Virtual Regulatory Assessment (VRA) report on compliance with HTA licensing standards
Assessment date: **29 April 2021**

**Plasticell Ltd**
HTA licensing number 12648

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 |
|---|---|---|
| **Plasticell Ltd** | Licensed | Not licensed |

**Summary of assessment 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 Plasticell Ltd (the establishment) had met the majority of the HTA's standards, two major and five minor shortfalls were found against standards for Consent, Governance and quality systems and Traceability. These covered a range of matters, including documented procedures, governance and audit arrangements, staff training, risk assessments and disposal.

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**

***Major 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 HTA's Codes 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. | Although the establishment does not seek consent directly, procedures that contribute to the assurance that consent is in place and how to deal with issues such as consent withdrawal are not documented.<br>*During the assessment, the establishment satisfied the HTA that all material currently stored was held with appropriate and valid consent*. | **Major** |
| **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. | Documents relating to licensable activites are not up-to-date. Prior to this assessment, standard operating procedures (SOPs) had not been reviewed since their creation in 2016.<br>Furthermore, the establishment does not have SOPs in place covering activities relating to consent, storage and disposal of relevant material. | **Major** |

***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** | | |
| d) Matters relating to HTA-licensed activities are discussed at regular governance meetings, involving establishment staff. | Governance meetings are *ad hoc*, meaning that matters relating to HTA-licensed activities are not discussed at regular meetings involving establishment staff. | **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. | There is no formalised process for conducting audits. There is no audit SOP, audit reports or details documenting the audit process and follow-up.<br>There are records of previously conducted annual audits; however, they resemble stock-checks rather than audits that seek to detemine compliance with the HTA's standards or demonstrate they are meeting the requirements of their own systems. | **Minor** |

| 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. | There is no human tissue-related training for staff that are directly working under the licence. | **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. | Risks relating to consent are not covered in the establishment's risk assessments. | **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. | For one project, specific disposal dates were not recorded. | **Minor** |

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

**Advice**

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

| Number | Standard | Advice |
|---|---|---|
| 1. | GQ1(a) | Although the ultra-low freezer is monitored, the SOP (SOP-P6) does not detail the monitoring and alarm arrangements that are in place. Furthermore, this SOP does not detail the contingency arrangements. The DI is advised to include details of these arrangements in the document to strengthen staff awareness. |
| 2. | GQ1(d) | The DI is advised to include a standing agenda item for HTA matters at a relevant regular scheduled meeting to help ensure that there is appropriate oversight of the licensed activities. Formalised minutes of governance meetings should be circulated to all relevant staff to help to ensure that they are aware of all important information relating to activities conducted under the licence. |
| 3. | GQ2(a) | As well as traceability audits, the DI is advised to include horizontal audits by staff involved in the processes, to ensure that SOPs accurately reflect actual practices and to identify areas for improvement; for example, audits of staff entering information on the sample database. |
| 4. | GQ3(a) | The DI is advised to ensure that all staff involved in undertaking licensed activities are aware of the requirements of the HT Act and the HTA's Codes of Practice. It may be valuable to include references to the HTA's Code of Practice A (Consent) and E (Research) in relevant training information. |
| 5. | T1(a) | The establishment is currently transitioning to a new laboratory software system. The DI is advised to audit this process to ensure that the transfer of information relating to samples is accurately transferred across systems. |
| 6. | PFE2(c) | The temperature-monitored, ultra-low freezer has an external alarm and call-out system that has never activated. The DI is advised to formally challenge the alarm system to ensure that, when temperature deviations are detected, it operates as expected. In addition, as the external alarm system is managed by a third party, the |

| | | |
|---|---|---|
| | | DI is also advised to consider reviewing temperature trends, which may identify when storage conditions may be deteriorating and to alert staff to developing equipment failure. |
| 7. | N/A | Given the range of shortfalls and advice, the DI is advised to consider appointing a PD to assist them in their role. |

**Background**

Plasticell Ltd is a biotechnology company that develops novel therapies through the manipulation of cells using screening technologies. Plasticell Ltd has been licensed by the HTA since November 2016. This was the first VRA of the establishment. Since the licence application, there have been changes to key people working under the licence including the Designated Individual in 2017 and the Corporate Licence Holder contact in 2021.

**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 assessment:

*Standards assessed against during inspection*

40 out of 47 HTA licensing standards were covered during the assessment (standards published 3 April 2017). Some standards relating to consent procedures (C1(b), C1(d), C1(e), and C1(f)) and standards relating to consent training (C2(a), C2(b) and C2(c)) were not applicable as the establishment does not directly seek consent from donors.

*Review of governance documentation*

Policies and procedural documents relating to all licensed activities, including standard operating procedures and traceability systems were assessed. Documents detailing staff training, adverse events, incidents, governance meetings and audits were also reviewed.

*Visual inspection*

There was no site visit inspection associated with the assessment.

*Meetings with establishment staff*
The assessment included discussions with the Research Director, who holds the position of DI, and the Safety Officer.

**Report sent to DI for factual accuracy:** 07 May 2021

**Report returned from DI:** 13 May 2021

**Final report issued:** 14 May 2021

## 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 Virtual Regulatory Assessment Report.

## Date: 06 August 2021

## 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
- 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 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
- 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.