Quality Systems, Accreditation and the Food Sector

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Presentation Outline

- My background
- The Quality Standards
- Accreditation of laboratories in the Food Sector
- How to implement a Quality System
- Problems, staff views and the pros and cons of accreditation
- Areas of non-conformances at assessment
- Fitness of purpose of Quality Systems
- Future developments of Quality Systems

My Background

- Initial technical expertise – food chemistry, pesticide residue analysis and pesticide safety issues in the context of Developing Countries
- Accreditation : helped to establish the UK national accreditation body – now UKAS
- Worked at UKAS for over 12 years and carried out 1500 laboratory assessment visits across the globe
- Assessments focused on food enforcement and food / environmental monitoring laboratories
- Present position – directing quality at the Central Science Laboratory, CSL, York

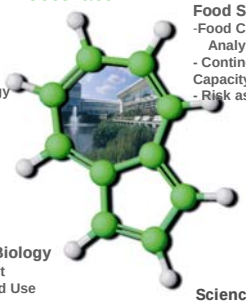
Science at CSL

Agri-Environment Directorate

Plant Health
- Plant disease detection
- Bee Inspectorate
- GM Inspectorate
- Environmental Microbiology

Wildlife Ecology And Management
- Statistics
- Wildlife Diseases
- Wildlife Management

Environmental Biology
- Risk Assessment
- Sustainable Land Use



Food Directorate

Food Science
- Food Chemistry and Analysis
- Contingency Capacity
- Risk assessment

Proficiency Testing

Quality Systems

Science Networks

Requirements of the different roles

National Institute

Representation at national and international level
Provision of experts (e.g. EFSA, CEN etc)
EU National Reference Laboratory (NRL)

Contract Laboratory

Cost-efficient, timely delivery, customer focussed

R&D Institute

Innovation, creativity, publications

Global Outlook

Present Quality Systems at CSL

Good Laboratory Practice GLP

ISO 17025 UKAS accredited testing

ISO Guide 43 UKAS accredited Proficiency Testing (PT)

CSL ISO 9001 Quality System

The Quality Standards

- Good Laboratory Practice (GLP) – Regulation for studies submitted to Regulatory Bodies
- ISO 17025 – technical Standard demonstrating the **competence** of the laboratory - assessed by Accreditation Body
- ISO 9001 – generic management Standard covering all aspects of the management of quality – assessed by Certification Body

ISO 17025

- Produced in 1999 and derived from 2 Standards – ISO Guide 25 and EN45001
- Up-dated in 2005
- Standard considers management and technical issues
- Standard is used by all recognised Accreditation Bodies for the assessment of the competence of laboratories

Accreditation and Food Enforcement

- European Community Regulation 882/2004 sets down the requirements for official control of foods and feeds
- Builds on the requirements of EU Directive 93/99/EEC
- Official control laboratories designated by a central competent authority

Food Control Directive Additional Measures Council Directive 93/99/EEC

Laboratories designated for Food Control purposes (OCLs) must:

1. Be accredited to ISO/IEC 17025
2. Participate in proficiency testing
3. Use validated methods of analysis

Impact of EU Directives in the UK

- In order to establish comparability of data between food laboratories providing due diligence data for food producers and the enforcement laboratories, it is now expected that the food laboratories will obtain accreditation to ISO 17025
- The major food retailers stipulate that all suppliers must use accredited laboratory services for production of this data
- Very often the accredited testing is linked to the food inspection activities as well

Proficiency Testing

- Enables labs to demonstrate performance on blind samples
- Assumes that stable, homogeneous materials are available
- Ideally 'true value' is known, but otherwise robust mean constitutes 'true value'
- Ideally realistic σ - value is known
- Results processed in terms of z scores – satisfactory, unsatisfactory or questionable

Why introduce a quality system and apply for accreditation ?

There are a number of reasons why :

- Commercial survival
- Customer confidence
- Independent recognition
- Legal requirements – eg compliance with EU Directives

Stages of implementing a quality system 1

Define Quality Objectives :

- establish a company wide quality system
- achieve accreditation for a defined scope of activities
- involve staff members
- raise profile of the company by improving quality standards
- meet customer requirements in terms of analysis and service

Stages of implementing a quality system 2

- Management decision to introduce a quality system
- Appoint Quality Manager
- Obtain appropriate information and training
- Set out plan for the introduction of the Quality System

Stages of implementing a quality system 3

Key stages of introducing the Quality System :

- document methods and produce validation data
- define responsibilities
- produce the Quality Manual and supporting procedures
- introduce audits
- ensure equipment control and calibration traceability
- formalise quality control regime

Problems of introducing a quality system

Problems reported include :

- time and money
- staff resistance
- structural changes within the organisation
- working to a system that is constantly developing

Staff views at time of accreditation

- Are the changes an improvement to the laboratory systems ?
  Yes – 83 %
- Has the quality of analytical data improved ?
  Yes – 72 %
- Has the standard of the service improved ?
  Yes 67%
- Has the workload increase ?
  Yes 67%
- Are the systems efficient ?
  Yes 78%
- Has the accreditation process been worthwhile ?
  Yes – 89 %

Perceived disadvantages by staff

- Costly
- Bureaucratic
- Increased workload
- Time consuming
- Stiffles innovation
- Restrictive
- Encourages a production line approach
- Pressure of assessments
- More paperwork

Perceived advantages by staff

- Improved customer confidence
- Increased recognition and company status
- Better training programme
- Harmonisation of systems across the laboratory
- Better quality of work
- Improvements in the accuracy of data

Areas of the ISO 17025 standard that lead to the most non-conformances

1. Insufficient documentation of methodology
2. Insufficient validation of methodology
3. Insufficient information recorded on the audit activities
4. Inadequate systems for quality control and the statistical monitoring of the results generated
5. Staff not following the documented procedure
6. Uncontrolled supporting documentation
7. Missing links in the records chain

Fitness for purpose – Quality System Requirements

- The Quality Standards do not define in detail the level of the Quality System
- It is up to the laboratory to define this level and then defend their decisions in terms of the fitness for purpose of the systems used

Fitness for purpose – key aspects to define

- Quality documentation- level of detail required
- Audit frequency and focus
- Calibration frequency
- Quality control procedures and frequency

Suggest a risk based approach to maximise the effectiveness of the system using past history to help define these aspects

The future for Quality Systems

- Integration
- E-solutions
- Simplification
- Process development and optimisation
- Developing the business

Integration

- The quality system Standards have a commonality in a number of areas including :
  - Quality system documentation
  - Document and records control
  - Audit
  - Equipment and environmental control
- Where possible, in order to increase the efficiency, a single coherent Quality System should be introduced

E-solutions

Move towards an electronic quality system covering :

- Document control
- LIMS
- Records management
- Web-based management of result reporting

Simplification

- Where ever possible simple approaches should be employed
- Historically, quality systems have tended to overcomplicate the workflow
- An excellent tool to help this is to use Process Mapping as a way of identifying waste, duplication and inefficiency

Process development and optimisation

- Quality systems have very often been seen in a policing role – compliance with a specific Quality Standard
- The purpose of the Quality System should be enhanced to a role of process development and optimisation
- As well as helping simplify processes, process mapping can be used as an excellent tool for process development and optimisation

Developing the business

The Quality System should :

- be fully integrated into the way the business is run
- **provide key business information to help run the Laboratory efficiently**
- be part of the development of business opportunities in terms of training, consultancy, marketing and development of new markets

Food Analysis Performance Assessment Scheme (FAPAS)

Chemical analysis proficiency testing (established 1990)
Participants from more than 99 countries

- Realistic test materials – wine, coffee, milk, fruit, whisky, canned meat, cornflakes etc.
- Diverse range of analytes – pesticides, mycotoxins, proximates, trace elements, food additives, nutritional components

2007/08 – 200 rounds of testing
+ 20 rounds of GMO testing offered

A report and test material issued every day