

FDA Warning Letter Excerpt: "...failure to conduct periodic inspections... to ensure adherence to applicable equipment maintenance schedules."

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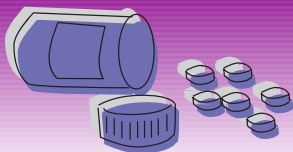
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**“...equipment is not maintained appropriately to prevent malfunctions that might alter the safety, identity, strength, quality or purity of drug products...”**

**DAY ONE  
THURSDAY, MARCH 8, 2007**

**7:45 REGISTRATION AND BREAKFAST**

**8:45 CHAIRPERSON'S WELCOME AND  
OPENING REMARKS**

**CASE STUDY**

**IN-DEPTH INTERACTIVE WORKSHOP**

**9:00 EXAMINATION OF OUT-OF-TOLERANCE  
(OOT) AND FAILURE ESCALATION**

*Marcus McNeeley, Project Manager*

BLUE MOUNTAIN QUALITY RESOURCES

In today's world of regulated healthcare metrology, assessing the impact of Calibration Out of Tolerance conditions to the end product is as essential as calibration itself. Regulatory bodies often pay particular detail to the necessary basics of a GxP compliant OOT investigation and Criticality Assessment system. The approach taken should incorporate a team-based approach to equipment and instrumentation implementation that matches process specifications and includes necessary CAPA (corrective and preventive action).

Through incorporation and documentation of a knowledge base through interdepartmental harmonization, every team within a supported process collectively contributes a sound rationale for the process limits, calibration limits, and purchasing the necessary IM&TE (Instrument Measurement and Testing Equipment) and systems relating to the supported process. When this knowledge is compiled, OOT conditions occur to a much lesser frequency, and sound OOT Impact Assessments can be made based upon a solid framework.

This workshop discusses the importance of OOT Impact Assessments and examines how a validated software package can improve the efficiency and effectiveness of discovering and properly responding to OOT conditions.

- Understand the importance of OOT Impact Assessments
- Implementing interdepartmental harmonization
- How a validated software can improve the response to OOT conditions

**About the workshop leader:** Marcus McNeely has been in the field of Biotech and Pharmaceutical asset management for over fourteen years. He has managed GxP biotech programs in both manufacturing and laboratory environments, in addition to involvement in various biopharmaceutical quality programs. He has also been responsible for GMP, calibration and systems

training for large groups and individuals. As project manager at Blue Mountain Quality Resources, Marcus consults with biotech, pharmaceutical, and medical device companies on best practices in every step in establishing, managing, and maintaining an asset management program. Marcus holds a degree in electronics engineering technology and is a member of International Society for Pharmaceutical Engineering (ISPE).

**12:00 LUNCHEON**

**CASE STUDY**

**1:00 HARMONIZATION OF PROTOCOLS FOR  
SERVICE, MAINTENANCE REPORTS, GLP  
OR GMP MULTI-VENDOR INSTRUMENT  
VALIDATION**

*Joseph Tehrani, PhD, Multivendor Validation Business  
Leader, and Arthur Boyer, PhD, Multivendor  
Validation Program Manager*

PERKINELMER LIFE & ANALYTICAL SCIENCES

The trend in most pharmaceutical organizations is moving toward vendor-neutral service providers because of the need for business as well as compliance simplification. Many pharmaceutical companies have acquired a complex array of instruments for laboratory testing in the GLP/GMP (GxP) compliance environment. These instruments are many times daunting to manage since they are manufactured by different vendors, have multiple models and are used in multi-vendor configurations. (For example, a typical LC/MS/MS system is composed of an injector made by company X, HPLC pump made by company Y and triple quadrupole mass spectrometer manufactured by company Z.)

GxP validation protocols and compliance data generated by companies X, Y, and Z are usually dissimilar with lengthy reports, difficult to comprehend, and most often do not test the overall function of the complete configuration. One step in reducing the complexity of the validation process and, therefore, harmonize the management process, has been to develop unified protocol (e.g., for LC/MS/MS) that covers all instrument configurations from instrument companies A – Z. At this point it becomes easier for a laboratory manager to understand, control, document and defend validation data and manage preventative maintenance (PM) and service to reduce regulatory risk. Prior to this point, the validation data from various vendors may be too complex and ill-documented to understand. Unfortunately, the overall system (holistic) validation may be completely overlooked and, therefore, the instrument validation may be suspect.

A straightforward and easy to follow protocol provides a solution to the problem by supplying a clear procedure for validation for all configurations from all instrument companies A – Z, or broad sub-set thereof.

Examples of LC/MS/MS validation data will include multi-vendor configurations with generic, transparent protocols designed to effectively streamline GxP instrument compliance, service and PMs. Minimization of down-time (of course) allows the pharmaceutical scientist to maximize throughput of mission critical samples.

- Standardization of procedures and reports to reduce regulatory risk
- Validation of holistic system as compared to individual sub-systems
- Eliminating the need for scheduling qualifications from multiple vendors that are disruptive, costly, and non-standardized documents
- Standardizing "Change Control" procedures and reports for re-qualification after PM software / firmware upgrade, and minor or major repair of components
- Simplified and straightforward protocol review and document management for all components and subsystems

## IN-DEPTH AUDIT AND REGULATORY ISSUE COVERAGE

### CASE STUDY

#### **2:00 CORRECTING OOS/OOT OBSERVATIONS AND EVENTS WITH APPROPRIATE RESPONSES**

*Sherri Robbins, Quality Assurance Manager*  
NELSON LABORATORIES

Correcting Out-Of-Specification (OOS) and Out-Of-Tolerance (OOT) issues stems far beyond just getting equipment up and running again. It requires knowledge of root cause analysis tools, risk analysis, and preventive and predictive maintenance techniques to incorporate preventive action measures.

This session will explore the utilization of:

- Various root cause analysis techniques
- HACCP and FMEA tools
- Utilization of reliability concepts in order to optimize resources and minimize downtime.

When working in a regulated industry, we need to think like the FDA! Therefore, this session will also cover how to prepare a response to audit observations. Become exposed to recent FDA 483 calibration issues and discuss ways to prevent these from happening in your systems.

#### **3:00 AFTERNOON BREAK • 7<sup>TH</sup> INNING STRETCH**

### **3:15 PLANNING FOR INTERNAL AND EXTERNAL AUDITS OF A PREVENTIVE/PREDICTIVE MAINTENANCE PROGRAM FOR GMP CONFORMANCE**

*Desiree Pritchett, Regulatory Manager*  
NELSON LABORATORIES

This presentation will describe methods for planning and performance of internal and external audits, focusing on applicability to maintenance programs. The session will cover preparation for audits from the point of view of the auditee and the auditor.

- What are the regulatory requirements for internal and supplier audits?
- Examination of preparation for audits from an auditor's perspective or auditee's perspective
- Audit performance and follow up

### CASE STUDY

#### **4:15 DEVELOPING A COMPREHENSIVE APPROACH TO THE FACILITIES AND EQUIPMENT SUBSYSTEM OF QSIT**

*Bill Taliaferro, Director of Global Sales*  
BLUE MOUNTAIN QUALITY RESOURCES

The FDA's Quality System Inspection Technique (QSIT) - which includes calibration management as part of its "Facilities and Equipment" category - is changing how the FDA inspects regulated sites and is driving the recent harmonization, integration, and application consolidation between systems for managing distinct aspects of a quality system.

The different disciplines within this category - most notably calibration, maintenance, and validation - interact with and affect each other in the context of an equipment's total life cycle to maintain the validated state. With these interactions and understanding the impact decisions in one department can have on another department, there are possible synergies between the departments to increase productivity through reduced downtime and better use of human resources. Likewise there are advantages to be had for sharing information across systems that manage these activities. Before heading down the path of system integration or consolidation, it is important to understand how the system requirements differ for each department, what requirements they each have in common, and how each prefers to interact with the data. For example, whereas the calibration department prefers to look at its data from an equipment-centric standpoint, the maintenance department is much more driven by work orders.

This presentation will discuss the different system options for a comprehensive approach to the Facilities and Equipment Subsystem of QSIT and provide some guidance on how to choose the option that is most appropriate for each company.

- Understanding what the FDA considers part of the Facilities and Equipment Subsystem of QSIT
- Investigating other driving forces behind a comprehensive approach for calibration, maintenance and validation
- Exploring the differences and similarities between these facilities and equipment disciplines
- Conduct Pros and Con analysis of different system options available

- Examining international and cross plant support
- Strategies for dealing with non-conformists
- Updating systems for new technology and ever more stringent demands
- Use of new technology, such as RFID's, which require Instrument repair and calibrations to ensure company systems work well

## 5:15 INTERACTIVE PANEL DISCUSSION

INCLUDING ALL DAY ONE SPEAKERS

The needs for calibration and maintenance today and tomorrow

- Challenges presented with implementing new technologies
- Trends in new technologies and their applications
- Future of remote technologies and methods
- Questions and answers

## 5:45 HAPPY HOUR MINGLER SPONSORED BY BLUE MOUNTAIN QUALITY RESOURCES



**DAY TWO**  
**FRIDAY, MARCH 9, 2007**

## 7:30 BREAKFAST

## 8:30 CHAIRPERSON'S OPENING REMARKS

### CASE STUDY

## 8:35 DEVELOPING GLOBAL LEADERSHIP IN CALIBRATION MANAGEMENT

*William Fons, Senior Project Engineer, Global Instrumentation and Calibration Services*  
ABBOTT

This session will examine long term benefits of Global Corporate Standards Abbott has 60,000 employees in 72 Countries at more than 100 manufacturing, distribution, research and development and other facilities. The corporation has moved into a global mode. In conjunction with metrology, efforts are being made to standardize instrumentation. The advantages of standardization are:

- Fewer manufacturers of instruments which will result in purchasing savings
- Fewer spare parts resulting in lower inventory cost
- Lower training costs for technicians
- Constancy in compliance with regulatory initiatives

The attendees will explore in detail:

## 9:30 EXAMINING CERTIFIED REFERENCE MATERIAL ARTIFACTS FOR ANALYTICAL METROLOGY

*Jerry Messman, Managing Director*  
STRANASKA SCIENTIFIC LLC

The use of certified reference material (CRM) artifacts is the cornerstone of analytical metrology in the life science industry for the qualification, systems suitability testing, performance monitoring, diagnostics, and routine quality control of analytical measuring instrumentation. Measurement traceability is the single most salient feature of CRM artifacts for demonstrating integrity and scientific defensibility of the metrological calibration process whether it is in the laboratory, in remote field environments, or at the process site. This session will provide unique insight into the metrological calibration process for selected analytical measuring instruments with an emphasis on spectroscopic instrumentation.

Relative to analytical metrology, attendees of this session will learn the following:

- Development of a science-based strategy for the metrological calibration of analytical measuring instruments
- Identify primary NIST SRM artifacts and secondary commercial CRM artifacts for specific user applications
- Recognize measurement traceability criteria for commercial CRM artifacts, and how to assess the validity of their "NIST-traceable" claims
- Examine commercial CRM artifact Certificates or Reports of Calibration for proof of measurement traceability of the certified reference values
- Asking proper questions when purchasing commercial CRM artifacts or recalibration measurement services

## 10:30 MID-MORNING BREAK

### CASE STUDY

## 10:45 BEST PRACTICES IN PREVENTIVE MAINTENANCE AND CALIBRATION TRAINING

*Philip Nicolini, Mid Atlantic Regional Manager*  
PHARMACEUTICAL SERVICES CORP.

This session will discuss the different methods used in the training of personnel for calibration and maintenance programs.

The discussion will include why proper training is not only mission critical but required by the FDA.

- Examination of current methods typically used for training
- Implementing enhanced personnel training
- Identifying typical problems associated with improper/inadequate training
- Choosing a provider to meet your training needs

Key questions that must be asked when looking at training programs:

- Are we being trained in our usage of the product as it is being used, or simply receiving standard/default training, and does this meet federal requirements?
- How often should refresher trainings be held, and by whom?
- What are the risks we are exposed to with our current training programs?
- What are the various methods being used throughout the biotech and pharma industry in regard to training?

## 11:45 LUNCHEON

### EXTENDED SESSION INCLUDING ARCFLASH STANDARDS CRITICAL TO PERSONNEL SAFETY

#### 12:45 UTILIZING BEST PRACTICES IN ALL ASPECTS OF MAINTENANCE AND CALIBRATION TO ENHANCE RELIABILITY OF SYSTEMS

*Gabriel Paoletti, Application Engineering Manager*  
*Mike Magin, Applications Engineer*  
EATON CORP.

There are many new approaches and pressures for the Pharmaceutical industry. The FDA is developing Site Risk Potential (SRP) scores and will be increasing the frequency of inspections for the sites that have scores related to higher potential risk. One reason for this new approach is for the FDA to more efficiently apply their limited funding. This same limitation of funding for traditional maintenance has resulted in some equipment having maintenance cycles extended well beyond historical levels. In addition, more maintenance funds are directed to rotating apparatus, such as electrical emergency generators, HVAC units, compressors and supporting motors. This is necessary due to the added wear associated with rotating machinery versus stationary electrical distribution equipment. The need for calibration and maintenance on electrical distribution equipment, such as oil-filled in-plant distribution transformers, low and medium voltage circuit breakers still exists, but is subject to greater cost constraints within larger facilities. A new approach can utilize past and ongoing equipment maintenance and calibration records to prioritize electrical distribution equipment with greater detail. This allows for applying maintenance dollars to the electrical distribution equipment with the

greatest need for maintenance, and also redirecting limited funds to more effective predictive practices or capital improvements. The process to be presented for electrical equipment can be adapted to any type of plant equipment. The savings that result from such programs can be applied to more productive predictive technologies such as thermographic surveys and partial discharge technologies.

The new ArcFlash employee safety requirements will be addressed for electrical power distribution systems. Arc Flash is the #1 subject today in all facilities. Arc Flash results when an unexpected failure occurs within electrical equipment. The amount of energy that is released can harm personnel who are not properly protected. In the past, most facilities conducted in-house safety training and practices, but with the publishing of NFPA 70E-2000, Standard for Electrical Safety Requirements for Employee Workplaces and IEEE Standard 1584-2002, Guide for Electrical Safety Regulation, the requirements to provide a safe working environment now has industry standards which MUST be incorporated into the facility plan. The key aspects of these new requirements will be presented.

The subjects of this presentation's focus will be:

- Traditional calibration and maintenance practices overview
- Development of a ranking system using multiple inputs to reduce decision-level risk
- Shifting of limited funding to the assets with the greatest need
- Comparing costs of traditional vs. predictive maintenance
- Maximizing the benefits of limited calibration and maintenance funding
- Predictive maintenance technologies (thermographic and partial discharge technologies)
- Understanding new ArcFlash employee safety requirements

#### 2:15 MANAGING COMPLIANCE PROCESSES FOR MAINTENANCE

*Marcus McNeeley, Project Manager*  
BLUE MOUNTAIN QUALITY RESOURCES

With the FDA's new focus on quality systems, greater attention now needs to be paid to how compliance processes are managed within the maintenance discipline. The compliance processes should ensure that the proper response is given to asset failures, provide proper review and documentation for substitute parts and provide a way to ensure that change control, recalibration and requalification occur reliably as needed. In many cases, these compliance processes will need to be harmonized with the processes and requirements of other departments, including calibration, validation and quality control.

Once the compliance requirements are firmly understood, the challenge remains to develop compliance processes that do not negatively impact productivity. This presentation will discuss

the compliance processes required in maintenance and approaches for implementing those processes while still maximizing productivity.

- A 30,000-foot view of the compliance requirements for maintenance in life science industries
- Theoretical mapping of the processes that should take place to ensure compliance
- Practical approaches from translating theoretical processes into real world processes that do not reduce productivity

### 3:00 AFTERNOON BREAK

#### CASE STUDY

#### 3:15 LEVERAGING SERVICE TECHNOLOGIES TO BOOST LABORATORY PRODUCTIVITY

*Dave Heckendorn, Lab Resource Management,  
Life Science & Chemical Analysis Services and  
Support Division  
AGILENT TECHNOLOGIES*

Many Life Science companies have identified lab instrument service as fruitful ground for invoice reductions. Conventional wisdom suggests that instrument technologies are becoming mature, so service contracts with original equipment manufacturers (OEMs) may not be as necessary as they once were. Some customers even treat maintenance and repair service as commodities, ignoring user requirements, simply hiring the low-cost bidder with minimal vetting to keep lab instruments up, running, and qualified. In fact, simply choosing the low-cost supplier will certainly impact laboratory productivity, service quality and contract administration. Vendors are introducing remote-diagnostics technologies, common in IT and medical devices, into analytical instruments, allowing remote solutions to many instrument problems. Technology is also affecting lab instrument compliance, with significant increases in instrument availability corresponding to accelerated qualification delivery. We'll discuss the relationships between technology, quality, and cost for traditional and novel instrument service delivery models, including:

- The features, benefits, and limitations of Original Equipment Manufacturer, Independent Service Organization, Service Consolidator, and In-house Metrology service models, models for instrument repair, maintenance, tracking and management
- A proposal for an integrated service delivery model that integrates and builds upon the advantages of traditional service models
- The impact of "smart devices" on lab instrument downtime
- Technologies that streamline regulatory compliance delivery and review

Case studies will include:

- The surprising results of one company's evaluation of lab productivity vs. service costs
- How companies reduce system downtime and total cost of ownership through predictive, proactive systems monitoring
- Optimizing return on capital purchases through next generation use and utilization reporting
- Facilitating operational readiness via use-based replenishment services
- Advantages of a common protocol for all technique-specific instrument qualifications

#### CASE STUDY

#### 4:15 IMPLEMENTING AN AUTOMATED DATA COLLECTION PROCESS TO EXPEDITE PERFORMANCE AND DRIVE IMPROVED ASSET UTILIZATION

*Scott Klages, Vice President, Senior  
Manufacturing Consultant  
PARSEC AUTOMATION CORP*

The key for pharmaceutical manufacturers to reduce waste, reduce production cost, increase capacity, and improve asset utilization is real-time performance management and manufacturing intelligence. This session will describe the methods, metrics, and tools being used by leading pharmaceutical manufacturers to optimize asset utilization and productivity. Attendees will learn the causes of efficiency losses, where to focus their efforts for the greatest benefit, the value of real-time performance management software, and the use of real-time OEE (Overall Equipment Effectiveness).

- Accurately identifying non-productive time lost, such as changeover, cleaning, waiting, and maintenance
- Leveraging existing investments in automation in order to optimize all sources of manufacturing losses
- Proactively detecting small drops in productivity as soon as they begin, driving a rapid response to the problem before serious losses can occur
- Identifying the top 10 production bottlenecks in your plant on any given day

### 5:15 CLOSE OF CONFERENCE



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