

An Interview with



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How is AI transforming quality management in the life sciences industry, and what specific benefits are companies seeing in terms of error reduction and compliance?

I think the main developments have been the automation of complex processes, improvement of data accuracy, and ensuring adherence to regulatory standards (GxP). This is what we hear from the top and leading global pharma companies as well when working with them. Vast datasets can be monitored in real-time, promptly identifying deviations or anomalies that may indicate quality issues. Obviously, this is beneficial for life sciences companies to address issues before they escalate so they can reduce errors and maintain compliance. Additionally, there is a huge potential to save time/cost in substituting manual tasks.

Also, AI algorithms can analyze historical data to predict and mitigate risks associated with adverse drug reactions or manufacturing deviations, facilitating more effective decision-making. Additionally, AI automates regulatory monitoring by continuously scanning for updates and changes in regulations, ensuring the latest standards are met.

Can you elaborate on the GxP-compliant AI applications Tenthpin has developed for automated process optimization and quality documentation?

Of course. We've recently launched our Tenthpin Intelligent Quality Suite, featuring a portfolio containing AI-powered solutions. These include the likes of Tenthpin Quality Management Evolved (T/QME), Tenthpin Intelligent Certificate Verification (T/ICV) and Tenthpin

Intelligent Certificate Generation (T/ICG). Each one plays its part in making quality management simple, safe and efficient.

First off, there's T/QME. Put simply, it enriches existing SAP S/4HANA processes in the area of quality management. It ensures GxP conformity, is fully embedded into the production and supply chain process. T/QME also successfully executes quality control and quality assurance activities by automating back-end processes from sample creation to batch release – with an enhanced and modern user interface. And yes, this covers the whole process from sample creation right through to batch release and is rolled out in only two weeks as we have proved in recent installations with our customers globally!

With T/ICV, it uses AI and LLMs to extract all data from CoAs (Certificate of Analysis), CoCs (Certificate of Conformity), and CoSs (Certificate of Sterilization). What does this achieve? It automates certificate comparison against corresponding specification documents. Basically, it handles the whole approval process end-to-end which is super-efficient. Plus, it reduces the time spent on this task by 90%. I'm sure most reading this will approve of the time they get back!

Finally, T/ICG is our flexible certificate generation solution. It covers a wide range of regulatory industry requirements towards batch certificates, significantly reducing manual human errors and ultimately boosting quality.

What challenges do life sciences companies face when implementing AI-driven quality management systems, and how does Tenthpin address these challenges?

A few challenges are: data integrity and integration, regulatory compliance and resource constraints.

We all know that ensuring data accuracy and consistency across multiple systems is complex, especially when data is scattered and not standardized. Keeping up with evolving regulations and ensuring that AI systems comply with these changes requires continuous monitoring and adaptation that's harder for some. Developing and maintaining AI systems demands significant investment in technology and skilled personnel.

Tenthpin addresses these challenges by offering integrated GxP solutions to make quality management simple, safe and efficient. They assist companies in automating processes and maintaining regulatory

compliance. The tools are built as industry standard to simplify the system landscape. Plus, we have a team that lives and breathes life sciences, to ensure that all technological investments effectively support our clients' quality and compliance goals.

How does Tenthpin's collaboration with SAP on products like the SAP Batch Release Hub and SAP Intelligent Clinical Supply Management contribute to improving quality control in pharmaceutical manufacturing?

The collaboration follows the same pattern as the ideas for our own products: We tried to close a gap in available standard software. Before we partnered with SAP on the SAP Batch Release Hub, life sciences companies were turning to custom-build batch release management solutions to overcome challenges like manual and cumbersome data collection, error-prone processes and long manufacturing lead times. Now, with the help of SAP, we have digitized the whole process and ensured faster and more accurate batch releases end-to-end.

With the SAP Intelligent Clinical Supply Management, it was our answer to companies looking for process simplification and improved clinical supply planning leveraging cloud technology. Overall, it helps to improve oversight and automation of actions across clinical trials, end-to-end visibility, and enables IRT and third-party integrations.

In what ways are AI and automation helping to streamline the quality assurance process for personalized therapies and decentralized manufacturing?

Right now, AI and automation are helping to automate critical tasks, enable real-time monitoring, and analyze data for predictive maintenance and defect detection in the quality assurance process. In personalized therapies and decentralized manufacturing, this ultimately improves efficiency and quality. Compliance is key and so is ensuring that products are shipped faster to patients and people. This is where AI plays a pivotal role. We're already seeing reduced downtime and preventative measures being implemented quickly.

How does Tenthpin ensure that its AI-powered quality management solutions remain compliant with evolving regulatory requirements in the life sciences sector?

Well, for starters we have a great solutions team that not only understands life sciences inside and out but also AI too! Of course, our consultants and solutions teamwork side by side and keep abreast of all the regulations and how it impacts what we do. That way we can ensure that every solution we make, and every bit of advice we give, is made from the highest level of expertise.

By proactively addressing regulatory changes and integrating compliance into our technological frameworks, we help life sciences companies navigate the complex regulatory landscape effectively. Together with our clients and partners we identify the shortcomings of standard software. In different approaches of co-innovation, we then close the gaps.

What future developments in AI and digitalization do you foresee having the most significant impact on quality assurance and control in the pharmaceutical and biotech industries?

One thing we all know for sure is that the rapid acceleration of AI will continue to introduce new approaches to tackling familiar challenges. As seen with our own Intelligent Quality Suite, AI will make mundane but critical processes in quality assurance and control faster, less prone to error and enable the highest level of automation with or even without human interaction. Additionally, we can expect disruptive advancements such as AI-driven inspections, NLP-based automated compliance tools, and the use of digital twins to replace physical trials.

This ultimately leads to medicines and other biologics hitting the marketplace faster and impacting the lives of people for the better. And that is what we must not lose sight of, in this ever-changing AI landscape for life sciences. It's people who will benefit from these developments, so we must ensure that they remain front and center.