Licence application assessment report on compliance with HTA licensing standards
Assessment date: **18 March 2025**

AbbVie DJS Antibodies

Proposed HTA licensing number 12791

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
AbbVie DJS Antibodies	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 AbbVie DJS Antibodies ('the establishment') had met the majority of the HTA's standards, four minor shortfalls were found against Consent and Governance and quality systems standards. These related to; consent and receipt procedures, document review cycles and 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
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's Codes of Practice		
a) Consent procedures are documented and these, along with any associated documents comply with the HT Act and HTA's Codes of Practice.	The establishment will be involved in seeking consent from healthy donors for blood samples to be removed for storage and use in research. The establishment has a standard operating procedure (SOP) for consent, that provides guidance on meeting the consent requirements, but does not provide sufficient detail on the consent seeking procedure. *"The establishment submitted sufficient evidence to address this shortfall before the report was finalised."*	**Minor**

GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process

a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities	The establishment has a procedure that deals with receipt of samples to be stored under the governance of licence once ethical approval has ended but it does not have a procedure for the receipt of blood samples. *"The establishment submitted sufficient evidence to address this shortfall before the report was finalised."*	**Minor**

GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process		
b) There is a document control system.	There is no system for managing document review cycles. *"The establishment submitted sufficient evidence to address this shortfall before the report was finalised."*	**Minor**

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 site visit, the establishment did not have the expected range of documented risk assessments associated with HTA licensable activities. *"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 blood donors can record whether their consent will be generic (permitting further research), study-specific and they also place time limits on their consent. The Consent SOP does not contain guidance on how the consent form should be completed by the donor. The proposed DI is advised to produce supporting guidance to help to ensure that the consent form is completed correctly.
2.	C1(c)	The establishment plans to purchase material from third party suppliers in the future. The proposed DI should ensure that agreements are put in place which confirm that appropriate and valid consent is in place for material that is received.

3.	C2(c)	To maintain competency in consent seeking, the proposed DI is advised to set the frequency of refresher training.
4.	PFE2(c)	The proposed DI is advised to display the defined temperature range for storage on 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.
5.	PFE2(d)	The proposed DI is advised to consider the labelling of contingency freezers, to help staff to readily identify them should human tissue need to be moved urgently.

Background

The establishment is a biotechnology company involved in antibody therapeutics in the areas of immunology, oncology, neuroscience, virology and gastroenterology. The establishment will be recruiting healthy volunteers (staff) and seeking consent for collection of blood samples for storage for research purposes. The establishment also plans to receive human tissue samples from commercial providers for storage for research. The establishment only plans to store material from living donors.

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) 46 were assessed. PFE2(b) is not applicable as the establishment will not be storing material from deceased donors.

Review of governance documentation
Local policies and procedural documents relating to licensable 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 and security access.

Meetings with establishment staff
A roundtable meeting was held with the proposed DI and Corporate Licence Holder contact (CLHc).

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

Report returned from proposed DI: 11 April 2025

Final report issued: 7 May 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.