Importance of Data Integrity in Corporate Life Cycle – Ethics

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Objectives

- To Discuss:
  - Common root causes of data integrity problems
  - Corporate cultural and behavioral factors that erode the assurance of data integrity
  - Methodologies for diagnosing and improving the "health" of your operating environment that influences the effectiveness of controls intended to ensure data integrity

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Why are we talking about this … Again?

❑ **GxP Data integrity is critical to patient safety, regulatory compliance and business success.**

❑ **Historical and recent FDA, MHRA and other regulatory inspections have shown the need for increased industry vigilance.**

❑ **Recent FDA inspection findings in India, China and other global sources highlight the concerns.**

❑ **Data integrity cannot be ensured by well designed systems, procedures, controls and documentation practices, without an enabling culture that fosters consistently** proper behaviors.

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Some Macro Root Causes & Contributing Factors

- Financial Motives … Business Pressures
- Lack of understanding at all levels (ethics; conduct; GMP; what is data integrity; expectations)
- Risk Tolerance
- Organizational culture and working environment
  - No real commitment to continuous improvement
  - Top down communications only
  - Unrealistic and Insensitive Demands for "Perfection"
  - Job competition

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Some Root Causes and Contributing Factors

- Ineffective QMS:
  - By design … By execution
  - Appropriateness and clarify of expectations
  - Knowledge/training at all levels re. company and regulatory requirements
  - Problem identification, reporting and resolution
  - Controls to prevent/detect data manipulation
  - Management controls and governance

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Some Factors that Erode Assurance of Data Integrity

- **No clear policy on ethical standards or code of conduct**
- **Systems not designed or managed to prevent data integrity problems**
- **Destructive supervision and management practices that suppress reporting problems**
- **Data manipulation and other misconduct are tolerated**
- **Poorly designed products, processes and test methods that create opportunities for wrong decisions**
- **Not finding or fixing the root cause resulting in recurring problems and "work arounds"**

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Improve the "Health" of Your Operating Environment

- Develop a corporate ethics program that includes clear policy statements and expectations for employee conduct

- Create an atmosphere where certain behaviors will not be tolerated, where appropriate behavior is encouraged, and where there is open and honest communication

- Conduct periodic ethics training to assure there is an understanding of expectations for employee conduct

- Develop procedures for taking disciplinary action against employees who do not follow the rules (weed out the bad apples)

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Improve the "Health" of Your Operating Environment

- Provide training to assure that individuals at all levels of the organization have a thorough understanding of requirements relating to GMP, GDP and security of data

- Conduct a thorough risk assessment to identify gaps in the quality system and its execution … and remediate gaps

- Develop a compliance unit to communicate the company's code of ethics to personnel, monitor compliance with regulatory requirements, and to enforce standards of conduct

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Ethical and Code of Conduct Principles

- **Company is committed to the development and commercialization of safe and effective medicines of high-quality that comply with all applicable standards and requirements of the regulatory authorities in markets served.**

- **Company and its management are committed to providing the necessary resources, training, support and work environment culture that enables open and transparent communications, competence, professional behavior and compliance at all levels.**

- **Management and supervision must ensure that responsibilities and tasks are assigned only to employees with adequate background, experience and/or training, and the time and resources necessary to perform the job properly.**

- **Each employee must seek guidance and training from their supervisor when they are not certain of Company requirements and expectations.**

Ethical and Code of Conduct Principles

- **Each employee must perform his responsibilities and tasks with the highest integrity, by consistently adhering to standards and requirements.**

- **The Company is committed and mandates all personnel at all levels and without any exception to maintain the integrity of all the data and records that are generated from product development to commercialization and supply of all products throughout the lifecycle of each product.**

- **Employees must ensure that all Company records and documentation regardless of their nature must be contemporaneously and truthfully recorded and maintained in accordance with corporate and regulatory requirements, and must never distort or disguise the true nature of any action, procedure or transaction.**

Ethical and Code of Conduct Principles

- **Employees must consistently follow Good Documentation Practices (GDP) to ensure that the data, records and other documentation are accurate, complete, readily retrievable and verifiable. GDP requirements are described in Company procedures against which all management and employees are initially and periodically trained.**
- **The company will not condone, implicitly or explicitly, any violation of data integrity and will have zero tolerance for any employee who is found to purposefully manipulate and/or falsify any data/records and/or commission of such acts.**
- **The Company will investigate all reported instances of questionable or unethical behavior. In every instance where improper behavior is found, the company will take appropriate action, including termination and other legal action, as appropriate.**

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Ethical and Code of Conduct Principles

- **The Company will not tolerate retaliation against employees who raise genuine concern in good faith. All employees are encouraged to report any coercion by co-workers, supervisors, implicit or explicit, to compromise data integrity as defined above. Such coercive behaviors should be reported to the management directly or through the existing whistle blower policy.**

- **No one is exempt from complying with this Code of Conduct, Ethics and Integrity Policy, and no one is allowed to order otherwise.**

- **All employees are encouraged to seek advice and counsel should they have any questions or concerns about any issue or matter, even if they are not sure that the matter involves an ethical question.**

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Minimize Opportunities for Mal-Behavior

- **Match Capabilities to Supply Commitments … People, Process, Volume, Timeframes, Competence**

- **Quality By Design reduces commercial "problems" that beg for "fixes" to meet supply pressures**

- **Provide suitable facilities and qualify/maintain reliable equipment, instrumentation and software suitable for intended use.**

- **Permanently fix the root cause of problems to prevent "work arounds"**

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Minimize Opportunities for Mal-Behavior

- **Start with materials and services from qualified, reliable suppliers … "low bidders" often are the lowest for a reason.**

- **Encourage problem identification and solving. Make it easy (and safe) for operators, analysts and their supervisors and management to report actual or potential problems.**

- **Really embrace "continuous improvement" and not just talk about it.**

- **Approach problem prevention/solving constructively**

- **Don't blame the regulator for your woes.**

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Quality Culture

❑ **Right Mindset … for the Right Reasons**

❑ **Knowing the "right thing" to do … and to do it.**

❑ **Environment that fosters consistent, proper execution**

❑ **Forthright identification and resolution of problems based on root cause and sustainability**

❑ **Living the proactive, continuous improvement philosophy**

❑ **Company enabled and nurtured**

❑ **Feeling good about the collective effort**

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Can Culture Be Measured?

- **Not Directly; it is organic, complicated and requires frequent assessment**
- **Industry continues to struggle to identify measurable attributes and tools**
- **Define Elements and Outcomes of the Desired Culture. Be Realistic.**
- **Key inputs are employee understandings of desired cultural elements and outcomes …and view of the reality.**
- **Reliable "Metrics" for desired outcomes can be insightful … but are not definitive measures of culture. Improper implementation of "Metrics" can foster mal-behavior and integrity problems**
- **Although an imperfect barometer, one can "feel" the culture based on sense of organization, cleanliness, maintenance, spirit, rigor of quality systems and execution, the willingness to acknowledge and correct mistakes, and evidence of a real commitment to learn and improve.**

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"Walking the Talk" <u>everyday</u> is key to fostering proper organizational culture and resultant behaviors

Inconsistent management behavior "trumps" any mission statement, ethics/code of conduct statement, pronouncements, banners, "corporate culture" days; etc.

Compliance Program Guidance For Pharmaceutical Manufacturers (May 2003)

Developed by the Office of Inspector General (OIG) of the Dept. of Health & Human Services

This Guidance provides the OIG's views on the fundamental elements of Pharmaceutical Manufacturer compliance programs and principles that each Pharmaceutical Manufacturer should consider when creating and implementing an effective compliance program. In order for a compliance program to be effective, it must have the support and commitment of Senior Management and the Company's governing body.

Compliance Program Guidance For Pharmaceutical Mfrs

MIMINUM ELEMENTS:

(1)The development and distribution of written standards of conduct, as well as written policies, procedures and protocols that verbalize the company's commitment to compliance

(2)The designation of a compliance officer and other appropriate bodies (e.g., a corporate compliance committee) charged with the responsibility for developing, operating, and monitoring the compliance program, and with authority to report directly to the board of directors and /or the president or CEO;

(3) The development and implementation of regular, effective education and training programs for all affected employees;

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Compliance Program Guidance For Pharmaceutical Mfrs

(4) The creation and maintenance of an effective line of communication between the compliance officer and all employees;

(5) The use of audits and/or other risk evaluation techniques to monitor compliance, identify problem areas, and assist in the reduction of identified problems;

(6) The development of policies and procedures and the enforcement of appropriate disciplinary action against employees or contractors who have violated company policies and procedures;

(7) The development of policies and procedures for the investigation of identified instances of noncompliance or misconduct and the taking of appropriate corrective and preventive actions.

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Next Steps?