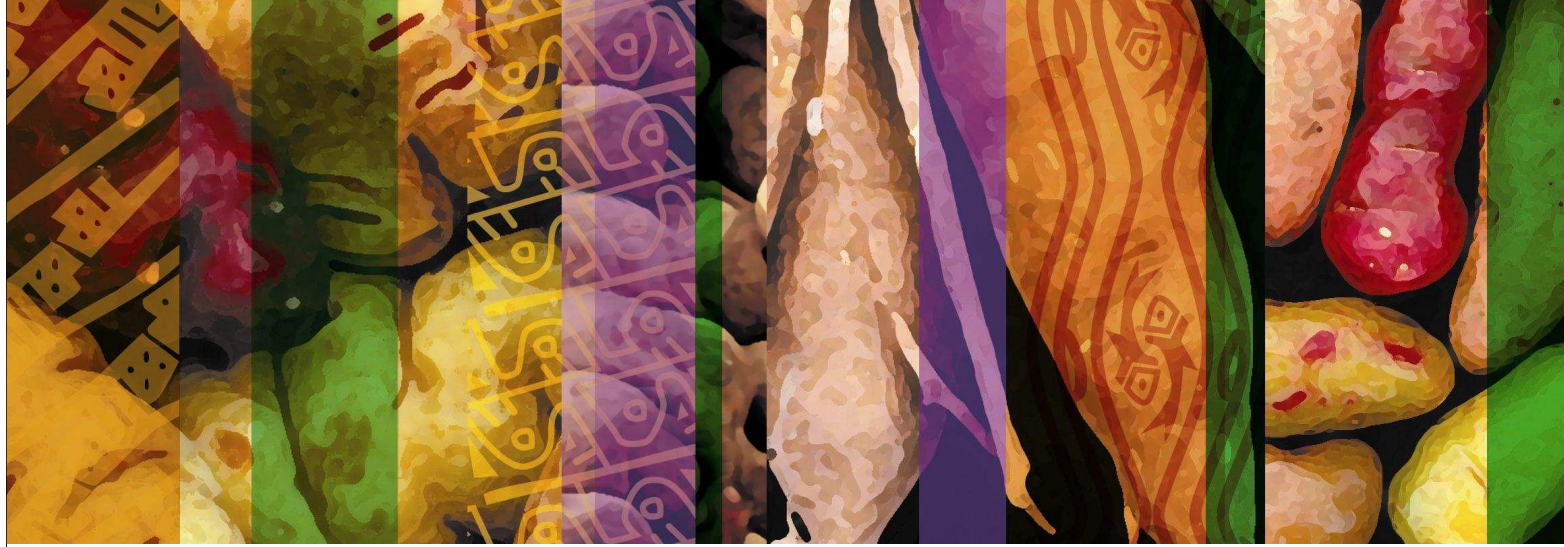


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# Quality Management Systems for Research Delivery

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# My background

***Technical background*** : food safety control and enforcement particularly in the area of pesticides and environmental contaminants

***Quality experience*** : 14 years working as an assessment manager for the UK National Accreditation Body (UKAS)

***Present Position*** : Director of Quality for the Central Science Laboratory, York UK

Responsible for the implementation of ISO 9001, ISO 17025, GLP and ISO Guide 43 compliant Quality Systems [CSL - About CSL](#)

***Work with CIP*** : Implementation of an ISO 17025 compliant Quality System for the Germplasm Distribution Process

# Central Science Laboratory



# Presentation Outline



- Quality Systems in Science and Technology
- Why do we need a Quality System
- International Quality Standards
- Requirements of a Quality System for Science Research
- Benefits of implementing a Quality System
- Model for the the CG's

# What is a Quality System

A quality management system directs and controls an organisation with regard to quality

The system establishes the policy and procedures to achieve the quality objectives

# Quality systems in science and technology

The implementation of a quality system has become the expected norm for many organisations in the areas of science and technology – customers demand it !

Quality systems are for example a regulatory requirement for food control, environmental management and chemical / drug development

Agricultural / biological science services and research have been slow in their response to this global trend

# When things go wrong!

Multi-million pound research contract for the UK Government used wrong brain material (cow instead of sheep) for work to establish link between sheep and cattle in BSE transmission

Discovered just before data was due to be released

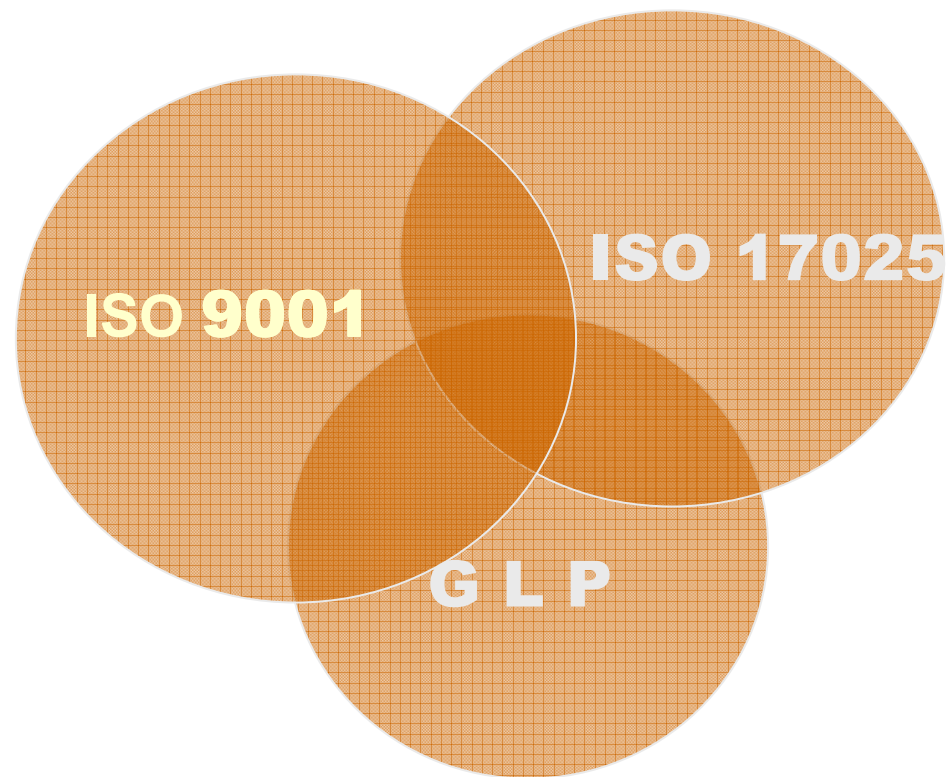
Outcome if not discovered would have been the total collapse of the UK lamb industry

UK Government implemented a policy of requiring all scientific research to be carried out under a quality system.

# Why do we need a quality system?

- Effectively manage risk
- Help improve the performance
- Assure the quality of the service or research provided
- Formalise systems for staff competence and training
- Gain recognition through Accreditation and Certification

# What are the international quality system standards ?



# What are the international quality system standards ?

ISO 9001 – covers the implementation of a quality system with limited or no technical input

ISO 17025 – covers the competence of a laboratory / organisation, a high level of technical input

Good Laboratory Practice GLP – covers the production of registration data for chemical submissions to registration bodies

# Requirements of Quality System for Research

The key aspects are :

- Definition of responsibilities
- Competence
- Project Planning
- Quality Control
- Health and Safety
- Handling of samples and materials
- Facilities and equipment
- Documentation of procedures and methods
- Research records

# Responsibilities

Responsibilities of managers, team leaders and supervisors to ensure a climate of good scientific practice including a commitment to the development of scientific and technical skills

Nomination of Principal Investigator or Project Leader responsible for all work conducted

Clear definition of staff responsibilities in relation to the all aspects of a project

# Competence

Clear definition of the competence of staff to perform technical scientific and support tasks

Supervision of staff undergoing training to ensure work is not compromised by inexperience of staff

Production of CV's / training records for staff

# Project planning

Risk assessed to demonstrate awareness of the key factors that will influence the success of the project

Production of a written project plan showing risks have been addressed

Milestones for the project clearly defined in the plan

Statistical validation of experimental plan and data analysis procedures documented

# Quality Control

Internal project reviews and auditing of projects undertaken at an appropriate frequency

Defined checking and approval procedures before publication of outputs

Regular review of processes and procedures to ensure continual improvement

# Health and Safety

Research must comply with relevant Health and Safety regulatory requirements

# Handling of samples and materials

Clear labeling of samples and other materials (clear, accurate, unique and durable)

Storage and handling of materials should be specified in the project plan and must be appropriate, monitored and recorded

Samples should be readily tracked through all stages of the process

Disposal by designated routes and dates

# Facilities and Equipment

Working environment must be appropriate to the work being carried out

Regular checks of special facilities ( e.g. fume hoods)

Measuring equipment must be appropriate for for the measurements being made, calibrated if necessary and in good working order.

# Documentation of procedures and methods

All procedures and methods used in project must be documented

Document control procedure must ensure staff only use approved procedural documentation

Analytical and statistical procedures should be included

Research methods must be validated to demonstrate fitness for purpose

# Research / work records

Records must be detailed enough to present a complete picture of the work enabling it to be repeated if necessary

Project Leader must ensure the validity of the work by carrying out regular reviews of the records of each scientist

Secondary processed information must be linked to primary data

Location of project records including critical data must be recorded and records stored under suitable conditions

# Benefits of quality system implementation

A clear management commitment to the quality objectives

Staff ownership of key processes

Clear documentation of all processes including effective internal quality control

Introduce a culture of opportunity focused on continual improvement

Effective internal audit of all processes adding value and improvement

# A model for the CG's

Possibility of the development and implementation of a “Code of Practice for Research” within the GC's

The management of the research project lifecycle can be formalised around project initiation, definition of responsibilities, implementation, milestone delivery and post project review

Code of Practice would define the framework giving enough flexibility to allow individual CG's to implement systems that meet local conditions