Quality Control and Quality Management in Tissue Banking
Outline

- A few definitions
- What value does quality management add from the patient’s perspective?
  - Why does donor documentation matter?
  - Why does process documentation matter?
  - Why does validation matter?
- Activity 1 – where did it all go wrong?
- Activity 2 - Quality failures – continuous improvement
- Some quality management standards: ISO, GMP
- Activity 3
| Quality Management                                                                 | The Coordinated activities to direct and control an organisation with regard to quality  
Draft of 2nd EU Commission Directive  
Council of Europe Guide to Safety and QA for Organs, Tissues and Cells |
| Quality Assurance                                                                 | Describes the actions, planned and performed, to provide confidence that all systems and elements that influence the quality of the product are working as expected individually and collectively.  
Council of Europe Guide to Safety and QA for Organs, Tissues and Cells |
More definitions…

Quality Control

Part of quality management focused on fulfilling quality requirements. This is the part of GMP which is concerned with sampling, specifications and testing and with the organisation, documentation, and release procedures which ensure that the necessary and relevant tests are actually carried out and that materials are not released for use until their quality has been judged to be satisfactory.

Council of Europe Guide to Safety and QA for Organs, Tissues and Cells
Potential Donor

Do No Harm

Recipient

Safety

Donor/donor family

Ethics

Staff

Health & Safety

Tissue Quality

Efficacy

Availability

Tissue transplant

Improve the Health of Recipients
• Identification of Potential Donor

• SOPs (with set criteria)
• Clear Responsibilities
• Training
• Documentation
• Third Party agreements

• Medical History
• Behavioural History
• Testing
• Physical Examination
  (including confirmation of identity)
- SOPs (with set criteria)
- Clear Responsibilities
- Training
- Documentation
- Third Party agreements

- Procurement
- Transport
- Packaging & Labelling
- Procurement records

Acceptance for Quarantine Storage

GO/NO
GO
**Acceptance for Quarantine Storage**

- Preservation to maintain required properties
- Preventing contamination or cross contamination
- Microbial inactivation or sterilisation
- Appropriate storage
- Traceability (labelling)
- Best use

**GO/NO GO**

- SOPs
- Training
- Documentation
- Process Design Validation
- Environmental control and monitoring
- Equipment qualification and calibration
- Third Party agreements

**Processing and Quarantine storage**
Storage

In

Inventory of

Available

Tissue

Processing
And
Quarantine
Storage

• Donor selection criteria met
• Tissue Testing (Quality control)
• Appropriate storage
• Labelling

• SOPs (with set criteria)
• Clear Responsibilities
• Training
• Documentation
• Third Party agreements

Clearance
GO/NO GO

Storage
In
Inventory of
Available
Tissue
• SOPs (with set criteria)
• Clear Responsibilities
• Training
• Documentation
• Third Party agreements

Storage in Available Inventory

GO/ NO GO

• Physical inspection
• Appropriate storage
• Accompanying documentation
• Transport

Issue and Delivery
• SOPs (with set criteria)
• Clear Responsibilities
• Training
• Documentation

Tissue Bank

Recall and Return
Clinical follow-up
Traceability info
Adverse reactions

Hospital
In summary…..

- The quality system enhances safety and quality by ensuring that essential steps are carried out consistently to the specified standard and are recorded.
- Control points should be strongest where risks are highest.
- Avoid multiple checking of the same thing (it dilutes the responsibility).
- Avoid giving all control point responsibility to one person.
Activity 1

1.0 Please read this real case carefully

2.0 Now work together to make a simple flow chart showing what happened (using just one colour)

3.0 Now mark on the chart in a different colour where steps could have been taken to prevent the adverse event occurring (hot spots/control points)

4.0 Now agree and list your group’s major recommendations for the avoidance of this type of event in the future (no more than 5). Do this from a Quality System perspective.
Your Recommendations
Official Report Recommendations

We believe some of the recommendations made here can be profitably applied to all organ and tissue donations in the UK. These include recommendations for:

- A standardised donor form which accompanies the tissue and which requires positive exclusion of contraindications to transplantation.
- A central register, or a few networked registers, of all transplant material, each register working to nationally agreed standards.
- Registration of all tissue banks and adherence to common standards within them.
- Improved dissemination of information and guidelines incorporating advice on best practice drawn up by appropriate expert bodies.
- Improved education and standardisation of procedures used by tissue explanters.
Activity 2
Learning from mistakes

- In your handout you will find 12 examples of common quality system failures
- Discuss each error and consider what could be the worst possible outcome for a patient – use your imagination and be pessimistic!!
- Consider a suitable preventive action in each case
ISO 9000 – advantages and disadvantages

Advantages
- International standard
- Ensures that good systems for procedure documentation and control, record keeping and training are in place.
- It very focused on satisfying the needs of customers
- Independent assessment and accreditation

Disadvantages
- Very general – must be adapted and interpreted
- Often not applied to the early steps before tissue arrival at the tissue bank
- May give a false sense of security
- Not enough on its own – also need technical standards
GMP – advantages and disadvantages

Advantages

- International standard – covers all basic quality system requirements
- More closely relevant to the field therefore more technical
- Focuses on issues such as avoidance of contamination and cross-contamination

Disadvantages

- No accreditation system (apart from inspections by Competent Authorities where mandated)
- Written specifically for pharmaceutical products therefore often needs interpretation and adaptation
- Not enough on its own – also need technical standards
Smartosis Cocoanaemia

This is a serious newly emerged condition affecting up to 50% of the population caused by a lack of chocolate brought on by a severe smartie deficiency. If left untreated the condition causes damage to the nervous system resulting in death. The progress of this disease is rapid, many patients dying within 6 hours of diagnosis. Fortunately there is a simple and readily available cure in the form of smartie transplantation. The success rate of the treatment is 100%.
Can we save the lives of the victims at risk?
You will play in 2 groups

Group 1
Saint Helpus Hospital
- 5 patients critical
- 5 doctors treating them
- 1 theatre nurse who orders from the sweet bank
- 1 driver to deliver the cure
Sweeteotech Bank
- 2 issue clerks

Group 2
Saint Saveus Hospital
- 5 patients critical
- 5 doctors treating them
- 1 theatre nurse who orders from the sweet bank
- 1 driver to deliver the cure
Chocolife Bank
- 2 issue clerks
Instructions

- Each theatre nurse must call the Bank and order the required 5 doses of product.
- The Bank clerks must record the order and allocate products recording the issue on the issue log (you will be given a copy).
- The Driver will come to collect the products and take them to the theatre nurse. S/he must hold them for 1 minute before passing them to the doctors.
- Each Doctor will give the smarties to the patient one by one and will complete the Smartie Transplant Log. All smarties must be given within 2 minutes of receipt.
Learning points

- Everyone is responsible for quality
- Small mistakes can lead to disaster
- Importance of labelling and product information
- Always check if you are not sure
- Don’t take anything for granted