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Insight Brief

MANAGING THE UNEXPECTED

How pharmaceutical organizations can use the unexpected to drive continuous improvement

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INTRODUCTION

Unanticipated, unpredicted, unplanned, unexpected. These words can be undesirable descriptors of many actions or events, but among pharmaceutical quality and compliance professionals, they elicit downright fear.

In this environment, the occurrence of unexpected events signals that something in their organization's processes or procedures is not completely under control and could possibly have a detrimental impact on product quality and patient safety. For this highly regulated industry, such occurrences not only carry risk, they have regulatory implications.

The FDA's 21 CFR 211.192, states that any unexplained discrepancy must be investigated, and that the investigation will extend to all batches related to that issue, which can have a huge time and cost impact. EudraLex, The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), the World Health Organization (WHO), and other agencies around the globe have similar standards and guidances.

These pressures will only increase as regulatory bodies shift their focus beyond compliance to quality, and more specifically, to the sustainability of quality within pharmaceutical organizations. This means that an organization's quality system needs to be built around the ability to identify and address the unexpected if they hope to meet regulatory expectations.

But how can a team manage what it doesn't anticipate? By properly documenting, investigating, and correcting unplanned events. Additionally, it should allow for preventive actions that minimize or eliminate risks of re-occurrence.

Well trained pharmaceutical quality professionals anticipate the unexpected and have tools and processes in place to manage these events as soon as they occur.

MANAGE THE UNEXPECTED

Well trained pharmaceutical quality professionals anticipate the unexpected and have tools and processes in place to manage these events as soon as they occur. When a batch doesn't come out as expected, a lab result is out of specification, or documented procedures aren't followed, the team must know exactly what steps to take to record the problem, understand its risk, and investigate accordingly.

That's why quality professionals rely on tools like Failure Mode and Effects Analysis (FMEA), procedures that detail the steps to take when a problem occurs, corrective and preventive action management processes, and change control.

Common unplanned deviations include, but are not limited to:

- Malfunctioning equipment
- Instrument breakdown
- Utility or service failure
- Human error
- Yield deviation
- Unapproved changes to processes or product ingredients
- Operation outside of defined limits

An enterprise Quality Management System (QMS) provides integrated, automated processes to manage, correct, and when possible, prevent the unexpected—smoothly and consistently.

Managing these quality processes – which ideally integrate with and trigger one another – in manual or disparate systems becomes tricky. Lacking holistic sight lines, it's difficult to ensure that the right steps are consistently taken to resolve a problem, and consistency is critical to maintaining quality and compliance. Whether you are recording a deviation, an out of specification result, a customer complaint, or other quality event, each must be carried out in a harmonized way to ensure ongoing improvement.

An enterprise Quality Management System (QMS) provides integrated, automated processes to manage, correct, and when possible, prevent the unexpected—smoothly and consistently. The goal of a QMS is to boost quality and efficacy through continuous improvement, thereby increasing patient safety and satisfaction. And harmonized, codified QMS data allows for the delivery of reports and analytics that adequately measure the unexpected, turning that data into actionable information.

A QMS Ensures

DATA ANALYSIS AND THRESHOLD ALERTS:
To understand ongoing results and trends, identifying systemic problems that need correction and prevention

CONSISTENT DATA CAPTURE:
For key elements such as failure mode, product, risk, and root cause

PLAY A ROLE IN SETTING THE INDUSTRY'S YARDSTICK

The Center for Drug Evaluation and Research (CDER) has recently begun focusing on pharmaceutical product quality and the effectiveness of manufacturing at the site level.

THE METRICS UNDER REVIEW ARE:

- Lot acceptance rate
- Product quality complaint rate
- Invalidated Out-of-Specification (OOS) rate
- Annual product review
- CAPA effectiveness
- Process capability

This program is in pilot mode, which means there is still time for industry organizations to influence its direction and embrace these measures as part of their own processes. Companies that join the pilot program now will be best positioned when the new measurements are required.

Beyond the implications for compliance, documenting and analyzing the unexpected will serve as a platform for organizational and product improvement, and risk prevention as well.

PREVENT THE UNEXPECTED

Once a quality team can consistently manage and measure the unexpected within their organization, it's time to move to the next step – prevention and ultimately prediction. While quality teams can't prevent every defect, they can minimize scrap and wasted batches, improve yield and product compliance, improve overall equipment effectiveness, ensure supply chain safety, and reduce errors. How? By using the data from unexpected events to predict and prevent future problems while identifying opportunities for improvement across the extended enterprise.

CONCLUSION

By capturing lessons learned from prior events and adapting processes accordingly, enterprise quality management programs can increase efficiency and reduce risk in future operations. But it's only possible if the quality team and its stakeholders are willing to learn from history and use the unexpected to drive continuous improvement.

To learn more about how IQVIA can assist your company with EQMS systems and continuously improving your quality and compliance, visit us at: iqvia.com/qualitycompliance

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As Regulatory and Product Management Leader for IQVIA Quality Compliance, Kari Miller is responsible for driving strategic product direction, and delivery of industry best practices and regulatory compliance solutions for quality management.

She focuses specifically on translating market and industry requirements into industry-leading enterprise quality management solutions that meet the needs of the heavily regulated Life Sciences market.

She also is responsible for the Quality Compliance product roadmap, product partner relationships, and overall product direction.

Miller earned a Bachelor of Science in Business Administration and a Bachelor of Science in Psychology from Marian College of Fond-du-lac, Wisconsin.

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