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Ajinomoto Genexine Boosts Commitment to Quality, Data Integrity, and Compliance with Computerized Systems Validation (CSV) Services from Waters

BACKGROUND

Ajinomoto Genexine (AGX) is located in Incheon Songdo, South Korea. AGX manufactures powdered formulations, from customized amino acid mixture supplements to the bulk production of commercial growth and feed media. One of their market-leading products is the CELLiST cell culture media, which applies the latest amino acid technology from AGX. **The high-quality and customized cell culture medium is being manufactured at Ajinomoto Genexine using amino acids of good quality raw material.**

AGX has a vision to become the most preferred and trusted cell culture media supplier in Asia. It intends to establish a quality system in compliance with global regulations and to maintain the quality of products under this high level of quality system. All AGX products are subject to rigorous quality control, assessed using tests such as appearance, solubility, loss on drying, pH, osmotic pressure, cell culture testing, endotoxin, microbial limit test, and mycoplasma.

COMPLIANCE LANDSCAPE

In the pharmaceutical industry, data integrity is mandated through strict regulations. Companies producing pharmaceutical drugs, active ingredients, and other similar products are subject to Good Practice regulations or GxP, a generic term that covers

Mr. Sang-Min Lee, Professional Analyst, Quality Control Group, Ajinomoto Genexine (AGX).

Moving from Workstation to Empower™ Enterprise brings multiple gains in work efficiencies and data integrity, such as:

1. Improving laboratory productivity with enhanced communication and system availability.
2. Securing chromatographic data with automated disaster recovery backup and centralized data archive.
3. Minimizing exposure during regulatory audits by facilitating GMP and 21 CFR Part 11 compliance.
4. Reducing IT support requirements by streamlining software maintenance.
5. Managing the cost of future chromatographic systems and upgrades with software and instrument maintenance support plans.

Empower™

all Good Practice Regulations, including Good Manufacturing Practice (GMP). Many regulations around the world, including FDA 21 CFR part 11 and EU GMP guideline Annex 11, require computerized systems that create, store, process, and report regulated data be fit for their intended use — and this is achieved through the process of Computerized Systems Validation (CSV).

However, "intended use" is unique to each company and laboratory, and is based on their products, markets, applicable regulations, corporate policies, and working practices. The CSV process must be optimized to address that "intended use". A properly implemented, validated, and maintained computerized system not only increases operational efficiency but can significantly improve data integrity. This in turn supports product quality and patient safety.

CHALLENGE

AGX's production sites operate in accordance with the current GMP standards set by the US and EU regulators. They have been using Waters™ Empower Workstations and ACQUITY™ UPLC™ Systems to analyze their amino acid products for many years.

AGX is committed to improving quality and productivity to meet client trust. AGX made the decision to upgrade from their existing standalone Empower Workstations to the networked Empower Enterprise — where all data is stored on a secure server — to increase work efficiency and improve data management. Empower Enterprise has many advantages compared to individual workstations, including enforcing the same user privileges across all connected chromatography systems and providing the means to review the entire system audit trail collectively in one location.

AGX knew that CSV was the key to maximizing data integrity with their upgrade to Empower Enterprise but, like many other companies, did not have the in-house expertise and capacity to complete the Empower CSV project themselves at that time.

THE SOLUTION

As a leader in compliance, Waters has a team of subject matter experts available to provide consultancy services to assist with CSV.

AGX had already received strong service support from Waters with their existing Empower Workstation and chromatography instruments. Knowing that Waters offered CSV consultancy, AGX chose Waters to assist with the validation of their Empower Enterprise System.

Seunghyun Lee, Group Manager, Quality Assurance Group at AGX, said, "We think that Waters engineers are focused on customer requirements and their abilities are outstanding. With a good understanding of global regulations, they can easily explain and fulfil their responsibilities and roles. In my personal opinion, Waters' strengths are software products that meet international regulations and excellent engineers."

THE VALIDATION PROJECT

The assigned Waters CSV consultant worked closely with the AGX project team throughout the CSV project. AGX provided essential information on the intended use of the system, allowing the Waters CSV consultant to expertly create the validation deliverables and activities to support that intended use.

Waters CSV projects implement industry best practices such as Quality Risk Management principles from ICH Q9, and apply the risk-based approach to CSV as laid out in ISPE GAMP® 5. As part of this process, the Waters CSV consultant chairs a risk assessment meeting and facilitates the customer project team agreeing a risk priority rating (high, medium, or low) for each data integrity function within the system. The risk assessment activity is key to a CSV project and, even with extensive help and facilitation from the CSV consultant, it can be time-consuming and quite challenging for an inexperienced customer team who is unfamiliar with this type of risk assessment.

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> *Group Manager, Quality Assurance Group*

Mr. Lee explained, "The risk assessment was very helpful. In particular, the assessment of user requirements by applying ICH Q9 (Quality Risk Management) was helpful. When assessing the risks that may arise after CSV has been done, the application of the [GAMP] method made it easy to assess and drive improvements. It was an opportunity to clearly

establish standards for risk assessments."

The ratings assigned by AGX during the risk assessment were used by the CSV consultant to scale the rigor of the data integrity controls and the extent of the validation testing. Through every stage of the CSV project, AGX reviewed and approved the CSV activities and documentation produced by the Waters CSV consultant. The Validation Summary Report was the final Waters deliverable in the project, summarizing all the validation activities completed and confirming the system was now validated as fit for the intended use within AGX.

Mr. Lee said he was "highly satisfied with the Waters assistance with CSV. Waters supported a system introduction through appropriate validation activities in accordance with global standards and also tailored focused on customer requirements and intended use."

THE RESULT

Positive results were immediately felt by the analysts from the AGX Quality Control team. AGX uses their Waters ACQUITY UPLC Systems to run quantitative tests for amino acids — the most important test for their product.

"The level of data integrity has increased through specific audit trails and custom field features for accurate calculation. This helped us meet the strict requirements set by our clients and helped us build even stronger trust with them. We think Waters is our best partner as it provides rapid technical support in any analytical task," Mr. Lee confirmed.

The detailed understanding of the features of Waters Empower Software gained during the CSV project increased the work efficiency of the QC team. AGX is now able to identify the exact status of each analytical task and identify potential deficiencies through audit trail reviews and using the built-in Empower Analytics for an overall view of the system operation and data activities.

Potential experimental errors have been greatly reduced in the validated system. Since the introduction of this system, their staff involved with quality control have recognized the importance of data integrity resulting in positive effects on the company and people.

LONG-TERM BENEFITS

The CSV project has provided AGX with confidence that they understand how to operate and maintain the system in compliance through its operational life. Mr. Lee confirmed that "the optimized configuration of the Empower system established through CSV prevents any unauthorized changes from personnel."

The project has also given AGX insight into the 'hows' and 'whys' of CSV that will help them in the future. Mr. Lee explained, "We felt that the consultant completed not only CSV activities but also included a detailed explanation of those activities. It was a chance to understand international regulations beyond the Empower CSV work. Based on this support/guidance, it is judged that operators were able to easily understand regulations and to perform validation activities."

"It is planned to validate all analytical instruments in the QC lab on the basis of CSV experience acquired from the introduction of LIMS and Empower which were big projects. Our analysts showed a high level of satisfaction after the introduction of Waters Empower Enterprise and agree that it contributes to the QC team and their personal development," Mr. Lee concluded.

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