Programme Accreditation and Validations

Hazel Bell

SANBS

ACCREDITATION

- Accreditation means third party confirmation related to conformity assessment and calibration facilities conveying formal demonstration of their competence to carry out tasks against criteria in national and/or international guides and standards
- South African National Accreditation System (SANAS)
- Blood Transfusion Standards and ISO 17025

SANBS

TYPES OF VALIDATIONS

- Validation: *Validation conducted prior to implementation of either a new equipment, product, reagent, IT system or process*

- Regarded as best practice
- Meets the required specifications prior to use
- Determine whether or not changes are required prior to production
- Decreases the risk of producing a poor quality product upfront
  Decrease in the number of product recalls due to quality deficiency

SANBS

TYPES OF VALIDATIONS

- Concurrent Validation: *Validation conducted on new equipment, product, reagent, IT system or process simultaneously with implementation*

- Possibly recall, loss of accreditation, non-compliance to legislation or harm to the customer
- Loss in revenue due to litigation, destruction of non-conforming products and loss of customers due reputation

SANBS

TYPES OF VALIDATIONS

- Retrospective Validation: *Validation conducted on new equipment, product, reagent, IT system or process post implementation based on historical data*

- Difference being that the loss in revenue will be much higher as this is directly proportionate to the higher amount of products already in circulation

SANBS

OTHER TYPES OF VALIDATIONS

There are other types of validations used in other sectors of industry. Other validations include but are not limited to:

- Procedure Validations
- Cleaning Validations
- Process validations
- Instrument Validations
- Computer Validations

SANBS

KEYS TAKE HOME POINTS TO VALIDATIONS

- A validation must be documented (Protocol and Reports)
- Acceptance criteria must be clearly defined
- A validation must be run concurrently with controls
- The conditions under which a validation is performed must mimic exactly what will take place in the true process and cover all potential extremes to which the process or system may be subjected
- Testing must be sufficiently rigorous as more data will provide a more accurate account of whether the machine/process is meeting the pre-determined specifications
- When required, only change one variable at a time as this will indicate which variable requires improvement

SANBS

ADVANTAGES OF VALIDATION

- Expanded real time monitoring and adjustment of process
- Enhanced ability to statistically evaluate process performance and product variables e.g., individuals; mean; range; control limits
- Enhanced data and evaluation capabilities and increased confidence about process reproducibility and product quality
- Improved ability to set target parameters and control limits for routine production, correlating with validation results
- Enhanced reporting capability
- Gives you confidence in the new equipment, product, reagent, IT system or process and proves it is fit for use

SANBS

QUESTIONS

How do mobile units ensure equipment is validated and producing the require quality product

Should mobile units be audited

How do we assure consistent products from mobiles

In countries where no technical support or funds how do they validate equipment?

SANBS

THANK
YOU