Maintaining Analyser Validation

Richard Haggas
Blood Transfusion Quality Manager
Leeds Teaching Hospitals

THE LEEDS TEACHING HOSPITALS

Remit

- Background
- Validation / Qualification
- Revalidation
- Summary

Background

- SI 2005/50 – Blood Safety and Quality Regulations 2005

- EudraLex - Volume 4 Good manufacturing practice (GMP) Guidelines – Annex 15 Qualification and Validation

Annex 15 Validation and Qualification

- Facilities, systems and equipment to be used should have been qualified and analytical testing methods should be validated

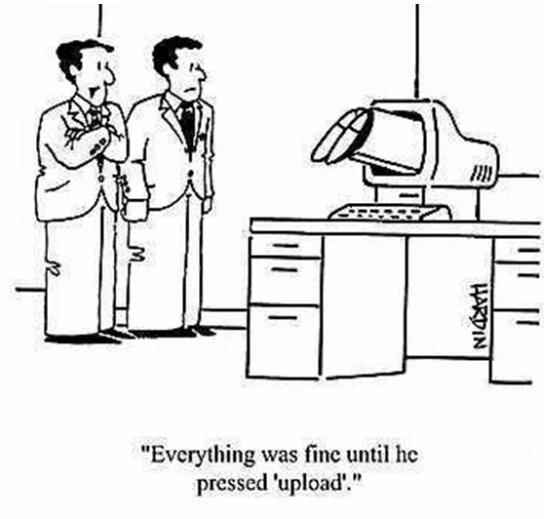
- Facilities, systems, equipment and processes should be periodically evaluated to verify that they are still operating in a valid manner.

Change control

- All changes that may affect product quality or reproducibility…should be evaluated, including risk analysis.

- The intent is to determine the need for action that would ensure and document that the system is maintained in a validated state.

When do we validate (qualify) analysers?



- When the risks are high
  - When first installed
  - Upgrade / change to software
  - Upgrade / change to hardware
  - Upgrade / change to interfaces
- Use test cases (samples) designed to ensure that the system / procedure is performing as it should; at its limits
  - Test grouping and screening results
  - Transfer of data across the interfaces

What about revalidation at other times?

- Regular revalidation after an appropriate timescale?
  - Yearly?
  - Every two years?
- Do we need to go through the whole validation testing process again?
- What about after servicing or repair?

Revalidation / requalification

- What does the guideline say about revalidation?
  - The need for, and the extent of, requalification and re-validation should be determined
- What does this mean?
  - You must re-perform validation testing regularly?

☒

  - Facilities, systems, equipment…should be **periodically evaluated** to confirm that they remain valid

☑

Revalidation

- Where no significant changes have been made to the validated status, a review with evidence that facilities, systems, equipment and processes meet the prescribed requirements fulfils the need for revalidation

After servicing or repair?

- Is this a significant change?
- What are the risks?
- Is running a set of grouping controls and weak antibody controls sufficient?
  - Probably yes
  - Depends on what the servicing or repair involves

What evidence is there?

- Maintenance logs
- Daily control results – group and antibody screens
  - Have there been any failures?
- Testing previously grouped patients
  - How many previously grouped and screened patient do you test?
  - How many incidents of the analyser incorrectly determining the group and screen results have you seen?
- Engineer servicing / calibration records
- Using all the above may be sufficient to demonstrate that the analyser continues to work in a validated state
- Document your assessment

Summary

- A risk assessment approach should be used to determine the scope and extent of validation
- Revalidation is about producing evidence that the process is still valid, this may involve retesting, but it doesn't have to.
- For further information
  - EudraLex - Volume 4 Good manufacturing practice (GMP) Guidelines
    - Annex 15 – Qualification and validation
    - Part III - GMP related documents – Quality Risk Management (ICH Q9)