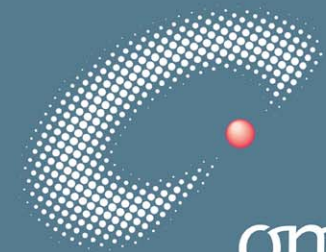


# Quality systems for research tissue banks.

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Quality Matters – A Workshop for  
Biobankers

15 - 16 January 2008



onCore<sup>UK</sup>

# Outline of talk

- What is quality?
- Fitness for purpose
- Quality management systems
- A quality management system for a research tissue bank

# What is quality?

- Product reliability / consistency
- Customer satisfaction
- Satisfaction of a need
- Regulatory compliance
- .....

Which is the higher quality?



# What is quality?

- Quality is defined as “the degree to which a set of inherent characteristics fulfils requirements”
  - ISO 9000:2000, Quality management systems – fundamentals and vocabulary

Quality is:

## ● Fitness for purpose



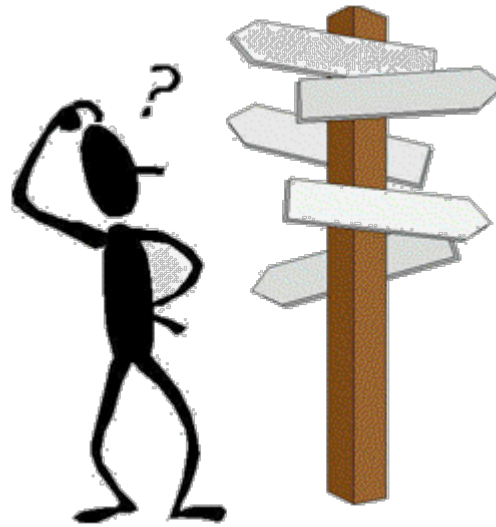
Congratulations, Martha, this really is a meal fit for a King



The food here is pretty bad but we make up for it with exceptionally large portions

# “Fit for purpose”?

- First, **define your purpose!**



# “Fit for purpose”?

- First, define your purpose!
- **Control** the output by testing for defined characteristics

“Press each key 5000 times and see if the computer crashes; I’ll see you again at lunch...”



# Wales Cancer Bank – example

- *“All frozen tissue samples have the presence of tumour verified by a pathologist and a digital image of the H & E slide is available for review.”*
- *“RNA quality is assessed by 260/230 and 260/280 ratio using a nanospectrophotometer and then subjected to QA by Agilent Bioanalyser. Additional QA will be provided by RT-PCR for different sizes of ampimers generated from a housekeeping gene eg. PBGD.”*
- *“DNA quality is assessed by spectrophotometry and by 1% agarose gel electrophoresis.”*

● [www.walescancerbank.com/sample\\_info.html](http://www.walescancerbank.com/sample_info.html)

## “Fit for purpose”?

- First, define your purpose!
- **Control** the output by testing for defined characteristics
- **Manage the inputs and the processes** so as to standardise the outputs
  - To do that, you need a **quality management system** that will give **assurance** of quality

# What is a quality management system?

- *“a management system to direct and control an organisation with regard to quality”*
  - BS EN ISO 9000:2000
- *“the organisational structure, procedures, processes and resources needed to implement quality management”*
  - BS EN ISO 8402:1995 – superseded!

# What is a quality management system?

- A quality management system:
  - *“defines and documents a series of systematic processes that are to be followed by all those working within an organisation”*
  - *is “designed to show that quality is present in every part of the organisation”*
  - *and “the objective is to avoid mistakes”*
    - - From: A Code of Practice for Tissue Banks, DoH, 2001

# Quality management in a research tissue bank will:

- act as a management tool
- provide compliance with regulatory requirements
- act as an external indicator of performance
- provide traceability for samples, data, processes, procedures and records
- show that procedures were carried out by trained staff using authorised methods, and using suitable reagents and equipment
- ensure that tissues and data are collected, stored and distributed in ways that:
  - give assurance to funders,
  - meet the wishes of donors,
  - respect the efforts of collaborators and
  - meet the needs of researchers
- and so ensure that tissues and data are “**fit for purpose**”

# Requirements for a quality management system

- The quality of a product or process is demonstrated by comparison with a **quality standard**

# Quality standards

- Written
- Consensus of what is needed to ensure quality
- Give you a standard to measure yourself against
- Give external, independent assessors and stakeholders a standard to measure you against
- Provide a basis for certification or accreditation

# Contents of quality standards

- **Management requirements** – general requirements applicable to any organisation
- **Technical requirements** – specific to the technical field

# Management requirements

- Organisation and management
- Quality system
- Document control
- Review of requests, tenders and contracts
- Sub-contracting
- Purchasing services and supplies
- Service to the client
- Complaints
- Control of non-conforming work
- Corrective action
- Preventive action
- Control of records
- Internal audits
- Management reviews

● BS EN ISO 9001:2000

# Technical requirements

- Personnel
- Accommodation and environmental conditions
- Methods and method validation
- Equipment
- Measurement traceability
- Sampling
- Handling of test and calibration items
- Assuring the quality of results
- Reporting the results

● BS EN ISO/IEC 17025:2005

# Tissue bank processes

- Donor recruitment including consent
- Data and sample collection
- Sample preparation and testing
- Sample transport to repository
- Sample storage and inventory management
- Sample request and allocation
- Sample retrieval, packaging and dispatch
- Ethically approved research
- Feedback to database

# Confederation of Cancer Biobanks Guiding Principles

- Biosample resources are for the public benefit
- Biosample resources should be based in donation with consent
- Biosample resources should protect public trust
- Biosample resources are integral to the provision of healthcare, although often secondary to the primary healthcare of the donors
- The operators of biosample resources act as custodians
- **Biosample resources exist to provide a quality service**
- Human biosample resources should be purposeful
- Biosamples should not be traded as commodities.



and finally.....

- Quality management systems are not static entities, therefore it is not possible to put one in place and then forget about it
- Quality management systems develop constantly and maintenance of a quality management system is an ongoing process



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being in "quality assurance" is  
the job equivalent of having  
your cd put in the "world  
music" section at the record  
store

