IVT NETWORK
INSTITUTE OF VALIDATION TECHNOLOGY
Unlimited Validation Knowledge Awaits...
UBM A division of UBM Americas
Published on *IVT Network* (http://www.ivtnetwork.com)

The 5P Model for Data Integrity

By Chinmoy Roy Sep 25, 2018 7:00 am PDT

Abstract

Contamination of biopharmaceutical products has held the limelight in years past. In the recent past, there is an increasing realization that in addition to product contamination, data is not contaminated since it is crucial in ensuring that manufactured products have the desired quality and guarantee for patient safety. Consequently, the focus of regulatory agencies and the pharmaceutical industry has undergone a shift to also include data contamination which is also referred to as data trustworthiness or data integrity.

The purpose of this paper is to suggest a management framework to ensure data integrity in a life science organization.

The Inflection Point

A review of FDA's recent product approvals, reveals their encouragement for personalized medicines also known as individualized therapies. As pharmaceutical companies get attuned to the challenges of transitioning from "one size fits all" approach to researching and developing drugs for individualized therapies, they are realizing the expediency of embracing digitalization as a business strategy. This digitalization is being aided by quantum advances in technology such as mobile and cloud computing, information science and data security etc. They also recognize that the transformation to digitalization, if not managed with care, could increase patient risk if data used for product release is untrustworthy.

Data Integrity's Secret Sauce: Process-Centric Organization

Data Integrity may be appropriately defined as "the state of completeness, consistency, timeliness, accuracy and validity that makes data appropriate for a stated use". It is a data characteristic that lends it the assurance of trustworthiness. It is defined by the oft-mentioned ALCOA+ attributes. NIST SP 800-33 defines data integrity as the state when data has not been altered in an unauthorized manner. It covers data in storage, during processing and in transit. Data integrity's guiding principles include:

- The care, custody and continuous control of data
- Measures implemented to ensure that GxP regulated computerized systems and paper based as well as computerized data are adequately and securely protected against willful or accidental loss, damage or unauthorized change.
- Such measures should ensure the continuous control, integrity, availability and where appropriate the confidentiality of regulated data

As data progresses through several groups within an organization, maintaining the integrity of data, requires management to leverage business processes to derive the desired business outcome of data integrity. In process-centric organizations, attention is not merely confined to business processes but also to associated

elements such as people, partners, management leadership etc. since they also impact process outcomes. Consequently, process-centric organizations create a more engaged and involved workforce who understand their roles better, develop better problem-solving skills and meet key business objectives such as data integrity.

The Process-Centric Organization's Centerpiece: The 5P Model

The 5P model is the centerpiece of the Strategic Management Model used by managements of process-centric organizations. It was developed by Pryor, Toombs, and White who studied under Dr. W. Edwards Deming, Dr. Joseph Juran and other well-known experts.

This model requires the alignment of the following 5 variables for organizational effectiveness:

- Principles
- Purpose
- Processes
- People
- Performance

Users of the 5P model design business processes using a systems approach. Although this approach is used and defined very differently in several disciplines, a global definition of system is one consisting of a group of individual parts that interact with each other to achieve a common goal.

Why Use a 5P Model?

Managing a pharmaceutical company's business requires management to effectively blend management tools with quality tools. While use of quality tools ensure achievement of business objectives such as patient safety and product quality, it stops short of managing from a strategic perspective to ensure that the business survives for the longer term through profitability, research in strategic areas etc. The 5P model serves as and integration tool to integrate quality and strategic management concepts to create a powerful systemic structure.

Use of 5P as a tool also aid managements to understand their organizational complexity arising from the existence of complex technologies, personnel structure, changing market dynamics etc. The changing nature and complexities is making it imperative for management to adopt a management style that is more science based instead of art based. The 5P model encourages and enhances managements' science-based style by focusing on system elements such as people, partners, processes, culture etc.

The Dependencies of the 5P Elements

The key elements for Data Integrity's 5P model are the following 3 elements:

- Principles
- Purpose
- Processes

The relations and interactions between the three elements shape a company's culture and human behaviors and influences the most important part of the work system which is the People element. Principles and Processes drive Purpose and impacts the degree to which the Purpose is being achieved. Since Purpose drives People and Performance, it is imperative for management to focus primarily on Principles and Processes which influence purpose which in turn influence People and their behaviors. The dependencies are enumerated in the following diagram.

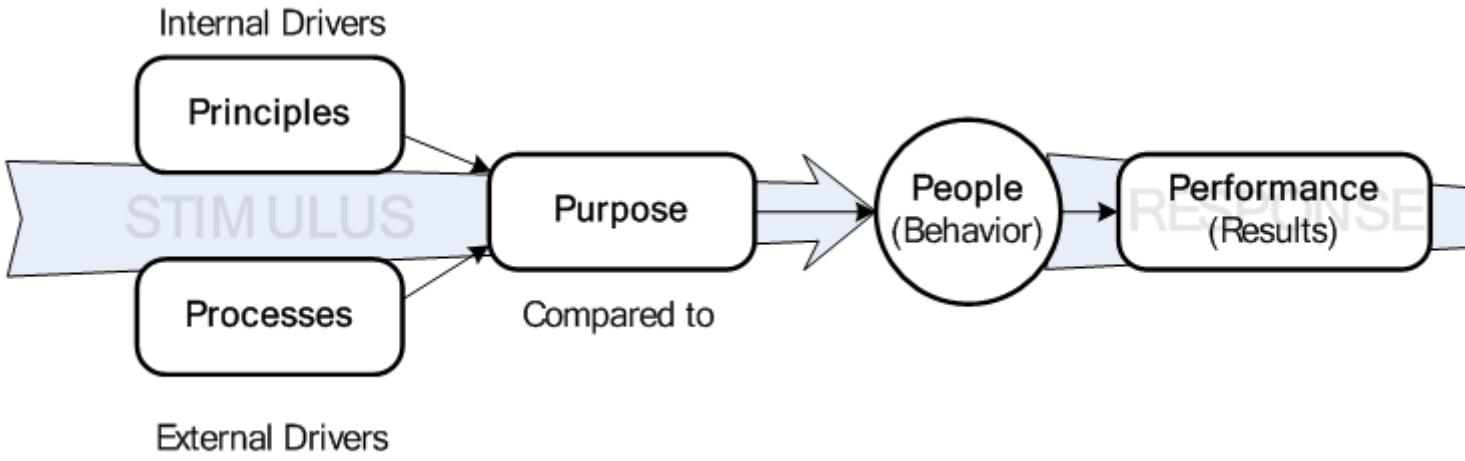

Figure 1: Interaction of 5Ps Influecting Cognitiave Behavior

The Drivers of Human Behavior

Since humans are the active components of the organizational system, their behaviors are extremely vital for ensuring the success of any organization's Data Integrity program. An exceptionally well-thought-out Purpose coupled with stellar Principles and best in class Processes do not get institutionalized without the involvement of People and the drivers for their behavior. Hence it is important to understand what the drivers are for human behavior.

Principles: They are what we usually refer to as values. Values that exist only within individuals are called personal values. They are a person's beliefs and they guide personal decisions and actions. They are influenced by different internal and external factors such as culture, family, traditions and more recently by media and the Internet. A person will filter all these influences and meld them into a unique value set that may differ from the value sets of others in the same culture. The personal values called "internal drivers", are an individual's internal conception of what is good, beneficial, important, useful, desirable etc. Personal values strongly influence behaviors at the workplace.

Groups of people, also referred to as an organization or enterprise, might hold the same or similar values. These are ascribed as shared values or organizational values and are a key part of the organization's culture. They are the organization's guiding philosophies, assumptions or attitudes about h ow the organization should operate and conduct business. These organizational values include the integrity, ethics and values to which employees are expected to make a commitment to at the time of their hire. The organizations business objectives are achieved when there is a congruence of personal and organizational values.

Processes: They are organizational structures, procedures etc. that are used to manufacture the products and services of the organization. Grouping people together in certain ways promotes or prevents specific human or group behaviors. Hence, they are considered as "external drivers" because they exist outside the individual. Hierarchical structures such as in the military does encourage people to function within the boundaries established. But it may force those who inadvertently move outside the rules of operation or produce outcomes other than that which is expected, to conceal and even misrepresent their actions with intent to deceive. On the other hand, team structures produce a much freer workplace. Unlike hierarchical structures, team structures decentralize decision making and authority wherein employee teams take charge and respond by exhibiting initiative, creativity and enthusiasm.

Purpose: The purpose statement defines a company's core goals and declares the intention of the organization. It conveys to employees the reason the company exists along with the company's message to their customers. A typical purpose statement for a biopharmaceutical company would consist of the phrase "…. ensure patient safety and product quality." Besides company's purpose statement, individuals also have their individual purpose such as survival, making more money, climbing up the management ladder or

anything else. The individual purpose may sometimes contravene with the company's purpose causing the individual to act or behave in a manner that may run contrary to the achievement of the company's business goals.

Organizational and Human Behavior Using the 5P Model

Behavioral scientists and cognitive psychologists suggest that between a stimulus and response, an individual has an opportunity to think about the situation and choose the response. Thus, an individual can respond differently to the same stimulus or situation. This behavioral difference is due to the degree of interaction between "Principles and Processes" in the individual. For every situation, the individual considers if the Purpose is achieved better by using the internal drivers (i.e. Principles) or external drivers (Processes). The driver or a blend of both that achieves the Purpose will be chosen by the individual to act accordingly. Thus, it is an interplay between the 3P elements (Principles, Processes, Purpose) that dictates the behavior (People) as depicted in the diagram above.

Employees in an organization often confront frustrating situations when Principles and Process conflict. For example, an organization's Principle may be teamwork. However, their Process of governance such as allocation of bonuses etc. may be based along functional lines. As an example, a department head with an excess budget may want to transfer the excess to another department which is facing a budget shortfall. Doing so would be in the interest of promoting the organization's principle of teamwork. But the governance structure, which is based on bonus awards being allocated on department's performance such as budget savings etc. inhibits the action of the department head. This conflict, results in inconsistent employee behaviors wherein some department head may decide to forego the department bonus and promote teamwork while another head may do the reverse. Without consistent behavior from employees, an organization cannot be assured that it will meet its Purpose. To ensure consistent organizational behavior, management must ensure that the Principles do not conflict with the Processes. If Principles and Processes support and reinforce each other, then the resulting behavior of People will be more consistent and will have a higher probability of achieving the Purpose.

Data Integrity's 5P Model

We have all heard about data integrity and how important it is. The challenges in taking it from a concept to reality are colossal. Organizations are charting a path to implement a Data Integrity Quality Management System (DIQMS) to integrate into their existing QMS. Crafting an effective DIQMS requires an understanding of the relations, dependencies and interactions of the enterprises' system elements such as principles, processes, behaviors policies, procedures and the like. Data Integrity's 5P model provides the tools to understand the dependencies of system elements and to identify leverage points to ensure the integrity of data.

Principles based QMS documents: These form the core of the organization's DIQMS. They form the basis for other DIQMS directives generated to fulfill the Purpose, Procedures, People and Performance of the 5P model. These are typically authored by senior management and declare management's intent, rigor and methodology for implementing data integrity processes. While skills-based hiring is important for achieving business goals, hiring employees based on their principles is equally important. In an organization, management sets company's principles by establishing and training all employees in company's Ethics Policy and Code of Conduct. These documents are developed and approved by management and enumerate the beliefs and behavior of the company and its employees along with the Data Integrity Policy document which is also management's declaration of specifics of the Ethics Policy and Code of Conduct.

All new hires are trained on these during the onboarding process. Management's commitment is also demonstrated by requiring each employee to sign a declaration that the document contents have been explained to them and that they understand the consequences of their actions leading to breach of data integrity. These documents should be retained and made readily available to regulators on demand.

Purpose based QMS documents: These documents explain why the company is in business, where the company stands now in its journey towards where it wants to be and the management strategy to get there. The strategic management model reflects the Purpose of the company and consists of the following Purpose based documents:

- Mission – Why the company exists
- Vision – Where the organization wants to be in the future
- Internal and External Assessments – Internal strengths and weaknesses and external threats and opportunities
- Goals and Objectives – Measurable outcomes to make the vision a reality.

Process based QMS documents: They are the procedure documents and constitute the largest set of documents to ensure Data Integrity. These documents are guidelines that require or advise people to act in certain ways with the goal of preserving data integrity. They are embedded in the company's core business activities.

Process designers should not labor under the impression that data integrity is limited to falsification or fraud. Data integrity issues also arise due to faulty design, inadvertent error in capturing and recording of data, lack of data integrity training etc. Hence procedures should be established to guide design phases. Procedures should also be developed to demonstrate continuous control of data during its lifecycle to include deviation/investigation procedures etc.

The following is a non-exhaustive list of process-based documents for the respective ALCOA+ dimensions of data integrity:

Dimension	Directive/SOP/Work Instructions
Attributable	*Access Control, Audit Trail Design, Date and Time*
Legible	*Good Document Practices*
Contemporaneous	*Date and Time, Good Documentation Practices*
Original	*Raw Data and Metadata retention*
Accurate	*Calibration, Laboratory controls, Change Control, Deviation and Incident management, Validation, Out-of-Specification*
Complete	*Laboratory Controls, Good Document Practices, Manual data entry*
Consistent	*Validation, Audit Trail Review, SDLC, GxP Records management, Manual Integration guidance, Out-of-Specification*
Enduring	*Data Backup & Recovery, Audit Trail Design, Building Monitoring System design, Data Migration and Archiving, Business Continuity*
Available	*Data Backup & Recovery, Data archiving, Building Monitoring System design*

People based QMS documents:

In an organization, management sets company's Principles by establishing and training all employees in company's Ethics Policy. This policy reflects the morals and values that the organization uses to guide its daily activities to ensure workplace integrity. However, individuals in an organization are regarded as the focal point for ensuring organizational integrity. They should be made aware of the organization's Code of Conduct, which is a document established by management and provides employees with guidance on

behaviors which are congruent with the organization's ethics. Besides Code of Conduct document, policy documents also provide guidance on human behavior. Some of those documents include:

- Hiring practices for Data Integrity
- VPN Access policy
- Maintenance of Electronic Records and Signature
- Good Document Practices (GDP)
- Examples of wrongful acts and their consequences
- Training of employees, vendors and consultants

Performance based QMS documents:

Performance monitoring ensures that established data integrity procedures and processes are achieving their desired goals. Choosing the monitoring parameters, establishing the frequency of monitoring, defining scoring criteria etc. are some of the issues addressed by Performance based documents. Some of those documents include:

- Performing Internal audits for data integrity
- Data Integrity Maturity model

Conclusions

In the face of manufacturing for individualized therapies, the managements of pharmaceutical companies will be confronted with more uncertainty and rapid changes in terms of internal and external environments, customer expectations and global competition. To be successful in meeting these challenges, management must have the ability to develop and implement operations that allow for flexibility and agility. They must be able to build the capability to learn, rapidly make and deploy strategic and tactical decisions and build fluid organizations of self-directed, cross-functional teams. These rapid changes will also demand a stronger integrity base. As organizations realize that continual improvement with an effective change management and performance monitoring mechanisms will be the differentiating factor, the use of the 5P model to comprehend the interactions and relative influences of the 5P elements will be critical. Using the 5P model as the basis for a Data Governance and Management infrastructure will have the requisite grounding to meet the desired goal of ensuring Data Integrity.

Chinmoy Roy
Chinmoy Roy has 40+ years of experience in the US Life sciences industry. He is an internationally recognized Subject Matter Expert (SME) in Data Integrity, CSV, CFR 21 Part 11, Annex 11 and manufacturing process...
View Author Bio

Source URL: http://www.ivtnetwork.com/article/5p-model-data-integrity