Inspection report on compliance with HTA licensing standards
Inspection date: **7 September 2026**

MDNA Life Sciences UK Ltd

HTA licensing number 12631

Licensed under the Human Tissue Act 2004

Licensed activities

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
MDNA Life Sciences UK Ltd	Licensed	Not licensed

Summary of inspection findings

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

Although the HTA found that MDNA Life Sciences UK Ltd ('the establishment') had met the majority of the HTA's standards, two minor shortfalls were found against Consent and Traceability standards. These related to the absence of documented consent procedures and incomplete disposal records.

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 inspection.

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice		
a) Consent procedures are documented and these, along with any associated documents, comply with the HT Act and the HTA's Codes of Practice	The establishment does not obtain consent directly; however, there was no documented policy or procedure/s for existing arrangements to verify consent obtained for samples received from third parties, including how they assure themselves that samples have been obtained in accordance with the requirements of the HT Act and HTA's Codes of Practice.	**Minor**
T2 Bodies and human tissue are disposed of in an appropriate manner		
b) The date, reason for disposal and the method used are documented	Disposal records were reviewed, and although it was detailed that samples had been disposed of, the date of disposal and reason for disposal were not documented.	**Minor**

Advice

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

Number	Standard	Advice
1.	GQ3(a)	There is currently no HTA-specific training identified within the establishment's training matrix. The DI is advised to review the matrix and, where appropriate, include HTA-specific training. The DI is also advised to incorporate relevant HTA Codes of Practice into staff training and induction procedures to enhance staff awareness and understanding of the regulatory requirements.

2.	T1(c)	To ensure that staff are aware of the necessity to maintain sample quality, safety and security, the DI is advised to consider improving signs on the freezers, highlighting that human samples are contained within.
3.	N/A	Due to the low levels of licensable activity being carried out, there are currently no Persons Designated (PDs) supporting the DI in their role. The DI is advised to review this position should levels of activity and number of staff involved in licensable activity increase.

Background

MDNA Life Sciences UK Ltd has been licensed by the HTA since February 2015. This was the third inspection of the establishment; the most recent assessment was an Evaluated Self-Assessment (ESA), which took place in October 2023.

Since the previous assessment, there have been no significant changes to the licence arrangements.

Description of inspection activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The Regulation Manager covered the following areas during the inspection:

Standards assessed against during inspection

39 of 47 HTA licensing standards were covered during the inspection (standards published 3 April 2017). Standards relating to consent (C1(b), C1(d), C1(e), C1(f), C2(a), C2(b) and C2(c)) were not applicable as the establishment does not directly take consent from donors. PFE2(b) was not relevant as the establishment does not store deceased donors.

Review of governance documentation

Policies and procedural documents relating to all licensed activities, including standard operating procedures (SOPs) were reviewed. Documents detailing internal audits, risk assessments, meeting minutes, incidents and the staff training matrix were also reviewed.

Visual inspection

There was no site visit inspection associated with the assessment although images of the premises, facilities and equipment were reviewed.

Audit of records
There was no site visit associated with this assessment; however, the establishment's annual audit reports were reviewed and no discrepancies were identified. During the virtual assessment, the sample traceability database was examined. It was noted that disposal activities were not documented in accordance with HTA standards (see shortfall under Standard T2(b)).

Meetings with establishment staff
The assessment included a meeting with the Chief Scientific Officer, who holds the position of DI.

Report sent to DI for factual accuracy: 16 September 2026

Report returned from DI: No factual accuracy or request for redaction comments were made by the DI

Final report issued: 22 September 2026

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 26 October 2026

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
- 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
   - 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 inspection.

   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
- 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.