

Why Calibrate?

How to create and sustain an effective Calibration Program in a GXP environment.

Quote

“You can’t manage what you don’t
measure”

Anonymous

Overview

- Regulatory Requirements
- Definitions
- Historical Issues
- Business Impacts
- Make it Effective
- Calibration Program
- Master Instrument List
- Activity Scheduling
- Documentation
- Safety Concerns
- Personnel Qualifications
- Calibration Laboratory
- Laboratory Accreditation
- Calibration Outsourcing
- CI

Regulatory Requirements

- 21CFR 211.68 Automatic, mechanical & electronic equipment
- 21CFR 211.160 Laboratory Controls
- 21CFR 211.194 Laboratory Records
- 21CFR 820.72 Inspection, measuring & test equipment
- EU GMP's
- Canadian GMP's
- ICH Q7A
- ISO 9000

Regulatory Requirements (Cont.)

- Common Themes:
 - Written Program
 - Routine calibration or verification at suitable intervals
 - Control of inspection, measuring and test equipment.
 - Calibration procedures including specific directions and limits for accuracy and precision
 - Deviation or discrepancies should be investigated
 - Traceable Calibration Standards
 - Calibration records
 - Visible Calibration status

Definitions

- Calibration: process of comparing an unknown against a reference standard within defined limits, accuracies and uncertainties
- Verification: process of comparing an unknown against a reference standard at usually one data point

Historical Issues

- Cost, cost, cost
- No clear goals
- Limited technical oversight or understanding
- Most QA staff afraid of it

Issues resolve themselves into business impacting events

- As components age and equipment undergoes changes in temperature or humidity or sustains mechanical stress, performance gradually degrades. This is called *drift*. When this happens your test results become unreliable and both design and production quality suffer. While drift cannot be eliminated, it can be detected and either corrected or compensated for through the process of calibration.

Compliance Consequences

- According to the FDA there were 42 warning letters involving calibration issues in 2006.

If it's done right, what it buys you!

Properly calibrated equipment provides confidence that your products/services meet their specifications.

Calibration:

- increases production yields,
- optimizes resources,
- assures consistency and
- ensures measurements (and perhaps products) are compatible with those made elsewhere.

By making sure that your measurements are based on international standards, you promote customer acceptance of your products around the world.

But if you're still looking to justify that the cost of calibration does add value, you need to measure it!

Make it Effective

- Select a champion
- Say what you do, do what you say
- Track costs and savings
- Tie into validation activities
- Tie into building commissioning activities
- Obtain technical competence
- Develop personnel
- Management and QA buy-in
- Use risked base approach

Calibration Program

- Define scope
- Responsibilities
- Definitions
- Qualification of personnel
- Identification of equipment & instrumentation
- Procedures
- Frequency or interval
- OOS reading and impact assessments
- Records and labeling
- Re-calibration
- Removal from program

Master Instrument List

- Description or name
- Unique identifier
- Instrument accuracy, range, etc.
- Criticality (using Risk assessment tools)
- Calibration frequency
- Location
- Expiration or due date
- Applicable calibration procedure and standards

Activity Scheduling

- When
- Where
- Who
- How long
- Use for management reporting of cost metrics

Documentation

- Individual Procedures
 - Instrument selection
 - Acceptance criteria
 - Error budget
 - Standards
- Calibration forms (GAMP compliant)
- Labels

Safety Concerns

- Chemical Safety
 - HazCom
 - MSDS
- Electrical Safety (NFPA 70E)
- Temperature Safety
- Stored Energy Safety (LO/TO)

Personnel Qualifications

- Train, Train, Train
- Develop CV's for responsible parties
- Certifications – ASQ CCT
- Create career paths for personnel development
- Obtain technical oversight for program and document review/approval
- Code of Ethics

Calibration Lab

- Suitable conditions
- Enough room for storage & work
- Proper utilities

Laboratory Accreditation

- ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories.

Calibration Outsourcing

- Bid for best value
- Qualifications package
- Procedures
- Audit for compliance
- Always review and approve certificates

Apply CI Tools

- Lean practices
- 6-Sigma
 - DMAIC
 - SWOT
 - Cause/Effect
 - Process Maps
 - Control Charts

Keep driving improvement and measure gains
to the bottom line!!!!