



A Quality Management System in the UK

Tony Herbert

WRGL 96 members of staff

Large Diagnostic Genetics laboratory with research staff and a reference lab

We run a good service – why do we need a QM system?

‘Clinical Pathology Accreditation’ (CPA) has decreed that every accredited lab shall have a ‘Quality Manager’

New CPA standards - April 2003

We can prove that we operate a good service if questioned.

Remit – to ensure 'quality' and improve efficiency

Quality of what?

Everything to do with the service !!

Reporting times

Written reports

Training

Facilities/equipment/supplies/waste management

Etc. etc.

All CPA standards

Could be massive undertaking !!

No funding to employ this person

No guidance on how this post should be managed

Who is going to be doing this ?



You are!

Quality management team – 13 people

Team members – represent every section of the department

Team members are responsible for QM in their own section

Team meets every 6 weeks and carries out 2 audits
between meetings – 16 scheduled audits/year

We discuss recent audits, QIN's, problems, future audits

Display the results of audits and minutes of meetings to the
Lab staff !!

Everybody contributes to quality, so involve everybody in
the process

Audits

Horizontal

Vertical

Witness/observation

How to conduct the audit?

Audits

Involve everybody but do not be disruptive

Lead auditor and an assistant – both conduct the audit and write the report

Lead auditor – member of QM team.

Assistant – member of staff

Feed back to lab – invite staff member to next QM meeting

No section ever audits its own section

Managing the data – software

We use iPassport – supplied by Genial Genetics Ltd

Benefits –

Ease of re-call - good search facilities – links to other documents

Problems -

Can be too prescriptive – tail wags the dog!

Strategy –

Avoid duplication of documents - always point to a source document if available – far easier to update

Problems with setting up a QM system:-

Selection of Quality Manager - important

Tend to be pedantic! – avoid at all costs!

Better if a senior member of staff

If it is a major job function the role will expand to fill the time available

Can be too bureaucratic – a good QM system should benefit the system, not impede it.

Too much paperwork eg.. UK police force.

Inspections

Main CPA inspections are every 4 years

Advance notice is given – huge performance.

Staff tend to relax vigilance in between visits –
difficult to motivate staff

The visit is not a true reflection of the QM system

In UK - problem recruiting peer reviewers!

- our CPA inspection has been postponed by 6 months!

In my opinion, Quality Management should be a way of life

These inspections should not be a big deal

A well organised lab should welcome spot inspections