Licence application assessment report on compliance with HTA licensing standards
Site visit date: **20 December 2024**

Yellowstone Biosciences Ltd

Proposed HTA licensing number 12792

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
Oxford Business Park South OX4 2GX	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 Yellowstone Biosciences Ltd ('the establishment') had met the majority of the HTA's standards, two minor shortfalls were found against standards for Governance and quality systems. The shortfalls related to the management of complaints and audit findings.

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.

Compliance with HTA standards
Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process		
e) There is a system for managing complaints	The establishment did not have a documented complaints policy in place to manage complaints relevant to HTA-licensed activities *"The establishment submitted sufficient evidence to address this shortfall before the report was finalised."*	**Minor**

GQ2 There is a documented system of audit		
b) Audit findings include who is responsible for follow-up actions and the timeframes for completing these	The establishment's approach to audit did not include how audit findings would be managed in accordance with this standard and there were no supporting documents or templates. *"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.	GQ1(b)	The establishment has several SOPs, with the current review period set to two years. As the establishment is newly operational, some SOPs may require review sooner or more frequently than currently specified. The proposed DI is advised to consider creating an index document that lists all the SOPs along with their next review dates. This should provide clear oversight of when each SOP is due for review and support management of the document control system. The index may help maintain compliance with the standards, supporting timely reviews and updates.
2.	T1(a)	The establishment assigns unique codes to each donation, ensuring traceability. However, to strengthen the system, the proposed DI is advised to update the SOP to include procedures for labeling aliquots, ensuring all derived products are traceable.
3.	PFE2(c)	The proposed DI is advised to display the defined temperature range for storage on LN2 and freezers where relevant material will be stored. This would provide staff with ready access to important information, supporting the maintenance of storage conditions to preserve the integrity and viability of the stored material.

Background

The establishment is a biotechnology company specialising in developing T-cell receptor-based therapeutics for oncology, targeting tumour cells. It focuses on advancing cancer treatment through innovative research and collaboration.

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) and members of staff taking on the role of Persons Designated (PD)

Report sent to proposed DI for factual accuracy: 03 January 2025

Report returned from proposed DI: 07 January 2025

Final report issued: 07 January 2025

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: 3 January 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.