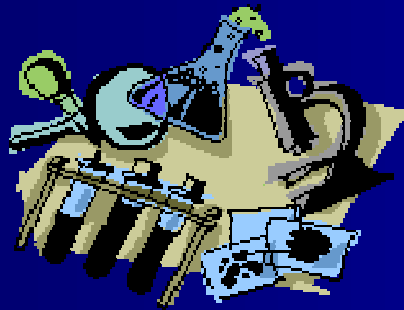


Validation of analytical systems – a hospital laboratory perspective





The thought of it !

WHY DO WE DO IT ????

Legislation and Standards



- CPA

- EU Blood Directive

- EU Tissue Directive

- ISO 15189

and more - IVD, ISO 9001:2000

EC4, ISO/IEC 17025:1999

etc..

CPA — Clinical Pathology Accreditation

Standard D – D1.2 (c)

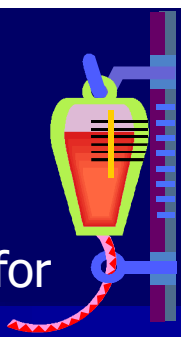
-Laboratory management shall establish a procedure for procurement and management of equipment that includes 'acceptance'

-What is acceptance ?

-Inspected by CPA UK

EU Blood Directive: 2002/98/EC

EU Tissue Directive 2004/23/EC and Irish Legislation S.I. 158 of 2006 (16 of 58 pages describe criminal penalties for failure to comply)



VALIDATION:

Validation is defined as the act of providing objective evidence that any procedure, process, equipment, material, activity or system actually leads to the expected result.

The aim of validation is to establish documented evidence which provides a high degree of assurance that the process/equipment works as intended by manufacturer and that it is reliable.

Irish Medicines Board (IMB) - regulator

ISO 15189

5.3.2

-Equipment shall be shown (upon installation and routine use) to be capable of achieving the performance required and shall comply with specifications relevant to the examinations concerned.

Thus validated for tests you are doing or range you are testing in

Inspected by INAB

So we have to do it

We all already validate pieces of new equipment – what's different is that we must now confirm what manufacturer is telling us

The following is an example of a new haematology analyser validation to illustrate the stages.



URS – User Requirement Specifications

Written before purchase – at tender stage

Describes:

- Applicable standards
- Exact description of item you require
- Functional and operational requirements
- Training requirements
- Maintenance and contract requirements
- Documentation requirements
- Software requirements



Validation MASTER PLAN



This describes the actions to be taken before new processes, equipment or facilities including software can be implemented. Similar actions may be required before change can be implemented to an existing equipment or facility.

Involves:

IQ/OQ/PQ

Acceptance criteria for all stages

Change control

Re-qualification criteria

Executive summary

Installation Qualification (IQ)

Confirming that we got exactly what we specified/purchased

IQ for FBC analyser

Verify correct equipment/documents received

including – operator manual (correct version)

- Maintenance manual
- Commissioning documents from engineer
- Calibration certificates (traceable to international stds)
- Serial no/printer/barcode reader/Sample racks/
- instrument positioned correctly
- Software versions/ operating systems/back-up disks etc.



Operational Qualification (OQ)

Establishes that the analyser operates at all times within design parameters as specified in the equipment/technical specifications

i.e. OQ = 'it does exactly what it says on the tin'

-Power up and self test

-Bar-code reader check (using all applicable labels)

-Unsuitable sample detection by system – short samples etc

-Sampling time – checked using stopwatch!

-Calibration verification – carry out a repeat of engineer's calibration

Operational Qualification (OQ) – cont'd

- Linearity verification – commercial kits available*
- Accuracy – QC material*
- Reproducibility – fresh samples – multiple runs*
- Alarm verification – simulate critical alarm conditions*
- Software security access – passwords etc.*
- Software functionality !!*
- Autoloader functionality*

Pass/fail recorded for each test and all raw data filed in appendix

Acceptance criteria confirmed

Any problems ? – Non-conformance created.

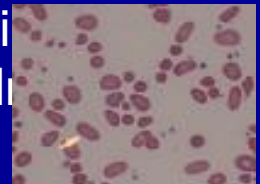
Performance Qualification (PQ)

Verify FBC results from new analyser with existing analyser by parallel testing (of course you are getting rid of old analyser – why?)

Number of samples to test ? – **150 minimum**
To include all main sample types – paediatric/
malignant/haemoglobinopathy etc..

Statistical analysis of comparison data and verify that they pass acceptance criteria.

FBC analyser produces FLAGS – alerting user to abnormal cells. Verify that new instrument 'flagging' as good as older machine. Might involve blood film subjective!



Analyser checks out !



Change control

- Inform all relevant personnel that new equipment in use.
- Staff training completed/training courses attended
- Staff Competency assessment
- IEQAS / NEQAS results returned (? Not critical)
- Interface to LIS – validated
- SOP's in place/signed off
- REFERENCE RANGE – if changed all users informed

EXECUTIVE SUMMARY:

Final sign off by Laboratory manager/Chief Medical Scientist

-relevant person with technical knowledge to adjudicate on any non-conformances that may have arisen

Re-Qualification:

Criteria set at this stage to re-qualify analyser in future

e.g. 2 PM visits per year – what is required after each visit

major part replacement – e.g. laser is re-verification required ?

Does 'flagging' require periodical verification.

Usually set in conjunction with manufacturer!

AND NOW -----

Now you can do some FBC's !

