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A Risk-Based Approach to Asset Management:

Building Quality into an Asset Management Program

By Evelyn Morris, Global Quality Manager, NEXA | EAM

Complying with regulations in the life science industry, while ensuring a cost-effective business model does not mean that all assets should be treated as critical. A risk-based approach to Asset Management ensures both time and effort are spent when and where it is needed, eliminating non-value add activities.

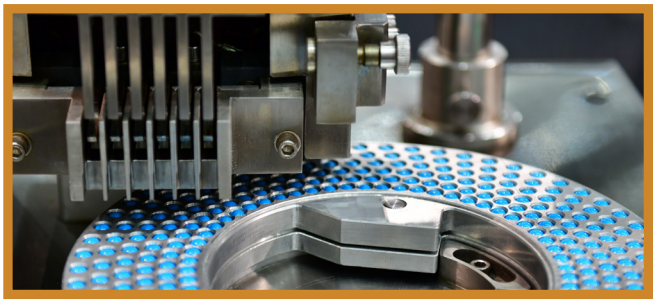
It is no surprise that a reactive environment, addressing issues only when they arise, can often lead to a dissatisfied, burnt-out workforce, as well as cause excessive cost implications for a company. Implementing a proactive approach and building quality into an Asset Management Program increases productivity, demonstrates control, and ensures quality.

A study recently completed by NEXA | EAM found that the typical cost of executing an out of tolerance calibration investigation is approximately $6,000.

Following the review of more than 250,000 out of tolerance investigations, across a number of industries, we found only ONE that resulted in a product hold, and ZERO that resulted in a product recall. This results in approximately $1.5B spent by companies to investigate calibration failures with ZERO impact.

By implementing a risk-based calibration program, industries can save hundreds of thousands of dollars year over year, and significantly improve quality. However, risk is not about taking risks.

A risk-based approach is about protecting products and processes based on science and data. It allows us to focus on the areas of a program that pose the greatest risk to product quality while **Reducing Time, Increasing Efficiency, and Reducing Cost**.



Case Study

NEXA | EAM delivered an Asset Management Program Improvement project for a global biotechnology company after the company received a number of audit findings that resulted in a manufacturing stoppage.

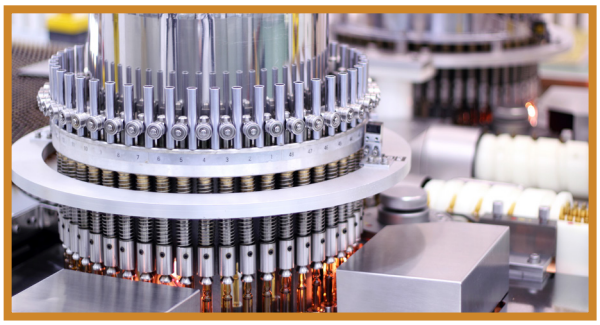
The NEXA | EAM team executed the following:

- Developed and implemented a risk-based asset management program for the company.
- Assessed all asset management related procedures across all global sites, to ensure processes were compliant, effective, and efficient.
- Executed an asset assessment process, which determined appropriate Classifications, Intervals, and Tolerances, for all assets.

Project Results

- Annual spend was reduced by 40%
- Critical assets reduced by 55%
- Calibrations per year reduced by 10%
- All audit and CAPA actions closed on time
- ZERO audit findings or observations during follow-up audit

Provided below are some key areas that, if implemented correctly, can provide significant improvements for your organization's Asset Management Program.



Instrument Classifications

Instrument Classification can improve the understanding of the instrument's:

- Function and purpose
- Role and expected performance in the program
- Appropriate calibration intervals
- Impact of failure

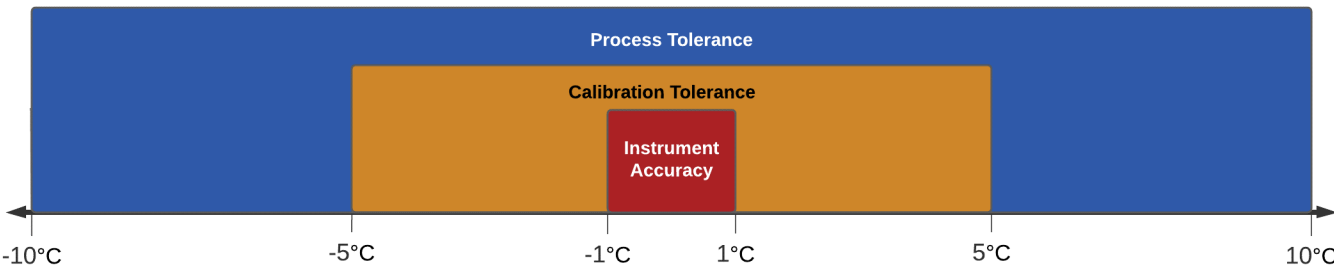
Determining if an instrument is critical to Product, Process, Safety, and Environment, or even if it is non-critical to the business can define the level of investigation needed if found to be out of tolerance. Classifying instruments can provide the framework needed to ensure critical attention and focus is directed where and when it is needed, eliminating non-value add investigations, reducing time and cost.

Calibration Tolerances

It is common to apply the manufacturers instrument accuracy statement as the calibration tolerance, but the manufacturer of an instrument cannot define your calibration tolerances. They don't know *how, where, when*, and *why* the instrument is used in your process.

In the example below:

- The instrument has an accuracy of +/-1°C
- The process has a tolerance of +/-10°C



We can see that a calibration tolerance equal to the instrument accuracy could be tighter than it needs to be, and this could result in non-value add out of tolerance investigations and actions. By opening up the calibration tolerance, based on the needs of the process, we can reduce out of tolerance events and investigations, saving time and money!

Calibration Intervals

As with calibration tolerances, it is all too common to implement the calibration interval stated by the manufacturer; but again, manufacturers don't know *how, where, when, and why* the instrument is used in your process.

We have also seen Instrument Grouping as a method for calibration intervals, where the same interval is assigned to similar or grouped instruments. Calibration intervals must be commensurate with the conditions in which it will be used and its expected performance, NOT the manufacturers statement or the group of instruments it falls into.

Procedures

Procedures are key to demonstrating and ensuring compliance in an Asset Management Program. In an audit situation, procedures can set the narrative or direction of the audit. If procedures are unclear or difficult to understand, this can demonstrate a lack of process understanding and control.

By implementing clear, concise, and easy to understand procedures, this will not only demonstrate compliance, but will also ensure the audience understands the instruction and expectations of the procedures, resulting in 'right first time' actions.

The NEXA | EAM approach to developing or improving procedures is to:

- Reduce the content
- Ensure content is audience specific
- Incorporate visuals where possible
- Prioritize the core requirements
- Ensure guidance and instruction is clear, concise, and easy to understand

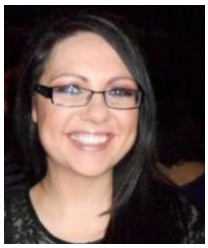
Is your Asset Management Program risk-based? Have you identified areas for improvement, but lack the in-house resources to implement a new program?

Seeking the guidance of an experienced professional services company, highly skilled in Asset Management Program improvements, may be the best strategy you need to assist your organization in implementing a risk-based, proactive process—ensuring time and money is only spent when and where it is needed. Taking this approach will ensure quality is built into the program, preventing unnecessary rework, investigations, and ensuring the safety of your product.

Procedure Concerns

- Between 2019 and 2020, there were more than 170 FDA citations issued relating to instrument control procedures; procedures not in place, not adequate, or not followed.
- Procedures must be developed to cover all aspects of the Asset Management Program, but they must be clear, concise, and easy to understand.
- Various researches have shown that 65% of people are visual learners. Also, 90% of information transmitted to the brain is visual, and visuals are processed 60,000 times faster in the brain than text.
- Therefore, not everyone training to a 10-20-page long document, with streams of text, will be able to absorb and understand the instruction.

About the Author



Evelyn Morris, Global Quality Manager at NEXA | EAM, is an experienced Quality Specialist with over 20 years' experience working in the medical device and pharmaceutical industries. She is highly skilled in project management, calibration systems, calibration regulatory compliance, metrology, validation, GMP, and technical writing. Evelyn is a Certified Project Manager and holds a IPMA Level D Certification, and earned her B.Sc. in Quality Engineering from IT Sligo, Ireland. Contact: emorris@nexaeam.com

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