Licence application assessment report on compliance with HTA licensing standards
Site visit date: **20 October 2023**

Alchemab Therapeutics Ltd

Proposed HTA licensing number 12760

Application for a licence under the Human Tissue Act 2004

Activities applied to be licensed

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
Hub site **Alchemab Therapeutics Ltd**	Applied to be licensed	Not applied to be licensed
Satellite site **1 Lion Works Business Park, Whittlesford**	Applied to be licensed	Not applied to be licensed

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.

Alchemab Therapeutics Ltd (the establishment) was found to have met all HTA standards.

Compliance with HTA standards

All applicable HTA standards have been assessed as fully met.

Advice

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

Number	Standard	Advice
1.	GQ1(a)	Although the establishment does not seek consent from staff, they had standard operating procedure (SOP) HTA-SOP-01 Consent within their suite of governance and quality documents which is used primarily as a training aid to assist in providing a comprehensive overview of the requirements of the Human Tissue Act 2004. For completeness, the proposed DI is advised to include a link to HTA Code of Practice A – Guiding Principles and Fundamental Principle of Consent.
2.	GQ1(a)	HTA-SOP-04 CAPA only referenced the corrective and preventive action process in relation to adverse events. The proposed DI is advised to amend the SOP to include the actions to be taken to record and resolve CAPAs raised in relation to audits.
3.	GQ1(a)	The proposed DI is advised to amend HTA-SOP-11 Maintenance and Monitoring of Cold Storage to include the use and management of the remote temperature monitoring system by staff to ensure the integrity of relevant material is maintained.
4.	GQ1(a)	The establishment had contingency plans in place and an agreement to move relevant material to another HTA licensed premises in the case of catastrophic critical storage failure. The proposed DI is advised to amend HTA-SOP-11 Maintenance and Monitoring of Cold Storage to include the process step of recording the new relevant material storage location(s) in the tissue tracking database to ensure traceability is maintained.
5.	GQ1(a)	The establishment had some user instructions for the tissue tracking database in addition to the instruction

		manual. The proposed DI is advised to formalise the procedures for using the tissue tracking database within a suitable procedural document to ensure traceability of relevant material is maintained.
6.	GQ1(c)	The establishment had change control mechanisms in place for the implementation of new operational procedures with high risk changes requiring approval from their HTA Committee. The proposed DI is advised to amend HTA-SOP-03 Control Change to include a scoring matrix to determine how change control requests will be classified based on risk and/or impact.
7.	GQ2(b)	HTA-SOP-07 Internal Audit described the audit process. Non-compliances classified as major and moderate are resolved through the corrective and preventative action (CAPA) process and corrective actions for minor non-compliances are recorded on the audit form. The proposed DI is advised to record all non-complicances identified from audits through the CAPA process to aid traceability of auditable information.
8.	GQ2(b)	Audit findings included who was responsible for follow-up actions and the proposed DI is advised to implement set timeframes for audit follow-up actions to be resolved based on the classification of the non-compliance.
9.	GQ2(b)	The proposed DI is advised to consider characterising audit follow-up actions with a unique identifier to aid traceability of auditble information.
10.	GQ3(a)	A spreadsheet of completed staff training is maintained. The proposed DI is advised to include an additional column within the spreadsheet to identify the date MRC refresher training is due to improve the ease in which employees can be identified and ensure training is arranged and completed in line with the establishment's policies and procedures.
11.	GQ6(b)	Risk assessments are reviewed annually. The proposed DI is advised to add the frequency and date of next review to risk assessments to ensure they are appraised within the stated time frame.
12.	T1(f)	The establishment did not have any formalised agreements with courier companies but does undertake courier questionnaires to determine suitability of relevant material transporters. The proposed DI is advised to review the

		suitability of couriers on a regular basis to ensure transport criteria, terms and conditions still meet the establishment's requirements.
13.	PFE1(b)	The establishment had identified a back-up freezer for storage of relevant material. The proposed DI is advised to to erect signage identifying the freezer for relevant material storage and, if necessary, secure it with a lock to prevent unauthorised access when in use.
14.	PFE2(c)	The establishment had a continuous remote temperature monitoring system in place for relevant material storage areas. The proposed DI is advised to record the reason for the cancellation of an alarm within the monitoring system when a temperature excursion has been logged to evidence the alarm had been acted upon.

Background

Alchemab Therapeutics Ltd identifies novel drug targets and therapeutics by analysis of patient antibody repertoires from individuals that are susceptible but resilient to specific diseases.

Description of activities undertaken during visit

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

Standards assessed

43 out of 47 HTA licensing standards were covered during the assessment (standards published 3 April 2017). Four standards were not applicable as the establishment does not have staff involved in seeking consent [standards C2(a), (b) and (c)] and does not intend to store bodies or body parts [standard PFE2(b)]. All other standards were assessed.

Review of governance documentation

The assessment included a review of documentation relevant to the establishment's proposed licensable activities. This included policies and procedural documents, audits, adverse event reporting, training requirements, temperature monitoring of the relevant material storage areas,

equipment servicing records, contingency plans and a review of the HTA tissue tracking database that will be used to record and track relevant material.

Visual inspection
The visit included a visual inspection of the areas where the establishment proposes to undertake the licensable activity. This included the areas where relevant material will be received into the establishment and stored.

Meetings with establishment staff
The assessment included meetings and discussions with the proposed DI, two Persons Designated, Vice President of Operations and the Head of Operations.

Report sent to proposed DI for factual accuracy: 7 November 2023

Report returned from proposed DI: 8 November 2023

Final report issued: 9 November 2023

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

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