SUMMARY

WORKSHOP ON
RISK MANAGEMENT IN INDIAN PHARMACEUTICAL INDUSTRY
6th & 7th March - Hyderabad
9th & 10th March - Mumbai

IN ASSOCIATION WITH:

Risk Management in Indian Pharmaceutical Industry - Summary

The following pages summarizes three critical presentations from UL's Risk Management workshops, held in Hyderabad and Mumbai in March 2017.

Through these presentations, attendees learned of key threats to quality culture: too many silos, a lack of risk-based approach, and investing in Total Quality Management approaches to improve culture.

Breaking Down Silos to Build Up Quality

Presenter: Mr. S M Mudda, Director Global Strategy (Technical), Micro Labs Limited, Chairman Regulatory Affairs Committee, Indian Drug Manufacturers' Association

Silos reduce efficiency, lower workforce morale and may even contribute to the demise of productive company culture. Factors that contribute to silos may be organizational, internal and external. For example, rapid expansion and globalization are external factors that build silos, while limited alignment between individual, team and organizational objectives is an internal factor.

Blind spots in the Indian Pharmaceutical Organization Include:

- Acceptance of a practice without questioning
- The many global GMP regulations and how they are interpreted
- Diversity of practices across regional facilities
- A lack of a true definition of "Good" GMP

These blind spots have executives equating "regulatory compliance" to "product quality." GMP may be considered a "need-based" risk averse and inspection oriented compliance goal. However, the formula for quality is:

"GMP Certified + Marketing Authorization = Product Quality"

We tend to incentivize performance by measuring outcomes rather than the means adopted for achieving it. And risks are exposed when department targets become more vital than organizational objectives. For example:

- "I know this is a compliant procedure -- I used it at my last company."
- "The lab test result is due. Quality is independent."
- "We don't have a quality plan. FDA hasn't been here recently to know were we focus."

And then there's the disconnect between the team overseeing GMPs and the business executives:

- "The validation results are marginal. We can improve the process later.
- "That test result is barely outside the spec. We know it's a good product to release."
- "Fines are just the cost of doing business."

Preventing poor quality pays. The cost of remediation can be 100 times the cost of prevention. Repeated observations can be eliminated. Companies are "connecting the dots" between GMP, Quality Systems and Quality Culture. Using a systems-thinking approach, companies can incorporate silo-breaking models that focus on leadership emphasis, message credibility, peer involvement and employee empowerment. These models stimulate the four key factors of a successful team, knowledge, collaboration, creativity and confidence, to build a culture of quality.

The Value of Quality Risk Management (QRM)

Presenter: Ann Early, Sr. GMP Consultant, UL, EX- Director Sterile Operations, Pfizer

QRM is a systematic process for the assessment, control, communication and review of risks to product quality and the safety of the patient. QRM also plays an integral part of the quality system that supports good decision-making and resource prioritization

Risk management is defined as "the process of identifying, addressing, prioritizing, and eliminating potential sources of failure to achieve objectives." As described in ICH Q9, QRM can help today's manufacturers demonstrate that their system or process is suitable for its intended use. QRM is about systematic processes being put in place for evaluating risk and taking steps to mitigate those risks. The quality system is there to facilitate that process.

And for this reason, QRM is essential to build a stronger quality culture.

QRM allows us as manufacturers to prove to ourselves - and to regulators – that we know what we're doing, and that we are in control, we know what the risks are, we've taken steps to mitigate those risks, we have procedures and policies to guide us in how we manage our processes, and also our quality systems. It's why regulators look closely at our ability to implement good risk management, to help them understand if we really know what we're doing based on scientific knowledge.

Risk Management Organizational Structure

To ensure the risk management process is a "living" process, senior management must provide adequate resources, including the establishment of a "risk office." This team would be responsible for integrating risk management into quality processes: change management, deviation and OOS Investigations, etc. This team must also prioritize ongoing risk activities, implement improvements, update documents, and communicate these activities to stakeholders as appropriate. This may involve regularly scheduled risk review meetings that consider the risks that stem from regulatory audits, internal quality trends, guidances and business Intelligence elements.

To be successful, the QRM team needs a Subject Matter Experts (SME), who has the appropriate level of knowledge and experience to support QRM activities. The SME could reside within several areas or business units, including quality, engineering, regulatory, production operations, and clinical. The team also needs a QRM Team Leader, who is an unbiased, independent expert in Risk Management, and a QRM Owner, who is responsible for ensuring that QRM activities are completed.

The Business Case for QRM

Beyond addressing these regulatory observations, adding QRM can drive better business results. Companies can recognize a drop in deviations and a drop in rejected lots. Importantly, companies can spend much less time and resources into investigating deviations. And because of a reduction of incidents, companies can experience less regulatory inspections and generate fewer post-market supplements.

QRM Success Story

Presenter: Hitesh Windlass, CEO, Windlas Healthcare Private Limited

Windlas Biotech has been a leading CDMO in India since 2001, and the Windlas Healthcare team was established in 2010 to cater to many global markets. The manufacturing facility is located in Dehradun, and the quality and operations team took a risk-based approach to quality, developing processes that reduce human error risks, while studying data on the most-cited US FDA observations.

Because there are multiple production sites, the company instituted several small specialized facilities rather than large multi-purpose sites. The company also relies on software for all routine workflows, which reduces ramp up time for new manpower. For example, all process-monitoring instruments are linked to a central unit and a laboratory information management system was installed.

Recognizing that many errors happen when functions are handed off to other areas, Windlas established an integration team that ensures "deep" learning between R&D, Manufacturing and Quality.

TQM and Quality Culture

Presenter: Dr. S M Jagadish, Founder Zero Defect Consultants, Doctorate in TQM

Total Quality Management (TQM) is one way to address the pains and challenges in the pharmaceutical manufacturing industry, such as global competition and bottom-line pressures. TQM is an organizational approach that focuses on quality as an over arching goal, so that defects are prevented, rather than detected.

TQM integrates functions and processes, involving all employees in improvement, and focusing on customer needs and expectations. TQM helps companies deliver total customer satisfaction on a continuing basis, through continual improvement of products and processes. The TQM pillars are product, process, commitment and leadership. Dr. Ed Deming was a pioneer for the concept of quality, and four of his 14 points that lead to quality improvements include:

- Constancy of purpose for continuous improvement of product and service;
- Cease dependence on inspection to achieve quality;
- Improve constantly and for ever every process of production and service
- Encourage a vigorous program of education/retraining.

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