Licence application assessment report on compliance with HTA licensing standards
Site visit date: **7 February 2025**

# Moderna Biotech Manufacturing UK Ltd

Proposed HTA licensing number 12789

Application to be licensed under the Human Tissue Act 2004

**Activities**

| Premises/area | Storage of relevant material which has come from a human body for use for a scheduled purpose | Removal from the body of a deceased person (otherwise than in the course of an anatomical examination or post-mortem examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation |
|---|---|---|
| **Moderna Innovation and Technology Centre (MITC)** | Application made | Application not made |

## Summary of findings

The HTA found the proposed Designated Individual (DI) and the proposed Licence Holder (LH) to be suitable in accordance with the requirements of the legislation.

Although the HTA found that Moderna Biotech Manufacturing UK Ltd ('the establishment') had met the majority of the HTA's standards, one minor shortfall was found against Governance and quality systems in relation to risk assessments.

The HTA has assessed the establishment as suitable to be licensed for the activities specified, subject to corrective and preventative actions being

implemented to meet the shortfalls identified during the assessment.

**Compliance with HTA standards**

***Minor Shortfalls***

| Standard | Assessment findings | Level of shortfall |
|---|---|---|
| **GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored** | | |
| a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice. | At the time of the assessment, the establishment did not have a completed risk register of risks associated with HTA-licensable activities.<br><br>*"The establishment submitted sufficient evidence to address this shortfall before the report was finalised."* | **Minor** |

**Advice**

The HTA advises the proposed DI to consider the following to further improve practices:

| Number | Standard | Advice |
|---|---|---|
| 1. | C1(a) | The establishment will act as a research sponsor for clinical trials, with NHS sites participating. The establishment has consent-related templates that will be adapted by local sites who will have responsibility for seeking consent from research participants, including sample donors. Although these samples will be collected |

| | | |
|---|---|---|
| | | under the governance of HRA approval, once this approval comes to an end, any remaining samples will need be stored under the governance of the establishment's HTA licence if associated donor consent permits. The prospective DI is advised to introduce safeguards to ensure that samples from clinical trials that have ended can only be stored for futher research with the appropriate consent. |
| 2. | GQ5(b) | The establishment has in place a Human Tissue Authority manual. This document provides detail on the reporting of adverse events relating to human tissue. The DI should consider adding further detail to the manual about how actions are expected to be followed up after an incident occurs. |
| 3. | T2(b) | The establishment will use a disposal form which will document the reason, method and date of disposal. The establishment is then required to document disposal on the local database as a free text entry. The DI should consider defining disposal reasons in a documented procedure, to ensure a consistent approach is used when staff update the database. |

**Background**

The establishment is a pharmaceutical and biotechnology company that focusses on RNA therapeutics. The establishment will act as a sponsor for clinical trials, with collaborating sites involved in seeking consent. Clinical sites will collect samples and send these to the establishment for storage and processing. The establishment plans to operate a research tissue bank in the future.

**Description of activities undertaken**

The HTA's regulatory requirements are set out in Appendix 1. The Regulation Manager covered the following areas during a desk based assessment and site visit:

*Standards assessed*

Of the 47 HTA licensing standards were covered during the assessment (standards published 3 April 2017) 39 were assessed. C1(e) and (f) and C2(a),(b) and (c) were not applicable as the establishment is not involved in seeking consent. PFE2(b) is not applicable at the establishment will not be storing material from the deceased.

*Review of governance documentation*

Local policies and procedural documents relating to licensed activities, contracts for servicing of equipment and records of servicing, audits, risk assessments, reported incidents, meeting minutes, temperature monitoring for the storage units, and staff training records were reviewed.

*Visual inspection*

The visual inspection comprised of reviewing sample storage areas. At the time of the visit, the ‘goods in’ area where sample receipt would take place was not accessible due to ongoing construction work; however, a discussion took place on the responsibilities of staff receiving samples.

*Meetings with establishment staff*

A roundtable meeting was held with the prospective DI, Persons Designated (PDs) and staff supporting the application process.

**Report sent to proposed DI for factual accuracy: 24 February 2025**

**Report returned from proposed DI: 28 February (with comments)**

**Final report issued: 11 March 2025**

**Appendix 1: The HTA's regulatory requirements**

Prior to the grant of a licence, the HTA must assure itself that the DI is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

The statutory duties of the DI are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity, and;
- the conditions of the licence are complied with.

Its programme of inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. They are grouped under four headings:

- consent;
- governance and quality systems;
- traceability, and;
- premises facilities and equipment.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that there has been a shortfall against a standard, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is provided.

HTA inspection reports are published on the HTA's website.

**Appendix 2: Classification of the level of shortfall**

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as ‘Critical’, ‘Major’ or ‘Minor’. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the Human Tissue Act 2004 (HT Act) or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the HT Act or associated Directions

   *or*

   A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

   A critical shortfall may result in one or more of the following:

   - A notice of proposal being issued to revoke the licence;
   - Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented;
   - A notice of suspension of licensable activities;
   - Additional conditions being proposed, or;
   - Directions being issued requiring specific action to be taken straightaway.

2. **Major shortfall:**

   A non-critical shortfall that:

   - poses a risk to human safety and/or dignity, or;
   - indicates a failure to carry out satisfactory procedures, or;
   - indicates a breach of the relevant Codes of Practice, the HT Act and other relevant professional and statutory guidelines, or;

- has the potential to become a critical shortfall unless addressed.

*or*

A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. **Minor shortfall:**

A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based review or at the time of the next site visit.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

**Follow up actions**

A template corrective and preventative action plan will be sent as a separate Word document with the final inspection report. Establishments must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up inspection;
- a request for information that shows completion of actions;
- monitoring of the action plan completion, or;
- follow up at next routine inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.