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Journal of Regulatory Science

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Regulatory Science

Journal of Regulatory Science 02 (2016) 19–21

Producing Quality Laboratory Data: A Systems Approach

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Abstract

With a myriad of laboratory testing services available to the customers in the current market, quality is one of the most important features that the customer desires for this service. In the production and service sectors, quality means meeting the customer's expectations. The quality data produced by the laboratory thus needs to be accurate, defensible and fit-for-purpose to meet the customer's expectations.

1. History of Quality Systems

Quality is the result of good systematic management practices. The famous PDCA Cycle lists plan, do, check and act (PDCA) as the four continuous steps to achieve quality. The PDCA cycle has also been referred as the Deming cycle, named after Dr. Edward Deming, the father of modern quality control. Dr. Edward Deming, further credited Walter Shewhart , the inventor of statistical process control and a longtime collaborator of Deming by referring the PDCA (plan-do-check-act) cycle as the Shewhart Cycle. In the early 1970s, companies in the western world started to design and develop quality management processes in manufacturing. The quality system concept further expanded to the service sectors, which includes laboratory services. Quality data production is never a static process and requires a systematic approach through continuous improvement.

2. Quality Management and toolbox

Generally speaking, quality data is the ultimate goal for a laboratory service. The goal is achieved through implementation of a successful quality management system. The managerial and technical requirements need to be fulfilled from both top-down and bottom-up. The laboratory organization needs to provide supportive infrastructure and clearly define responsibilities for all laboratory personnel, including both managerial personnel and technical personnel. Top management's commitment to the organizational quality policy is crucial to maintain a sustainable quality system for the whole laboratory. Quality assurance (QA) program and quality control (QC) are designed to uphold the quality policies, maintain and improve the laboratory quality to assure quality data production. QA, QC programs are essential components of the laboratory quality system.

Besides the QA and QC programs, the laboratory quality management system is also connected and/or involves management of the capital, budgets, purchasing, supplies, equipment, inventories, training and customer service. The management team needs to ensure adherence to quality polices that include the quality manual, quality assurance plan, and standard operating procedures (SOPs). Within quality assurance, there are many laboratory activities that are vital to provide accurate and defensible data. SOPs are controlled documents that describe and specify procedural details of a laboratory activity. A SOP can be issued for how to perform an analytical method to measure the chemical component in a certain sample matrix, and can also be issued to describe the procedures to purchase an instrument. Typically a SOP should follow a format that is adherent with the laboratory management system. A SOP is a controlled document that requires authorization from the responsible parties. Statistical process control (SPC) is routinely used in quality control as a decision-making tool to monitor a process in which the laboratory data is continuously produced. Monitoring and tracking change is the foundation of SPC and the occurrence of a change initiates the quality manager or a quality specialist to start an investigation and determine the cause of this change, if possible. The most utilized SPC tool is the control chart and monitor the trend change in the measurement of a testing method. The mean and range calculated from multiple sets of measurement are used to determine if one set of data is out of control or not. The use of the control chart to validate

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whether the process is out of control or not allows for , the entire analytical process to be monitored. The control chart is not able to identify the cause for the change, rather provides a mean to signal potential factors that might impact data quality.

The routine use of reference materials and proficiency tests are also important tools for quality control and quality assurance. Reference materials provide standards to evaluate the accuracy of a measurement method and are important in method validation. Commercial available certified reference materials (CRMs) are invaluable to a laboratory in terms of method evaluation. Typically, a certificate is provided with those commercial available CRMs, reporting the assigned value along with the measurement uncertainty. Proficiency testing involves participating in an external process by enrolling the laboratory to test one or multiple sets of samples that are measured by a group of laboratories at the same time. Statistical evaluation is performed outside of the participating laboratory and results are reported to all participants. PT tests are often arranged according to a fixed schedule with results being reported within a required timeframe.

Corrective actions are important aspects for quality assurance. Once a deficiency is found during the quality monitoring process, the laboratory needs to take actions to correct the deficiency and follow up to make sure the corrective actions truly eliminate the deficiency. Personnel training and continuous improvement with sufficient documentation enables the system to track potential gaps in the laboratory quality system. In summary, appropriate documentation is the backbone of the quality assurance system.

3. Laboratory Quality System Models

There are no standards for quality. However, there are several quality system models that a laboratory can follow and implement right procedures to achieve quality. Quality system models offer standards to assess a quality system.

3.1. ISO Standards

In 1947, the International Organization for Standardization (ISO) was created by industry and this marks the global efforts for international standards. In the laboratory testing, the most relevant standards are ISO9001[1], ISO 17025[2], and ISO 15189[3]. The ISO catalogue is generally organized by International classification of Standards (ICS) or Technical committee (TC). Under the ISO/TC 176 quality management and quality assurance is the ISO 9001:2015 Quality management systems-requirements; Under ISO /CASCO (Committee on conformity assessment) is the ISO 17025:2005 General requirements for the competence of testing and calibration laboratories; Under ISO/TC 212 Clinical laboratory testing and in vitro diagnostic test systems, is the ISO 15189:2012 Medical laboratories-requirements for quality and competence. ISO accreditation is a process in which an external laboratory accrediting body assesses the laboratory against the ISO standards and confirms that the laboratory conforms to the ISO standards. It might be a common misconception that laboratory ISO accreditation can guarantee the accuracy and precision of the laboratory data. ISO accreditation does not guarantee the quality of the laboratory data but rather substantiate the consumer's confidence of the data quality. In a regulatory scheme for laboratory testing such as product safety, legal language might require the testing laboratory obtaining ISO accreditation before authorizing laboratory reports for legal actions. In the United States, third party accreditation is a common practice that is recognized by the government and the industry. The International Laboratory Accreditation Cooperation (ILAC) is the international cooperation of laboratory accreditation bodies working on development and harmonization of accreditation practices. Many international or regional organizations sign into the Mutual Recognition Arrangement (MRA) with ILAC to work with the similar quality objectives and offer laboratories accreditation services worldwide.

For most general testing and calibration laboratories that are not in the clinical field, ISO 17025 is the benchmark standard for accreditation. However, as a standard, ISO itself does not specify how the laboratory should implement the standards, but leaves it to the individual laboratory to fulfill the standard requirements. Accreditation bodies interpret the ISO language and work with the laboratories to obtain ISO accreditation.

3.2. GLP

Originated in New Zealand and Denmark in 1972, Good Laboratory Practice (GLP) is current a quality model adopted by the Organization for Economic Co-operation and Development (OECD) in 1992. GLP is more specific designed for chemical nonclinical safety test from physic-chemical properties to toxicity tests. The GLP model has been widely recognized by many countries globally and has been incorporated into some countries' legislation. For example, the US FDA has written into rules in Code of Federal Regulations (21CFR58) that preclinical animal trials have to follow GLP prior to clinical studies in humans. Regardless of legislation in some countries, there are arguments that compliance with GLP regulations is not necessarily a guarantee for good science.

4. Next Step

The essential role of a quality system in quality data production should not be underestimated. With the economic globalization, the testing community is moving forward with the merging of global companies that provide laboratory testing services. The testing results have also been important subjects of international trade disputes. With the development of numerous computerized tools for laboratory data and documentation, there are new challenges and opportunities for traditional quality assurance programs. Nevertheless, quality data is not produced without a cost. Investment of capital, personnel and management commitment is the key to ensuring laboratory quality. Besides being regulatory requirements for laboratory testing in some countries, ISO accreditation also serves as a good practice to gain customer's confidence. The 21^{st} century will embrace a mature quality concept in the laboratory testing service sector.

5. Article Information

The article was received March the 23rd, 2016, in revised form April the 22nd, 2016 and available on-line May the 5th, 2016.

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