Site visit inspection report on compliance with HTA minimum standards

Wescott Medical Limited

HTA licensing number 22586

Licensed for the

- **storage and distribution of human tissues and cells for human application under the Human Tissue (Quality and Safety for Human Application) Regulations 2007**

7 February 2013

Summary of inspection findings

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

Although the HTA found that Wescott Medical Limited (the establishment) had met the majority of the HTA standards, a shortfall was found in relation to risk assessments.

Shortfalls identified during the previous inspection have been addressed.

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.

Licensable activities carried out by the establishment

'E' = Establishment is licensed to carry out this activity.

'TPA' = Third party agreement; the establishment is licensed for this activity but another establishment (unlicensed) carries out the activity on their behalf.

Tissue type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Acellular Bone chips				**E**	**E**		
Acellular Bone blocks				**E**	**E**		
Cartilage				**E**	**E**		
Membranes (e.g. Fascia)				**E**	**E**		

Background to the establishment and description of inspection activities undertaken

Wescott Medical Limited (the establishment) is primarily involved with the supply of medical devices. However, it also supplies xenograft material and receives, stores and distributes acellular human allograft implant material, which falls within the HTA licensing regime. This material is received from a company licensed by the appropriate competent authority in Germany.

The establishment received the following acellular bone and soft tissue products in 2012: cancellous bone (blocks and struts), bone chips, fasciae lata/temporalis, pericardium and costal cartilage. These products are distributed to end users within the UK.

During the inspection, the DI confirmed that no distribution or export takes place to any establishments outside the EEA, although an agreement had previously been put in place with a specific exporter.

There is a service level agreement between the supplier in Germany and the establishment, with more recent addenda covering the requirement to report incidents or events, including Serious Adverse Events or Reactions (SAEARS), back to the supplier.

The establishment has entered into a Third Party Agreement (TPA) for transport services with the courier company used to transport material to end users. It has also entered into end user agreements with customers, and these detail the requirement to maintain traceability records and to report SAEARS, as well as how disposal should be effected, if required.

Material from the German supplier is received at the establishment by trained staff. The packaging is checked, and label details cross referenced with the delivery note. The unique identifier, being the individual lot number, is logged within an Excel spreadsheet by scanning of the label bar-code. Expiry dates, product codes and material descriptions are all input manually to the spreadsheet and all of the data is then imported to an Access database, before the material is placed in store.

Allograft material is stored within a monitored facility, temperatures being data-logged four times a day with the electronic records being backed up and also converted to printed format for alternate safe storage. The temperature requirements are wide, being “room temperature”, which is stated within packaging insert information as 15-30 degrees centigrade. Storage temperatures sometimes extend outside these parameters, but the establishment has sought advice from the supplier and the variations are deemed not of sufficient magnitude to have any effect on the material itself.

Sales are managed by a proprietary sales and invoicing system. On receiving a request for supply of allograft material, sales staff check to ensure an end user agreement is in place and if not, send a standard agreement by email for signature and return (by fax if necessary).

Product for dispatch is then selected by staff, who check for material with the shortest expiry date. Lot numbers are entered manually onto the customer delivery note and dispatch is recorded on the sales database by inputting the relevant details. Delivery is by tracked courier. All delivery and dispatch notes are retained on file at the establishment.

The establishment has systems in place to maintain an overview of expiry dates, by periodic query of the database records. Material reaching expiry is returned to the supplier for disposal or allocated for use for surgical training.

This was the establishment’s second site visit inspection, the previous one having taken place in February 2011. Shortfalls identified during the previous inspection have been addressed by the establishment.

This inspection comprised a visual inspection, document review of quality documentation and interviews with key staff. Some documents, drafted or reviewed to address previous shortfalls, including the pro-forma end user agreement and temperature recording standard operating procedure, were reviewed in advance of the inspection. Signed copies of end user agreements, the TPA and the distribution agreement were reviewed.

In addition, an audit of traceability was carried out:

The lot numbers of two products within store were taken, along with details of product description, product code and expiry dates, and these details were checked against the corresponding database entries.

Two entries on the database were selected, lot numbers, product description, product code and expiry dates noted and the items located in store. All details were compared.

No discrepancies were found.

The spreadsheets were examined to confirm that end user addresses were being recorded. For each item dispatched, an end user was listed. Delivery notes were also reviewed.

Inspection findings

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

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.		
b) Risk assessments are reviewed regularly, as a minimum annually or when any changes are made that may affect the quality and safety of tissues and cells.	While risk assessments have been carried out covering both health and safety and regulatory risks, there is no provision within the Quality Management System for the scheduling of risk assessments to meet this standard. By drafting a procedure detailing how risk assessments are to be reviewed and having them scheduled in advance, the DI will help to ensure that any change in process is risk assessed and procedural documentation updated as necessary.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1d	The DI is advised to ensure that on any subsequent review of documentation within the quality management system, particular care is taken to ensure that where documents reference others, the reference itself is correct. The DI is also advised to review the list of SOPs contained within the document control system to ensure that there are no duplicate documents in existence. By doing so, the DI will help to ensure that staff access the correct documentation when carrying out any procedures.

2.	GQ4b	The DI is advised to schedule audits using the same method as that used for scheduling the review of SOPs. Although audits have been carried out frequently, this has largely been on an ad hoc basis and, by scheduling these, the DI will minimise the risk of audits not being completed.
3.	PFE3c	The DI is advised to consider re-siting the storage cabinet for human tissue allograft material in order to minimise storage temperature fluctuations resulting from it currently being located within a warehouse building, where temperature control is difficult to maintain. Although the supplier confirms that variations in temperature have no marked effect on the materials themselves, there is the possibility of the packaging plastics being affected, and attempts should be made to maintain temperatures at room temperature as defined in the product information cards supplied.
4.	PFE5a	While it is noted that the allograft materials stored are not sensitive to the temperature fluctuations experienced at the establishment, the DI is advised to periodically validate the temperature data-logging system, to ensure that readings recorded are as accurate as possible. By doing so, the DI will ensure that the storage facility is suitable for storage of any allograft material which has a narrower temperature tolerance range than that presently being stored.
5.	N/A	The DI is advised to notify the HTA in the event any decision is made to supply allograft materials to a third party distributor, not licensed by the HTA, for export to any country outwith the EEA. This is required in order that export is included as an activity on the establishment's licence. The DI is also advised that, in such circumstances, a TPA would need to be put in place with the exporter, and this also notified to the HTA.

Concluding comments

The establishment primarily deals with the manufacture and supply of medical devices, and its Quality Management System (QMS) has been implemented to meet the requirements of ISO 13485 certification relevant to that business area. As a result, many of the procedures in place are suitable for the storage and distribution of human tissue allografts. The HTA noted that the DI has, where appropriate or needed, created specific documentation relevant to the licensable activity.

Only a small stock level is held at any one time, and only a small number of staff are involved in the licensed activity, meaning that there is good oversight of the material stored and familiarity with the procedures in place.

There is regular provision for audit of both procedures and documentation (as required for the ISO certification), and the establishment's QMS is audited annually by an external certification body. Internal audits follow an audit procedure and use documentation which ensures they are carried out in an independent manner.

The DI has insisted on supplying only to those establishments for which an end user agreement is in place and has managed to put in place a TPA for services with the couriers used. Both are important with regard to the obligation for end users or third parties to report SAEARS.

There is some room for improvement, namely one minor shortfall in relation to risk assessments. The HTA has given advice to the Designated Individual with respect to some elements of documentation, storage location temperatures, validation of the data-logger and on potential future licensing requirements.

The HTA requires that the Designated Individual addresses the shortfall by submitting a completed corrective and preventative action (CAPA) plan 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.

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 shortfall identified during the inspection.

Report sent to DI for factual accuracy: 26 February 2013

Report returned from DI: 12 March 2013

Final report issued: 13 March 2013

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: 31 May 2013

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.

Human Tissue (Quality and Safety for Human Application) Regulations 2007 Standards

Governance and Quality

Standard
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.
a) There is an organisational chart clearly defining the lines of accountability and reporting relationships.
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.
c) There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes.
d) There is a document control system to ensure that changes to documents are reviewed, approved, dated and documented by an authorised person and only current documents are in use.
g) There are procedures to ensure that an authorised person verifies that tissues and / or cells received by the establishment meet required specifications.
h) There are procedures for the management and quarantine of non-conforming consignments or those with incomplete test results, to ensure no risk of cross contamination.
i) There are procedures to ensure tissues and / or cells are not released from quarantine until verification has been completed and recorded.
k) There is a procedure for handling returned products.
l) There are procedures to ensure that in the event of termination of activities for whatever reason, stored tissues and / or cells are transferred to another licensed establishment or establishments.
o) There is a complaints system in place.
GQ2 There is a documented system of quality management and audit.
a) There is a quality management system which ensures continuous and systematic improvement.
b) There is an internal audit system for all licensable activities.
c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.
d) Processes affecting the quality and safety of tissues and / or cells are validated and undergo regular evaluation to ensure they continue to achieve the intended results.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.
a) There are clearly documented job descriptions for all staff.
b) There are orientation and induction programmes for new staff.
c) There are continuous professional development (CPD) plans for staff and attendance at training is recorded.
d) There is annual documented mandatory training (e.g. health and safety and fire).
e) Personnel are trained in all tasks relevant to their work and their competence is recorded.
f) There is a documented training programme that ensures that staff have adequate knowledge of the scientific and ethical principles relevant to their work, and the regulatory context.
g) There is a documented training programme that ensures that staff understand the organisational structure and the quality systems used within the establishment.
h) There is a system of staff appraisal.
i) Where appropriate, staff are registered with a professional or statutory body.
j) There are training and reference manuals available.
k) The establishment is sufficiently staffed to carry out its activities.
GQ4 There is a systematic and planned approach to the management of records.
a) There are procedures for the creation, identification, maintenance, access, amendment, retention and destruction of records.
b) There is a system for the regular audit of records and their content to check for completeness, legibility and accuracy and to resolve any discrepancies found.
c) Written records are legible and indelible. Records kept in other formats such as computerised records are stored on a validated system.
d) There is a system for back-up / recovery in the event of loss of computerised records.
e) The establishment keeps a register of the types and quantities of tissues and / or cells that are procured, tested, preserved, processed, stored and distributed or otherwise disposed of, and on the origin and destination of tissues and cells intended for human application.
g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 003/2010.
h) Raw data which are critical to the safety and quality of tissues and cells are kept for 10 years after the use, expiry date or disposal of tissues and / or cells.
i) The minimum data to ensure traceability from donor to recipient as required by Directions 003/2010 are kept for 30 years after the use, expiry or disposal of tissues and / or cells.
k) There are documented agreements with end users to ensure they record and store the data required by Directions 003/2010.

l) The establishment records the acceptance or rejection of tissue and / or cells that it receives and in the case of rejection why this rejection occurred.
m) In the event of termination of activities of the establishment a contingency plan to ensure records of traceability are maintained for 10 or 30 years as required.
GQ6 A coding and records system facilitates traceability of tissues and / or cells, ensuring a robust audit trail.
a) There is a donor identification system which assigns a unique code to each donation and to each of the products associated with it.
b) An audit trail is maintained, which includes details of when the tissues and / or cells were acquired and from where, the uses to which the tissues and / or cells were put, when the tissues and / or cells were transferred elsewhere and to whom.
c) The establishment has procedures to ensure that tissues and / or cells imported, procured, processed, stored, distributed and exported are traceable from donor to recipient and vice versa.
GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.
a) There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of any corrective or preventative actions.
b) There is a system to receive and distribute national and local information (e.g. HTA regulatory alerts) and notify the HTA and other establishments as necessary of serious adverse events or reactions.
c) The responsibilities of personnel investigating adverse events and reactions are clearly defined.
d) There are procedures to identify and decide the fate of tissues and / or cells affected by an adverse event, reaction or deviation from the required quality and safety standards.
e) In the event of a recall, there are personnel authorised within the establishment to assess the need for a recall and if appropriate initiate and coordinate a recall.
f) There is an effective, documented recall procedure which includes a description of responsibilities and actions to be taken in the event of a recall including notification of the HTA and pre-defined times in which actions must be taken.
g) Establishments distributing tissue and / or cells provide information to end users on how to report a serious adverse event or reaction and have agreements with them specifying that they will report these events or reactions.
h) Establishments distributing tissues and / or cells have systems to receive notifications of serious adverse events and reactions from end users and notify the HTA.
GQ8 Risk assessments of the establishment’s practices and processes are completed regularly and are recorded and monitored appropriately.
a) There are documented risk assessments for all practices and processes.
b) Risk assessments are reviewed regularly, as a minimum annually or when any changes are made that may affect the quality and safety of tissues and cells.
c) Staff can access risk assessments and are made aware of local hazards at training.

d) A documented risk assessment is carried out to decide the fate of any tissue and / or cells stored prior to the introduction of a new donor selection criteria or a new processing step, which enhances the quality and safety of tissue and / or cells.

Premises, Facilities and Equipment

Standard
PFE1 The premises are fit for purpose.
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.
b) There are procedures to review and maintain the safety of staff, visitors and patients.
c) The premises have sufficient space for procedures to be carried out safely and efficiently.
d) Where appropriate, there are procedures to ensure that the premises are of a standard that ensures the dignity of deceased persons.
e) There are procedures to ensure that the premises are secure and confidentiality is maintained.
f) There is access to a nominated, registered medical practitioner and / or a scientific advisor to provide advice and oversee the establishment's medical and scientific activities.
PFE2 Environmental controls are in place to avoid potential contamination.
a) Tissues and / or cells stored in quarantine are stored separately from tissue and / or cells that have been released from quarantine.
c) There are procedures for cleaning and decontamination.
d) Staff are provided with appropriate protective clothing and equipment that minimise the risk of contamination of tissue and / or cells and the risk of infection to themselves.
PFE3 There are appropriate facilities for the storage of tissues and / or cells, consumables and records.
a) Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination.
b) There are systems to deal with emergencies on a 24 hour basis.
c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.
d) There is a documented, specified maximum storage period for tissues and / or cells.
PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination.
a) There is a system to ensure tissue and / or cells are not distributed until they meet the standards laid down by Directions 003/2010.
b) There are procedures for the transport of tissues and / or cells which reflect identified risks associated with transport.
c) There is a system to ensure that traceability of tissues and / or cells is maintained during transport.

d) Records are kept of transportation and delivery.
e) Tissues and / or cells are packaged and transported in a manner and under conditions that minimise the risk of contamination and ensure their safety and quality.
f) There are third party agreements with courier or transport companies to ensure that any specific transport conditions required are maintained.
g) Critical transport conditions required to maintain the properties of tissue and / or cells are defined and documented.
h) Packaging and containers used for transportation are validated to ensure they are fit for purpose.
i) Primary packaging containing tissues and / or cells is labelled with the information required by Directions.
j) Shipping packaging containing tissues and / or cells is labelled with the information required by Directions.
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.
a) Critical equipment and technical devices are identified, validated, regularly inspected and records are maintained.
b) Critical equipment is maintained and serviced in accordance with the manufacturer's instructions.
c) Equipment affecting critical processes and storage parameters is identified and monitored to detect malfunctions and defects and procedures are in place to take any corrective actions.
d) New and repaired equipment is validated before use and this is documented.
e) There are documented agreements with maintenance companies.
f) Cleaning, disinfection and sanitation of critical equipment is performed regularly and this is recorded.
g) Instruments and devices used for procurement are sterile, validated and regularly maintained.
h) Users have access to instructions for equipment and receive training in the use of equipment and maintenance where appropriate.
i) Staff are aware of how to report an equipment problem.
j) For each critical process, the materials, equipment and personnel are identified and documented.
k) There are contingency plans for equipment failure.

Appendix 2: Classification of the level of shortfall (HA)

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 direct risk of causing harm to a recipient patient or to a living donor,

   Or

   A number of 'major' shortfalls, none of which is critical on its own, but viewed cumulatively represent a systemic failure and therefore are considered 'critical'.

   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.

   A shortfall in the carrying out of licensable activities which poses an indirect risk to the safety of a donor or a recipient

   or

   A shortfall in the establishment's quality and safety procedures which poses an indirect risk to the safety of a donor or a recipient;

   or

   A shortfall which indicates a major deviation from the **Human Tissue (Quality and Safety for Human Application) Regulations 2007** or the **HTA Directions**;

   or

   A shortfall which indicates a failure to carry out satisfactory procedures for the release of tissues and cells or a failure on the part of the designated individual to fulfil his or her legal duties;

   or

   A combination of several 'minor' shortfalls, none of which is major on its own, but which, viewed cumulatively, could constitute a major shortfall by adversely affecting the quality and safety of the tissues and cells.

   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 and, which can be addressed by further development by the establishment.

   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 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.