CALIBRATION OPTIMISATION PROGRAMME

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Pharmaceutical facilities cannot function without calibration. Adhering to the stringent EudraLex/FDA regulations, ISO standards and the vast quantity of instruments requiring regular calibration is a time consuming, costly process. Our Calibration Optimisation Programme is a quality orientated process that will ensure your calibration effort is streamlined. The identification of **what** instruments need calibration and determining **when** they need to be calibrated is the output of this risk based approach to calibration programme management.

INCREASED EFFICIENCY

Optimal efficiency is achieved by examination of the calibration programme as a whole, identifying waste, and implementing a stepped robust process to eliminate the waste. Increased efficiency and optimal cost risk balance for all facility calibration activities is achieved on implementation. Our cients have experienced a positive impact not only in the calibration department efficiency, but also across the entire engineering department.

REDUCED COST

This risk based approach provides a bespoke solution to instrument classification and interval determination that can reduce the number of yearly calibrations using scientifically justifiable methods. We use statistical data to derive appropriate calibration intervals. The statistical approach ensures over calibration of facility assets is eliminated and can result in a 50 % saving in the yearly calibration spend.

THE STEPS

1. CRITICALITY RISK ASSESSMENT (CRA)

- PERFORM PROCEDURE REVIEW
- ENSURE EVERY INSTRUMENT HAS THE CORRECT CLASSIFICATION
- VALIDATION DOCUMENTATION LEVERAGED IN THE DECISION MAKING PROCESS, REMOVES AMBIGUITY

2. INTERVAL DETERMINATION

- INTERVAL DETERMINATION USING STATISTICAL ALGORITHM
- ENCOMPASSES HISTORICAL PERFORMANCE & ENVIRONMENTAL CONDITIONS

3. QUALITY RISK ASSESSMENT (QRA)

- DETERMINED INTERVAL RISK ASSESSED FOR SUITABILITY
- CONTINUOUS IMPROVEMENT TOOL TO IMPROVE PROCESSESS & PROCEDURES

INCREASED EQUIPMENT AVAILABILITY

Asset management is of high importance and when carried out correctly, the effects can be multifaceted. As a direct result of a decrease in the number of yearly calibrations, equipment availability will see a corresponding increase. Production time will be optimised as our process is setup to identify problems, determine the root cause and use specifically developed tools and procedures to solve complex problems with simple, highly effective solutions.

REDUCED RISK

It is counterintuitive to think that a reduction in cost could be accompanied by a reduction in risk to product quality, patient/operator safety and the environment but it's true in this case. Our Calibration Optimization program was developed using the International Society for Pharmaceutical Engineers (ISPE) GAMP Good Practice Guide: A Risk Based Approach to Calibration Management. The GAMP guide was produced with a multifaceted agenda; both, to represent the regulatory bodies' current thinking and also to provide some uniformity across the industry.

TRUSTED CALIBRATION SPECIALISTS

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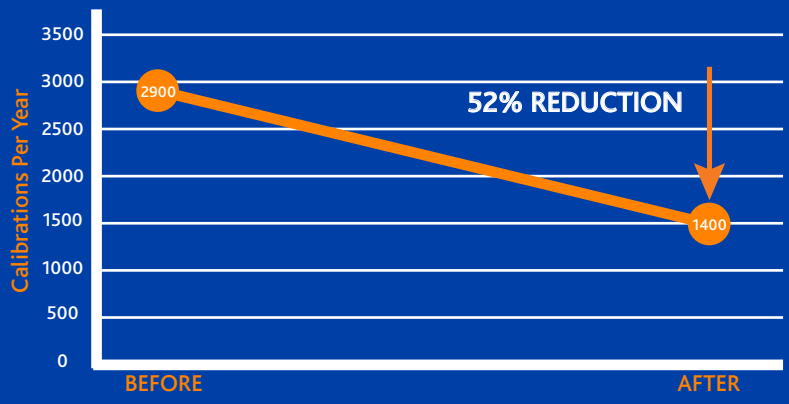
WHY CHOOSE LOTUSWORKS

- HIGHLY SKILLED ENGINEERS & TECHNICIANS
- GREAT CUSTOMER SERVICE
- 27+ YEARS PHARMACEUTICAL EXPERIENCE
- CONTINUOUS IMPROVEMENT CULTURE

CASE STUDY

Facility X specialises in the fermentation, purification and sterile filling of biotech products. It is also involved in the manufacturing of products used in clinical studies worldwide. The plant is approximately 30 years in operation and has approximately 2900 calibrations per year.



THE RESULTS: Implementation of the LotusWorks Calibration Optimisation Programme led to a reduction in the number of instruments classified as critical from 64 % to 46 %. The number of yearly calibrations was reduced from 2900 to 1400.

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ISO 9001:2008 Quality Assurance
OHSAS 18001:2007 Health and Safety
ISO 14001:2004 Environmental Management