Use Cases for Life Sciences: Manufacturing Quality Deviation Management

Challenges.

The company was struggling with inefficiencies throughout the deviation management process, including:

- **High manual effort.** Despite a robust technical landscape, including a leading deviation management system, much of the deviation management process was being done manually outside of systems. The company was relying heavily on Word documents and emails, treating the deviation management system as the final source of truth rather than the place where the ongoing process activities were conducted.
- **Operational inefficiency and long cycle times.** The high manual effort of a fixed team of resources limited the volume of deviations that could be processed in a given time period. This led to long deviation management closure times.
- **Risk and compliance issues.** The disproportionate amount of time spent on lower-value incidents put the company at risk of not meeting critical investigation timelines, often requiring extensions to be filed.
- **Poor employee experience.** The high volume of manual effort also impacted employee experience, as many highly valuable knowledge workers were spending time doing menial activities and being called in on nights and weekends to process incidents.
- **Lack of visibility.** Because so much of the deviation process was being done outside of systems, the company could not track deviations in real-time nor measure performance.
- **Standards and governance risk.** Despite documented procedures, there was no programmatic approach for this process on the tactical level. This resulted in each person and each manufacturing facility doing it "their way," largely based on experiential knowledge. This made it difficult to perform the process at scale in a reliable and consistent way and difficult to train new people.

Solution.

The company was looking for a deviation management system that focused on business process and workflow at its core, with an engaging user experience that would support widespread adoption. The solution must have configurable workflows to align to the company's specific processes, including variations and exceptions. It had to be fast to show

Customer profile.

One of the top 10 largest pharmaceutical companies is using the Appian Platform to facilitate the deviation management process. This is a highly regulated area governed by Good Manufacturing Practices (GMP), with all deviations requiring documentation, analysis, and disposition in a timely manner and in accordance with quality procedures.

value, easy to maintain, and easy to change over time in response to process changes and optimizations.

The Appian solution created is comprised of the following capabilities:

- Logging/capture of the event: A custom intake form capturing all information deemed necessary by the customer's unique and specific SOP. This includes dynamic fields based on logic, such as auto-population of information from other systems or modification of drop down values in real time to align with previous information entered in other fields. The use of standard language in selection fields allows for common terminology to be shared across all deviations.
- Deviation classification: To determine severity, a custom designed business logic triage flow based on SOP to suggest classification. This offers an initial suggestion, which must later be reviewed and confirmed by Quality.
- Root cause, review, and approval process: Workflow to assign, route, and notify resources of their needed actions.
- Publish to source of truth: Integration to write information to the deviation management system of record.
- Reporting: Tracking of individual and aggregate deviation status, progress, and performance.

This solution has:

- Reduced the time from open to closure by 65%, from 20 days to 7 days per incident
- Reduced the touch time (hands on keyboard time) by 94%, from 22 hours to 75 minutes per incident
- Improved employee satisfaction and adoption, evidenced by 87% of all new incidents being raised in the system within the first week
- Improved visibility by making available real-time information such as deviation status, progress, and cycle times, as well as aggregated information across all deviations for trend analysis and insights
- Improved process standardization as all users are creating, managing, and dispositioning deviations in the same way as per a guided process

In 16 weeks, a fully live and deployed application was developed and released to 4,000 people across manufacturing sites around the world.

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Appian is a software company that automates business processes. The Appian AI-Powered Process Platform includes everything you need to design, automate, and optimize even the most complex processes, from start to finish. The world's most innovative organizations trust Appian to improve their workflows, unify data, and optimize operations—resulting in better growth and superior customer experiences. For more information, visit **appian.com**. [Nasdaq: APPN]