

Challenges in GxP Multi-Site Monitoring

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For GxP products, like drugs and medical devices, it has always been important to monitor environmental conditions like temperature and humidity to avoid a negative quality impacts. Monitoring Systems are critical for product quality. They are also a target for auditors, with current concerns about Good Distribution Practices, Data Integrity and Electronic Records.

The competitive nature of the pharmaceutical industry is driving companies to leverage cost-effect enterprise solutions to monitor multiple facilities with a single system. There are challenges inherent in deploying and managing a centralized Enterprise System. Furthermore, it is always challenging to make a single solution fit the needs of multiple-stakeholders. The general challenge is to balance standardization with localization. How do you leverage the benefits of a standardized Enterprise solution, without burdening diverse user groups with a system that is not adaptable to their needs? This presentation will present three different GxP customer profiles to share the ways in which these challenges appear, and how they were solved.

Customer Profiles

We have identified three types of distinct GxP customers for our viewLinc Monitoring System. They differ in the following terms:

- Geographic organization from single city, single nation, to global organization.
- Variety of instrument types.
- Validation Requirements
- Centralization of Administration
- IT Infrastructure

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By comparing these three customer types we can identify typical challenges in implementing and leveraging Enterprise Monitoring System.

- Managing a monitoring system in multiple languages.
- Reporting time-dependent data from multiple time-zones.
- Supporting multiple instrument types and multiple site types (Warehousing, Manufacturing, Laboratories)
- Simplifying validation and audits.
- Overcoming IT Infrastructure Issues

Focused on Solutions

With these typical challenges identified, we will then present the solutions used by our customers to overcome these challenges.

- Simplify management of large installations by employing templates for configuration and validation.
- Employ smart security for “custom” user experience in standardized interface.
- Engage single vendor for sensors and software to maximize compatibility and simplify validation.
- Leverage emerging IoT Technologies to overcome infrastructure limitations.

Summary

It is important in the modern marketplace to save money and increase regulatory compliance by standardizing on Enterprise Solutions. The downside of centralization and standardization, is that diverse sites and users get burdened with tools that don't match local needs. The solution is to carefully select a system that is adaptable enough to meet user's needs. Adaptability in an Enterprise System means it must be able to:

- Support various geographic organizations for languages and time zones.
- Support many site types with multiple measurement parameters.
- Localize the user interface through Security and Virtual organization.
- Provide multiple connectivity options for diverse IT Infrastructure.

This presentation will show how to apply these solutions to solve the challenges of multi-site GxP Monitoring, regardless of the system used.