

Licence application assessment report on compliance with HTA licensing standards
Assessment dates: **17 February (remote) 20 February (site visit) 2025**



**Astellas Engineered
Small Molecules UK Ltd**
Proposed HTA licensing number 12798

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
Astellas Engineered Small Molecules UK Ltd CB1 3LQ	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 Astellas Engineered Small Molecules UK Ltd ('the establishment') had met the majority of the HTA's standards, one minor shortfall was found against standards for Governance and quality systems.

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
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills		
a) Qualifications of staff and all training are recorded, records showing attendance at training.	<p>The establishment did not have training records available for staff. There was no documented evidence of staff qualifications or attendance at relevant training sessions.</p> <p><i>The establishment submitted sufficient evidence to address this shortfall before the report was finalised.</i></p>	Minor

Advice

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

Number	Standard	Advice
1.	T1(b)	At the time of inspection, the establishment experienced internet service disruptions, preventing access to the updated register of all materials. The proposed DI is advised to consider implementing contingency measures,

		such as maintaining a locally accessible backup of the register, to ensure uninterrupted access to traceability records in case of system failures.
2.	PFE2(c)	The proposed DI is advised to implement a process to regularly test and periodically manually challenge fridges and freezers temperature alarms to provide an assurance that they are operating as expected

Background

The establishment is a pharmaceutical research organisation specialising in drug discovery, focusing on the development of novel medicines. It conducts research using human tissues and cells to advance therapeutic innovation through collaboration with commercial suppliers, biobanks, and academic partners.

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

There are 47 standards in the Research sector, of which 40 were assessed (standards published 3 April 2017). Standards C1(d)(e) and (f) and Standards C2(a)(b) and (c) were not applicable because the establishment will not be seeking consent. Standard PFE2(b) could not be assessed as the establishment does not intend to store bodies or body parts.

Review of governance documentation

A review of policies and procedural documents relating to licensable activities, records of servicing, audit procedures, risk assessments, incident reporting, temperature monitoring for the storage units and staff training records was carried out.

Visual inspection

An inspection of the storage areas was undertaken at the time of the licence application assessment visit. The facility was accessible by access card only and had appropriate temperature monitoring in place

Meetings with establishment staff

A roundtable discussion was carried out with the proposed Designated Individual (DI) , Facilities and Laboratories Lead, Senior Scientist and a member of staff taking on the role of Person Designated (PD).

Report sent to proposed DI for factual accuracy: 10 March 2025

Report returned from proposed DI: 10 March 2025

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.