Inspection report on compliance with HTA licensing standards
Inspection date: **30 March 2023**

# Drug Development Solutions Ltd

HTA licensing number 12609

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 |
|---|---|---|
| **Drug Development Solutions Ltd**<br>**Newmarket Road, Fordham, Cambridgeshire** | Licensed | Not licensed |

**Summary of inspection 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 Drug Development Solutions 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 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** | | |
| a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities. | The establishment did not have a standard operating procedure (SOP) that covered the collection of all relevant material being stored for a scheduled purpose. | **Minor** |

| | | |
|---|---|---|
| **GQ4 There is a systematic and planned approach to the management of records** | | |
| b) There are provisions for back-up / recovery in the event of loss of records. | The establishment did not have provisions in place to recover information held on paper records in the event of their loss. | **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. | C1(a) | To optimise assurances for informed consent, the DI is advised to provide information on all risks associated with donation within the documents used to support the seeking of consent. This information should describe the likelihood of adverse occurrences and their severity, in language all potential participants are likely to understand. In this setting, relevant documentation includes the consent form or 'SOP 6170 Control Matrix (Regulated Studies)' . |
| 2. | C1(a) | The DI is advised to amend the 'consent withdrawal' paragraph within the consent form to improve clarity that all reasonable steps will be taken to remove and dispose of samples if consent is withdrawn by the donor. |
| 3. | C2(c) | In-house HTA training is required to be completed every two years and the DI is advised to consider including alternative external training resources for staff at regular intervals to additionally support consent training. |
| 4. | GQ1(a) | SOP 5956 Sample Receipt and Log states that consignments received should be checked on receipt and any damage, inaccuracies or unexpected samples reported on form 5876. The DI is advised to update SOP 5956 to include a link to SOP 5187 Quality Incident Management so users are aware that any logged incident which may affect the safety or integrity of relevant material is to be raised as an adverse event for investigation. |
| 5. | GQ2(a) | Scheduled audits are undertaken at a regular frequency and the DI is advised to consider including a regular audit against HTA standards. |

| | | |
|---|---|---|
| 6. | GQ3(b) | The DI is advised to include examples of adverse events within the HTA induction training for new staff to ensure employees are fully trained in identifying adverse events and how to report them. |
| 7. | GQ6(c) | All risk assessments are available to employees and the DI is advised to ensure new starters are made aware of risks during their induction training and to signpost to where assessments can be accessed on the establishment's IT system. |

**Background**

The establishment provides a service to research programmes of both sponsors and customers in the pharmaceutical and biotechnology industries. Drug Development Solutions Ltd has been licensed by the HTA since 2013. This was the second inspection of the establishment; the most recent previous inspection took place in September 2014.

Since the previous inspection, there have been no significant changes to the licence arrangements or the activities carried out under the licence.

**Description of inspection activities undertaken**

The HTA's regulatory requirements are set out in Appendix 1. The inspection team covered the following areas during the inspection:

*Standards assessed against during inspection*

46 out of 47 HTA licensing standards were covered during the inspection (standards published 3 April 2017). One standard was not applicable as the establishment does not store bodies or body parts [standard PFE2(b)]. All other standards were assessed.

*Review of governance documentation*

The inspection covered a review of documentation relevant to the establishment's licensed activities. This included policies and procedural documents, equipment servicing records, risk assessments, minutes of meetings, a review of the traceability database, monitoring of storage conditions, training records and audits.

*Visual inspection*
No site visit was undertaken as part of this inspection. However, the establishment provided photographs of the storage facility and security arrangements.

*Audit of records*
The establishment's traceability database was reviewed and checked with samples from receipt and storage location through to use or disposal.

*Meetings with establishment staff*
The inspection included virtual meetings with the following staff: the Designated Individual (DI), the Person Designated (PD), a phlebotomist, the Team Lead for Quality and Internal Audit and a member of the QA team working under the licence. The meetings covered: consent, quality management, traceability, and premises, facilities and equipment.

**Report sent to DI for factual accuracy: 24 April 2023**

**Report returned from DI: 25 April 2023**

**Final report issued: 8 June 2023**

## 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: 19 June 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 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 inspection.

   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
- 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.