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2025 QUALITY + COMPLIANCE TRENDS

As life sciences companies develop new therapies and technologies, patient safety remains a top priority. Pharmaceutical manufacturers are continuously enhancing their quality systems to align with evolving regulatory standards, ensuring the safety and effectiveness of their products. In 2024, we saw a rise in a quality-driven culture that emphasized the use of mature Quality Management Systems. Now, companies are turning to innovative technological approaches to further strengthen these quality systems. As these therapies become more complex, the FDA continues to release new guidance to uphold patient safety.

Below, we dive deeper into five key quality and compliance trends for 2025:

1 STREAMLINING LABORATORY AND QUALITY MANAGEMENT SYSTEMS

2 RISE OF REAL-TIME RELEASE TESTING

3 AI USE IN QUALITY MANAGEMENT SYSTEMS TO MONITOR MANUFACTURING BATCHES

4 QUALITY SYSTEMS FOR CELL AND GENE THERAPY

5 DIGITAL TWINS FOR QUALITY MANAGEMENT IMPROVEMENT

1 STREAMLINING LABORATORY AND QUALITY MANAGEMENT SYSTEMS

Life science companies utilize both Quality Management Systems (QMS) and Laboratory Information Management Systems (LIMS) to maintain safe and reliable product manufacturing. These systems are integrated to allow the flow of information between the two. For example, test data from a rejected batch can be transferred from the LIMS to populate a deviation record in the QMS. Veeva, a leading Quality Management System, has created the Veeva Vault LIMS, a novel software that unifies LIMS and QMS. More than 175 companies use the Veeva Vault Quality Management system, all of which can benefit from the novel integration of systems.

This integrated system will allow for more streamlined functionalities. For example, test results out of specification in LIMS can be communicated to QMS, which will trigger an investigation of the batch. The system integration reduces cycle time, or the turnaround time from batch execution, data review, and analysis, leading to batch release or investigation. This reduced time will increase manufacturing productivity, leading to faster production and potentially even faster research and development.

The system has completed the initial pilot program and has entered Phase 2 implementation, in which the LIMS Vault is available to a limited number of users.

2 RISE OF REAL-TIME RELEASE TESTING

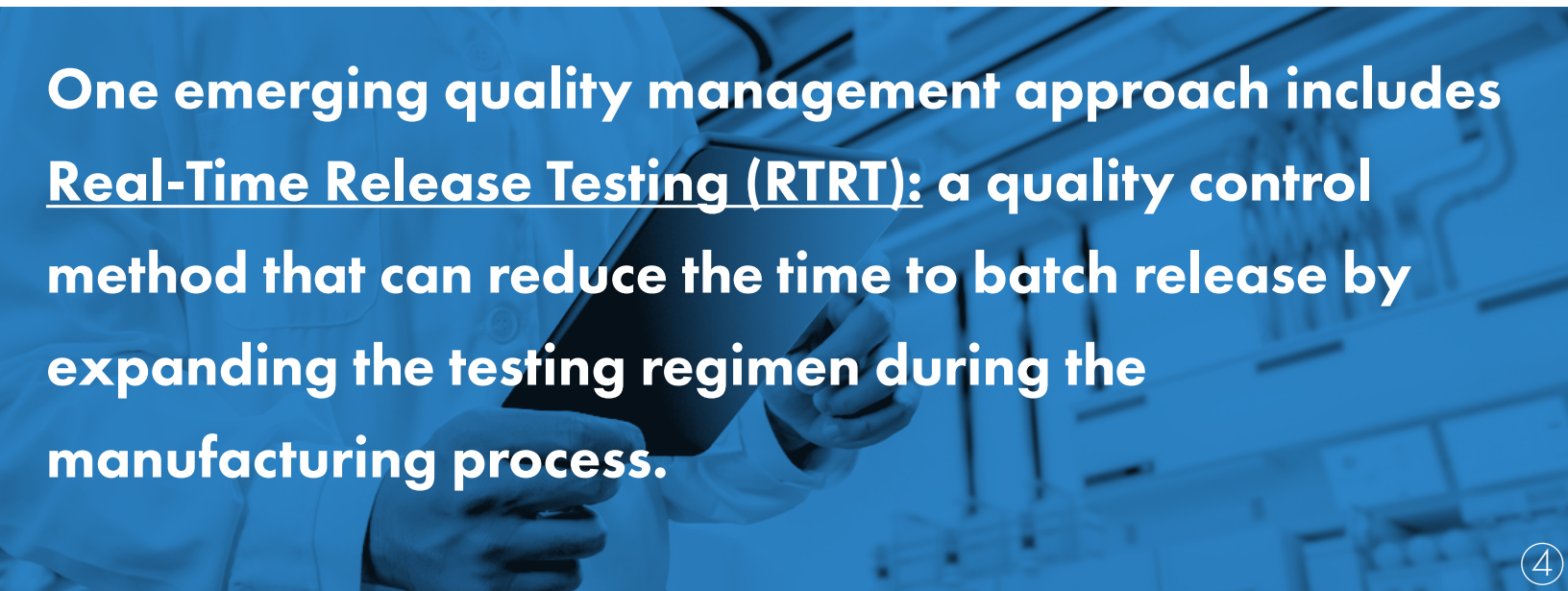
Pharmaceutical and biotechnology companies are constantly enhancing their manufacturing capabilities to improve product reliability. One emerging quality management approach includes Real-Time Release Testing (RTRT): a quality control method that can reduce the time to batch release by expanding the testing regimen during the manufacturing process. By collecting samples at various production stages, companies can closely monitor intermediate products for inconsistencies or errors. This proactive approach enables faster adjustments to the manufacturing line, reducing product waste and improving overall efficiency.

Process Analytical Technology (PAT), a standard of intermediate product specifications, is one method used to achieve RTRT. The FDA addressed evolving quality assurance methods regarding PAT in 2004. Though this concept is not new, few companies have successfully realized RTRT. One challenge to achieving RTRT is that current tests require sample handling. This inhibits complete automation of in-process testing.

One solution is to utilize in-line sample testing, which eases the burden of manual sample handling. Instead, sensors can quickly perform tests on the batch, further automating the process. The increased number of tests also increases the amount of relevant data, and companies may need to expand cloud storage and take additional precautions to ensure data traceability.

Integration between laboratory equipment and LIMS can contribute to a more automated quality assurance system. Empower is one example of software that can provide an interface between laboratory instruments and LIMS while remaining compliant with regulatory standards. This reduces the time laboratory personnel spend manually entering and analyzing data, also reducing the risk of human error.

By implementing RTRT systems, companies can decrease testing time and create a leaner manufacturing process.



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3 AI USE IN QUALITY MANAGEMENT SYSTEMS TO MONITOR MANUFACTURING BATCHES

Automation continues to transform the world, now including the life sciences industry through Quality Management Systems. Life sciences product manufacturing generates a substantial amount of data, and there is a need for a faster way of analyzing the results to develop the Certificate of Analysis (CoA). Artificial intelligence (AI) is a solution to the growing need for quick and accurate data analysis, especially during sample testing analysis.

One benefit is the rapid speed at which AI tools can analyze data. For example, if test results from a manufacturing batch indicate the product attribute is not within specifications, an AI tool can quickly analyze the data for further review. This can prompt manufacturers to quickly identify the cause of a deviation and implement a Corrective or Preventative Action (CAPA). Quick responses prevent waste of the product, and the AI tool reduces time spent manually analyzing data.

AI continues to be a growing industry that has a wide range of applications, now including manufacturing batch analysis. In 2023, 21% of venture capital investment ($7.2 billion) in the healthcare industry was invested in artificial intelligence. Quick adoption of AI will allow pharmaceutical companies to adapt to Quality 4.0 by prioritizing analytic efficiency and patient safety.

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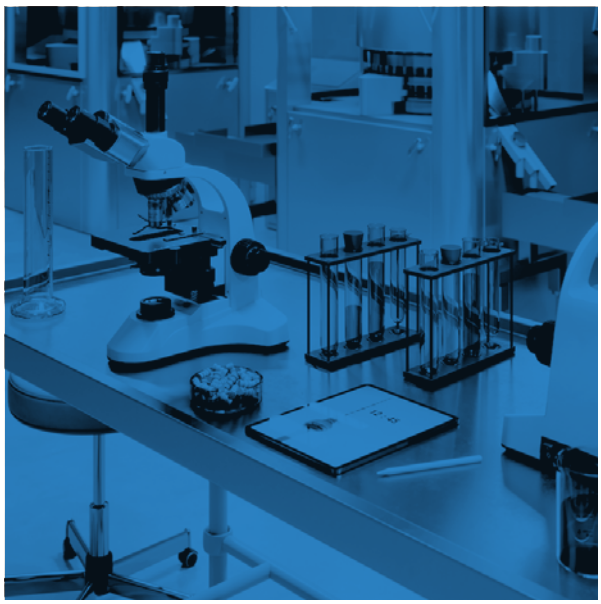

4 QUALITY SYSTEMS FOR CELL AND GENE THERAPY

Healthcare treatment options are becoming more complex, and FDA Quality Management regulations must follow suit to protect patients. An emerging treatment modality is cell and gene therapy, in which a patient receives modified cells, either their own or a donor's, that are equipped to treat a particular disease.

According to the FDA, there are currently 38 approved cell and gene therapy treatments spanning conditions from thermal burns to cancer. This area is expected to significantly increase over the next decade, with over 4,000 treatments in development. Cell and gene therapy is expected to reach a market value of $60.1 billion by 2032, and this growth area of the life sciences industry must meet regulatory standards.

Biologics and pharmaceutical products require meticulous data integrity programs to ensure patient safety, but cell and gene therapy requirements add complexity due to the addition of sensitive patient information to the manufacturing process. With quickly adapting treatments and evolving regulations, life sciences companies must remain diligent in their regulatory intelligence to protect their patients' safety and confidentiality.

One challenge for pharmaceutical companies is to comply with separate regulatory standards for multiple treatment types. For example, autologous vs. allogeneic cell and gene therapy products require different methods to maintain confidentiality and quality standards. Autologous products are created from a patient's cells, while allogeneic products are created from donor cells. As pharmaceutical companies develop new treatment modalities, patient safety and confidentiality must continue to be a priority.

5 DIGITAL TWINS FOR QUALITY MANAGEMENT IMPROVEMENT

Life sciences companies can leverage new technologies to enhance operational efficiency while gaining deeper insights into manufacturing complexities. One such solution is digital twin technology, which helps improve quality forecasting.

Digital twins are a virtual model of a manufacturing system that can simulate outcomes based on changing internal and external inputs. Digital twins have been used previously for supply chain applications, such as planning system maintenance and reducing downtime. This simulation allows companies to conduct tests and analyze outcomes prior to investing in any changes, leading to process improvements with lower associated risks.

This technology can be applied to help companies refine their quality systems. For example, a company can use a digital twin to test the effect of proposed changes to a process condition on product quality. Digital twins can also aid manufacturers in achieving Process Analytical Technology Quality Management, leading to RTRT capabilities. As new data is added to the digital twin, it will not only become more accurate for future predictions, but also serve as a tool for data traceability and integrity. A well-maintained digital twin can include batch quality information that can be easily accessed alongside QMS and LIMS.

Digital twins can help companies move towards Industry 4.0 by connecting physical processes with digital analysis, leading to better optimized product quality.

LOOKING AHEAD

Companies are embracing innovation and new technological approaches to Quality Management to enhance manufacturing systems and boost operational efficiency – all while ensuring high-quality products. As technology evolves, staying informed about shifting FDA regulations is crucial to compliance and patient safety. Further, implementing these technology advancements will drive organizations toward more mature and effective quality management practices.

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