly Clean Cleanroom 5 Only | 10 | 70% IPA Klerwipe 70/30 IPA Mop Wipe | 1 | Surfaces, Equipment, Class II MSC's, Pass Through Hatches |
| | | Klerwipe Sporidical Low Residue Quat Mop Wipe | 2 | Floors |
| | | 70% IPA Klerwipe 70/30 IPA Mop Wipe | 3 | Floors |
| Monthly Clean Cleanroom 1 and 5 | 9 | 70% IPA Klerwipe 70/30 IPA Mop Wipe | 1 | Surfaces, Equipment, Class II MSC's, Pass Through Hatches |
| | | Klerwipe Sporidical Enhances Low Residue Peroxide Mope Wipe | 2 | Floors and Walls |
| | | 70% IPA Klerwipe 70/30 IPA Mop Wipe | 3 | Floors and Walls |
| Monthly Clean (post shutdown only) Cleanroom 1,2,3,4 and 5 | 2 | 70% IPA Klerwipe 70/30 IPA Mop Wipe | 1 | Surfaces, Equipment, Class II MSC's, Pass Through Hatches, inside cupboards, Fridges and Freezer |
| | | Sporidical Enhanced Peroxide | 2 | Floors and Walls |

| | | | | |
|----------------------------|---|---|---|--|
| | | 70% IPA Klerwipe 70/30 IPA Mop Wipe | 3 | Floors and Walls |
| Bi-Annual (every 6 months) | 2 | 70% IPA Klerwipe 70/30 IPA Mop Wipe | 1 | Surfaces, Equipment, Class II MSC's, Pass Through Hatches, inside cupboards, Fridges and Freezer |
| | | Sporicidal Enhanced Peroxide | 2 | Floors and Walls |
| | | 70% IPA Klerwipe 70/30 IPA Mop Wipe | 3 | Floors and Walls |

Supply training Deep Cleaning technicians to complete the following rooms in line with table 1A

Bi Weekly Deep Clean Cleanroom 5:

- Change 1
- Change 2
- Clean Corridor
- CC Lobby
- Cleanroom 5
- Cleanroom 5 associated Change “3”

Monthly Deep Clean Cleanroom 5 and 1

- Change 1
- Change 2
- Clean Corridor
- CC Lobby
- Cleanroom 1 and 5
- Cleanroom 1 and 5 associated Change “3”

“Monthly” Deep Clean (Post Shutdown Only) All Cleanrooms

- Change 1
- Change 2
- Clean Corridor
- CC Lobby
- Cleanroom 1, 2, 3, 4 and 5
- Cleanroom 1, 2, 3, 4 and 5's associated Change “3”

Bi-annual Deep Clean (Post Shutdown)

- Change 1
- Change 2
- Clean Corridor
- CC Lobby
- Cleanroom 1, 2, 3, 4 and 5
- Cleanroom 1, 2, 3, 4 and 5's associated Change “3”

Annex 3

Service Specification:

| | |
|---|---|
| Procurement | |
| Testing service that affect quality or safety | |
| Distribution | |
| Import | |
| Export | |
| Supply of goods | |
| Service that affect quality or safety | x |
| Calibration or maintenance service | |
| Other (please specify) | |

Human embryonic stem cell lines (hESCs) produced by the Customer are intended to be used in the clinical applications. According to HTA regulations the cell banking activities of hESCs must take place in the cleanroom laboratory in which the level of particulate and microbial contamination is strictly controlled. In order to minimise the risk of particulate or microbiological contamination of hESCs resulting from airborne and surface contaminants cleanroom facility must be cleaned on the regular basis following validated cleaning procedures. The cleaning services shall be performed in accordance to the Specifications and the Customer requirements.

Specifications

The Services provided by the Supplier shall be in accordance with:

The Human Tissue (Quality & Safety for Human Application) Regulations 2007 (as amended)

&

Human Tissue Authority Directions 001/2021 (as amended), and the 'HTA Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment', herein referred to as The Guide.

Responsibilities of the Supplier

1. The Supplier must not subcontract cleaning services to another service provider without the Customer written agreement.
2. The Supplier must deploy sufficient number of appropriately trained staff to perform cleaning of Customer facility within one working day. The cleaning activities must take place on Monday afternoons (or Tuesday afternoon in case of Bank Holidays).
3. All cleaning services performed by the Supplier must be carried out by suitably qualified and trained staff. The Supplier training program should cover operator hygiene, behaviour and correct working practices in GMP compliant cleanrooms.
4. Entry into the Customer cleanroom facility is only authorised to the Supplier staff who have undertaken training provided by the Customer. Training must cover:

- UKSCB Cleanroom Entry & Exit procedure
 - Operators Gowning procedure
 - UKSCB Cleanroom cleaning procedure
 - Waste disposal procedure
 - How to document cleaning activities in the cleaning log books
5. All cleaning services must be performed in accordance to the Customer cleaning procedures. All site health and safety rules must be adhered to including any government guidance in place at the time of entry to site i.e. social distancing
 6. The Supplier must follow the Customer cleaning schedule which specifies rotational disinfectant use. The cleaning agents provided by the Customer must be used at all times. The Supplier must ensure that disinfectants used during cleaning services are not beyond the expiry date.
 7. All cleaning activities including the cleaning agents used must be documented by the Supplier using Customer cleaning logs. The supplier Clean Team Leader will register with a member of the UKSCB team on arrival at the facility to collect the logbook and will hand the log book back for review by a UKSCB staff member before leaving the site.
 8. The Supplier Clean Team Leader must inform the Customer (UKSCB Production Manager or designee) of any issues found that impacted in the cleaning activity on exiting the cleanrooms.
 9. Only sterile garments that are compliant with GMP Grade B cleanroom environment must be used by the Supplier as supplied by the customer.
 10. The Supplier Clean Team Leader must inform the Customer (UKSCB Production Manager) of any issues related to the Supplier staff health.
 11. The Service Provider must work with the UKSCB production team in investigation of environmental monitoring warning / limit breaches including participating in any corrective / preventative actions that may arise from an investigation if required.
 12. Any SAE/SARs that could potentially affect cleaning services must be reported to the customer within one business day.

Responsibilities of the Customer

1. The Customer must allow the Supplier to access cleanroom facility.
2. The Customer must provide all relevant training to the Supplier staff.
3. The Customer must notify the Supplier in case there are any changes to the Customer cleaning procedure. Training (if needed) must be provided by the Customer.
4. The Customer must provide sufficient stock of cleaning agents and sterile cleanroom garments to be used by the Supplier.
5. The Customer must notify the Supplier in advance if any additional cleaning services are required.

6. The Customer shall monitor the disinfection effectiveness. The Supplier will be notified by the Customer in the event of an environmental monitoring breach. Additional training might be provided to the Supplier staff if deemed to be necessary and spot checks of cleaning technique may be carried out at any time. Where there is a continuous failure of effective disinfection, the Customer may terminate the Agreement in accordance with clause 16 of the Conditions.
7. Any SAE/SARs must be reported to the HTA by the Customer within 24 hours of occurrence. Any SAE/SARs that could potentially affect cleaning services must be reported to the Supplier within one business day.
8. The Customer must notify the suppliers of any issues that they are aware of that may impact on the cleaning preferably before the scheduled visit but at least on the arrival of the Cleaning team on site before they enter the cleanroom facility.

Responsibilities of the Parties

1. Communication on all matters relating to this Agreement shall take place between Supplier principle contact (Mr. Ryan Keyes) and persons designated by the Customer. An authorised users list will specify these designated persons.
2. Any changes or amendments to the Agreement must be in writing and signed by the two parties.

Complaints

1. The Supplier will provide all necessary information to the Customer without delay.
2. The Supplier will log all complaints and together with the Customer instigate a thorough investigation as per written procedures.

Documentation

1. The Supplier is responsible for maintaining a full and complete set of operational documentation. Upon request the Supplier will forward documentation relevant to the Services to the Customer for their records.

Quality Requirements for the Service

1. The provision of cleaning services must be carried out by the Supplier who has provided evidence that they have suitable specialist experience and where appropriate are licenced by a competent national authority. The Customer must be informed immediately in the event of the license suspension or termination. Copies of Certificates of Registration must be provided to the Customer if applicable.
2. The Supplier must have an organizational structure and operational procedures appropriate for the activities being undertaken. There must be an organizational chart which defines accountability and reporting relationships.
3. Wristwatches, personal mobile phones, make-up and jewellery must not be worn by the Supplier staff in the Customer cleanroom facility.
4. Eating, drinking, chewing or smoking, or the storage of food, drink, smoking materials or any personal medication in the Customer cleanroom facility is prohibited. The Supplier staff must adhere to this rule.
5. High standards of personal hygiene and cleanliness must be maintained by the Supplier staff. The Supplier must have system in place (e.g. periodic health checks) to assure that personnel involved in the cleaning services are fit to do so.
6. The Supplier staff with health issues such as skin condition (e.g. eczema, psoriasis, cold sore or open lesions on the exposed skin surface) or infectious diseases (e.g. common flu or chest infections, etc.) must not enter the Customer cleanrooms.

Deviations

1. Any deviations to the Customer cleaning procedure must be notified immediately to the Customer (Production Manager).
2. In the event that additional corrective / preventative actions are required, the planned course of action must be agreed between the Customer and the Supplier.

Review

1. Any changes or amendments will be subject to the issue of a new revision of this agreement. All revisions must be signed and dated by all parties prior to becoming effective.
2. The Customer shall monitor all service level agreements to ensure satisfactory performance. Monitoring may lead to a review of the agreement.
3. The Customer shall review all service level agreements on biannual basis. The persons responsible for review are: UKSCB Quality Coordinator and Production Manager
4. This Agreement may be re-negotiated following a review.

General Adherence to Human Tissue Act Requirements

1. The Supplier will meet the requirements of the licence held by the Customer for the carrying on of the Services.
2. Both the Parties confirm they are independent entities which have entered into a contract for the carrying of the Services described above.
3. The Customer confirms that it has evaluated and selected the Supplier on the basis of their ability to meet the requirements of the HTA licence and The Guide.
4. The Customer confirms that it has considered whether there are any specific criteria that the Supplier is required to meet in relation to quality and safety.
5. The Supplier confirms that it is able to meet the requirements of the HTA licence in relation to the Services

Copy sent to HTA on date:

Annex 1

Enbloc Quality Questionnaire



Enbloc Completed
Quality Questionnaire.