Site visit inspection report on compliance with HTA minimum standards

BBI Solutions

HTA licensing number 12443

Licensed under the Human Tissue Act 2004 for the

- **storage of relevant material which has come from a human body for use for a scheduled purpose**

29 March 2017

Summary of inspection findings

BBI Solutions (the establishment) was found to have met all HTA standards.

The HTA found the Designated Individual (DI), the Corporate Licence Holder (CLH), the practices and premises to be suitable in accordance with the requirements of the legislation.

Particular examples of strengths and good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

The HTA must assure itself that the Designated Individual, Licence Holder, premises and practices are suitable.

The statutory duties of the Designated Individual are set down in Paragraph 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.

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. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, 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 given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Background to the establishment and description of inspection activities undertaken

BBI Solutions joined BB International in 2010 and the group has manufacturing sites around the world servicing the diagnostics industry. They manufacture reagents used in the production of monoclonal and polyclonal antibodies, cell culture reagents, immune-diagnostic kits and positive controls used in life science research, pharmaceutical industry and hospitals.

The establishment uses several suppliers of relevant material based in the UK; however, the majority of relevant material (also referred to as 'raw material' by the establishment) is sourced and imported from companies based outside the UK, including the USA. 'Disease state' serum and plasma is from donors with clinical conditions. BBI Solutions also obtains urine from members of staff. Clinical research studies, carried out in collaboration with an NHS partner organisation and approved by recognised research ethics committees (RECs), are currently in progress, involving serum, plasma and urine.

Relevant material stored under the licence includes cardiovascular, hepatic, thyroid, spleen, neural and post-natal tissue (placenta and umbilical cord) along with seminal fluid, saliva and urine. All relevant material is stored on-site and is frozen.

The establishment has been licensed by the HTA since March 2007 and was last inspected in May 2012.The visual inspection of the premises included sample receipt and specimen processing areas, processing laboratories and storage facilities. The outside, walk-in -20 freezer facility contains all relevant material stored at the establishment. An external company monitors the freezer temperature constantly and alerts a member of staff, via a dial out system, if the temperature deviates from its expected range. A member of staff is on call at all times.

Interviews were conducted with the DI, the CLHc, the Production Manager, the Global Procurement Professional and other staff working under the licence. The DI is the Technical Specialist of the business, reporting to the site leader and liaising with other members of staff to ensure systems are in place to conform to the HTA's codes of practice. The CLHc is the Compliance Manager, with responsibilities for risk assessments and audits.

The establishment does not hold consent forms on site for imported tissue. The establishment seeks assurances, through service level agreements, that suppliers of human tissue, including non-UK companies, meet regulatory requirements for consent and provide evidence of informed consent.

Consent forms are kept on site for urine procured directly from staff and from individual donors outside the organisation. Appropriately trained individuals obtain consent for these samples.

All tissue samples are assigned a unique identification number on receipt at the premises. The establishment currently maintains an in-house, paper-based system to track samples, consisting of an incoming material checklist and a 'raw material' specification (RMS). Historic records, and records relating to some on site tissue, are archived off site due to storage restrictions (see Advice, item 1). Testing results for samples are scanned electronically and kept as part of production batch records. The batch records include a copy of the disease state testing (DST) certificates that are relevant to tissues used to manufacture that batch. A traceability audit was carried out on four samples. Each audit trail included (as appropriate): review of evidence of consent, receipt, storage and disposal, and data entry onto the establishment's management information system. No anomalies or discrepancies were found on the selected examples during the traceability audits.

A document review of the establishment's policies and operational procedures was also conducted. This included review of service level agreements, audit schedules for 2017, examples of non-conformances, risk assessments, audits and the quality manual.

Inspection findings

The HTA found the existing Designated Individual and the Corporate Licence Holder to be suitable in accordance with the requirements of the legislation.

Compliance with HTA standards
All applicable HTA standards have been assessed as fully met.

Advice

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

No.	Standard	Advice
1.	GQ4	The DI is advised to implement an electronic database/log to reflect sample receipt documentation, including the checklist and the RMS. This will provide a back-up database to the paper-based system for traceability. It will also allow the establishment to access information pertaining to the sample when the paper documentation has been archived off site, which may be important, particularly when the sample is still on site.
2.	GQ3	The Production Manager is currently implementing a new training programme for all staff around procedures and processes at the establishment. The DI is encouraged to support the rolling-out of competency-focussed training for all staff in the future.
3.	PFE1	There are currently several on-site improvements taking place at the establishment. To reduce the inherent risks of the circulation of several keys amongst staff, the DI is advised to consider the introduction of swipe-card access to relevant facilities and laboratories.

Concluding comments

The establishment has enthusiastic and experienced staff, who appear to work well together and seem dedicated to providing a high quality service to their customers. Respect for donors and the value of human tissue is at the centre of their work and training.

There were many areas of good practice identified throughout the inspection:

- The establishment carries out external audits of their suppliers to assure themselves of their processes;
- The design of the Raw Material Specification (RMS) and incoming goods checklist for imported samples allow for rapid detection of non-conforming products;
- In addition to the designated training on the HTA and the Human Tissue Act given to all members of staff on induction, the DI delivers an advanced training module to staff working with human tissue;
- Visual indicators are placed on samples to identify when they are ready for use i.e. samples that have successfully passed through quality control systems and are out of quarantine;
- Confidentially is of fundamental importance to the organisation and no confidential documentation is stored off site. Only certain staff have access to this information on site;
- After a set period of time has elapsed, consent is re-sought from previous donors, by appropriately trained members of staff.

The HTA has given advice to the DI regarding the establishment's approach to record keeping, training and security.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Report sent to DI for factual accuracy: 24/04/17

Report returned from DI: 26/05/17

Final report issued: 30/05/17

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

Consent standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice
• Consent forms comply with the HTA's Code of Practice • Consent forms are in records and are made accessible to those using or releasing relevant material for a scheduled purpose • If the establishment obtains consent, a process is in place for acquiring consent in accordance with the requirements of the HT Act 2004 and the HTA's Codes of Practice • Where applicable, there are agreements with third parties to ensure that consent is obtained in accordance with the requirements of the HT Act 2004 and the HTA's Codes of Practice • Consent procedures have been ethically approved
C2 Information about the consent process is provided and in a variety of formats
• Standard operating procedures (SOPs) detail the procedure for providing information on consent • Agreements with third parties contain appropriate information • Independent interpreters are available when appropriate • Information is available in suitable formats, appropriate to the situation • Consent procedures have been ethically approved
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent
• Standard operating procedures (SOPs) detail the consent process • Evidence of suitable training of staff involved in seeking consent • Records demonstrate up-to-date staff training • Competency is assessed and maintained

Governance and quality system standards
GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process
• Policies and procedures in place are in place, covering all activities related to the storage of relevant material for research in connection with disorders, or the functioning, of the human body • Appropriate risk management systems are in place

- Regular governance meetings are held; for example, health and safety and risk management committees, agendas and minutes
- Complaints system

GQ2 There is a documented system of quality management and audit

- A document control system, covering all documented policies and standard operating procedures (SOPs).
- Schedule of audits
- Change control mechanisms for the implementation of new operational procedures

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

- Qualifications of staff and training are recorded, records showing attendance at training
- Orientation and induction programmes
- Documented training programme, (e.g. health and safety, fire, risk management, infection control), including developmental training
- Training and reference manuals
- Staff appraisal / review records and personal development plans are in place

GQ4 There is a systematic and planned approach to the management of records

- Documented procedures for the creation, amendment, retention and destruction of records
- Regular audit of record content to check for completeness, legibility and accuracy
- Back-up / recovery facility in the event of loss of records
- Systems ensure data protection, confidentiality and public disclosure (whistle-blowing)

GQ5 There are documented procedures for distribution of body parts, tissues or cells

- A process is in place to review the release of relevant material to other organisations
- An agreement is in place between the establishment and the organisation to whom relevant material is supplied regarding the tracking and use of material and eventual disposal or return

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail

- There is an identification system which assigns a unique code to each donation and to each of the products associated with it
- An audit trail is maintained, which includes details of when and where the relevant material was acquired, the consent obtained, the uses to which the material was put, when the material was transferred and to whom

GQ7 There are systems to ensure that all adverse events are investigated promptly
• Corrective and preventive actions are taken where necessary and improvements in practice are made • System to receive and distribute national and local information (e.g. HTA communications)
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately
• Documented risk assessments for all practices and processes • Risk assessments are reviewed when appropriate • Staff can access risk assessments and are made aware of local hazards at training

Premises, facilities and equipment standards
PFE1 The premises are fit for purpose
• A risk assessment has been carried out of the premises to ensure that they are appropriate for the purpose • Policies in place to review and maintain the safety of staff, authorised visitors and students • The premises have sufficient space for procedures to be carried out safely and efficiently • Policies are in place to ensure that the premises are secure and confidentiality is maintained
PFE 2 Environmental controls are in place to avoid potential contamination
• Documented cleaning and decontamination procedures • Staff are provided with appropriate protective equipment and facilities that minimise risks from contamination • Appropriate health and safety controls are in place
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.
• Relevant material, consumables and records are stored in suitable secure environments and precautions are taken to minimise risk of damage, theft or contamination • Contingency plans are in place in case of failure in storage area • Critical storage conditions are monitored and recorded • System to deal with emergencies on 24 hour basis • Records indicating where the material is stored in the premises

PFE 4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination
• Documented policies and procedures for the appropriate transport of relevant material, including a risk assessment of transportation • A system is in place to ensure that traceability of relevant material is maintained during transport • Records of transportation and delivery • Records are kept of any agreements with recipients of relevant material • Records are kept of any agreements with courier or transport companies
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored
• Records of calibration, validation and maintenance, including any agreements with maintenance companies • Users have access to instructions for equipment and receive training in use and maintenance where appropriate • Staff aware of how to report an equipment problem • Contingency plan for equipment failure

Disposal Standards
D1 There is a clear and sensitive policy for disposing of human organs and tissue
• Documented disposal policy • Policy is made available to the public • Compliance with health and safety recommendations
D2 The reason for disposal and the methods used are carefully documented
• Standard operating procedures (SOPs) for tracking the disposal of relevant material detail the method and reason for disposal • Where applicable, disposal arrangements reflect specified wishes

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 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 Human Tissue Act 2004 (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:

   (1) A notice of proposal being issued to revoke the licence

   (2) 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.

   (3) A notice of suspension of licensable activities

   (4) Additional conditions being proposed

   (5) 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 CoPs, 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 or 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 both the draft and final inspection report. You 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 desk-based or site-visit inspection.

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