Quality Management System

Performance Assessment

for

Medical Device Industry

Prepared by

Compliant, Effective, Efficient®

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Quality of Operations

In today's ultra-competitive business environment, and unforgiving regulatory environment, organizations do not have the time, money or resources to support inefficient or non-value-added activities. The primary purpose of a Quality Management System is to ensure the quality of the output of the work the company does. Therefore, it is important that the activities and resources that are used to accomplish this purpose be compliant, effective and efficient to provide maximum value to the organization.

The *'quality'* of operations is dependent upon both the *'quality'* of the Quality System, and of the *'quality'* of organizational *'management'* of the Quality System. Together, these elements comprise the *'Quality Management System'* of an organization.

Foundational Tenants

The Quality Management System **Performance Assessment** is designed to provide an understanding of the operational *'quality'* of the Quality System, itself, and is built upon the foundation of three tenants.

- **First**, the stakeholders, whether they are regulatory stakeholders or business stakeholders, require that the Quality System is **compliant** to the regulation or standards that the company must adhere to.
- **Second**, the processes within the Quality System must be **effective** at obtaining the results that are expected of them.
- **Third**, the business stakeholders have an expectation that those processes are **efficient** in operational execution.

Why conduct an Assessment?

A Performance Assessment would be conducted to provide the information to a management team that would be necessary to conduct performance improvement efforts in fulfilling their management responsibility to their stakeholders or as a necessity to obtain the information necessary to plan for improvements that would be required, and resultant from regulatory trouble.

Performance Improvement

Executive management teams routinely seek to understand the *'quality'* of their Quality Management System and want to better understand the performance of their QMS in practical business terms. This information can now be made readily available through a Performance Assessment which provides a thorough understanding of the Quality Management System. The information provided will enable your management team to minimize risk to the patient, and reduce the regulatory risk to your organization by ensuring your organization is:

- ✓ **Compliant** to regulation
- ✓ **Effective** in obtaining results
- ✓ **Efficient** in execution

Such an assessment, proactively conducted ahead of regulatory observations, are indicative of actions taken by responsible management teams.

Management Responsibility

It is clear the FDA believes company officials are responsible for compliance.

FDA Regulatory Procedures Manual: 4-1-1 - Warning Letter Procedures:
Responsible officials in positions of authority in regulated firms have a legal duty to implement whatever measures are necessary to ensure that their products, practices, processes, or other activities comply with the law. Under the law such individuals are presumed to be fully aware of their responsibilities.

Regulatory Trouble

When a regulated life sciences company receives FDA 483 observations notifying them of violations to requirements, appropriate actions must be taken. An adequate and timely response is imperative upon receipt of an FDA 483 observation to provide the FDA with the confidence that organizational leaders are in control and fully understand how to address the concerns raised. Many companies do provide a timely response, however, their response is often found to be inadequate. This results in the escalation of the 483 issues to a Warning Letter. What is an "*adequate*" response?

The answer to this question is found within the instructions provided by the Food and Drug Administration when they observe violations of the quality system requirements in both, a Form 483 and a Warning Letter:

FDA 483 Instruction: "*The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for*

conducting internal self-audits to identify and correct and all violations of the quality system requirements."

FDA Warning Letter Instruction: "*You should know that this letter is not intended to be an all-inclusive list of the violations at your firm's facility. It is your firm's responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the FDA 483 issued at the close of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality management systems. Your firm should investigate and determine the causes of the violations, and take prompt actions to correct the violations and bring the products into compliance.*"

Very clear. Yet, one of the biggest mistake most firms continue to make is to believe the only thing that is wrong with their Quality Management System is what the FDA pointed out to them in the examples of non-compliance provided by the Investigator. This is a significant error! Upon issuance of an *official action indicated* (OAI) Form 483 observation of a violation, or a Warning Letter, the reality of the situation has changed. The FDA now believes the company has systemic issues and they now expect a holistic approach to systemically fix or improve anything and everything identified as an issue of noncompliance, including the things that they did not identify themselves. That is the challenge that must be addressed. This begins with a Performance Assessment to identify the issues that must be addressed.

Assessment Components

A Performance Assessment is comprised of three components that provide a structured approach to better understanding:

1. **Audit** to determine **compliance** to regulation
2. **Appraisal** to determine **effectiveness** in obtaining results and **efficiency** in execution;
3. **Analysis** of data to confirm the 'quality' of the product and QMS processes.

➢ Audit

An audit process is used to assess the compliance, or conformance, to regulation and standards that a company must adhere to.

- The auditor's focus will be on the identification and verification of the policies, processes, procedures and instruction the organization has developed to satisfy the regulatory requirements and standards that a company must adhere to.
- Regulation and standards detail *'what'* should be done, not necessarily *'how'* to do it.
- A compliance audit is only used to confirm the conformance to the required regulation and standards.

➢ Appraisal

An appraisal of the organizations *'management'* of the Quality System is conducted to understand the effectiveness of results obtained through the execution and management of the processes within the *'system'*.

- While the compliance audit focused on *'what'* should be done, the appraisal of the management of the system focuses on *'how'* to do it.
- The assumption is that if we simply follow the procedures and practices specified within the Quality System, we should produce the desired result. Not necessarily so.
- The *'quality'* of the output of the system is dependent upon both the design of the system and on the management of the system to produce the desired results.
- The system of processes that comprise the Quality System must be integrated and in *'alignment'* in terms of sequence and interaction, with defined inputs and outputs, to properly function and perform within the *'system'*, as intended.
- The expected outcome of each process within the system should be defined and measured in terms of effectiveness and efficiency.

This appraisal will consider five (5) integrated components against seventeen (17) key principles, across three (3) primary objectives. This approach is applied to processes at the functional level and is then aggregated to all levels of the organization for a complete understanding of the quality of the management system from the perspective of management control.

➢ Analysis

An analysis of data is conducted to determine the *'quality'* of:

- the output of Quality System processes:
    - compliance to requirements
    - effectiveness of required results, and
    - efficiency of operational execution
- the quality of product the organization produces:
    - Maude analysis of post-market effectiveness:
        i. malfunction
        ii. injury
        iii. death
    - Industry benchmark against competitive products

Pre-market conformance analysis and improvement of the production control for high concern issues, based upon a benefit-risk approach, can then be targeted for improvement.

Data analytics is becoming more and more important to business operations. It is vital for your company to analyze the ever (faster) growing disparate data that can be found within your operational environments and give it meaning with the goal of discovering useful information, suggesting conclusions, and supporting decision-making.

Performance Report

Upon completing each of the Performance Assessment components, the *'quality'* of the Quality Management System is defined through Performance Report that provides a comprehensive assessment of the *'quality'* of its operations. This information can then be utilized to create an appropriate 'roadmap' for planning and conducting performance improvement activities in a risk-based manner.