CUSTOMER CASE STUDY

Fujirebio Diagnostics Implements Paperless Electronic Initiative for its Biomarker Manufacturing

Fujirebio Diagnostics, Inc.
www.fujirebio.com

INDUSTRY
Life Sciences

Goal

- To replace an existing paper-based GMP record system and manual process with an electronic monitoring system

Challenges

- Significant time is spent each day manually reviewing reports
- The existing paper-based system was time-consuming and vulnerable to reporting errors
- A new system must enable the company to remain in compliance with federal regulation

AVEVA Solution

- System Platform
- Workflow Management
- Historian®
- InTouch® HMI

Results

- The company's electronic initiative helps produce 75 million tests that are distributed throughout the world
- The solution is completely paperless and provides electronic record collection with electronic signatures while maintaining 21 CFR compliance and ISO 9001 and 13485 certification
- The equipment monitoring system saves about 1,100 man hours per year
- The tasks related to manually logging equipment parameters and reviewing paper logs and charts is eliminated and has reduced data reviewing time from 15+ hours to just minutes
- Electronic monitoring saves 2/3 of time, or about 10 hours per month in quality assurance

Wonderware® by AVEVA

MALVERN, Pennsylvania — With a reputation of more than 20 years as a trusted source of innovative solutions in clinical diagnostics, Fujirebio Diagnostics, Inc.'s proven manufacturing process for the production of biomarkers has made it a global partner of choice among leading diagnostics companies around the world. Being in the life sciences industry, Fujirebio adheres to a strict manufacturing process which is based on Wonderware by AVEVA. These processes are certified with compliance for reporting and documentation requirements that are very detailed and extensive. The biomarkers produced by Fujirebio help physicians, lab professionals and patients better manage disease.

"The biomarkers manufactured by Fujirebio are basically blood tests, and our core competency is in oncology. The products which we have intellectual property for are mainly centered on cancer testing. At Fujirebio, we are looking to take advantage of our electronic systems. We installed the equipment monitoring system to electronically capture data from Fujirebio's temperature-controlled areas. The new monitoring system also provides the company with a scalable infrastructure which we can implement other electronic data capture projects as we go forward."

Mike Koch
Vice President
Fujirebio Diagnostics, Inc.

Maintaining the Most Extensive Array of "Gold Standard" Biomarkers for Oncology

Over the course of the year, Fujirebio's 160,000-foot production facility produces about 75 million tests that are distributed throughout the world. It is a FDA-registered facility that is 21 CFR Part 11 compliant, and is both ISO 9001 and ISO 13485 certified for quality systems.

"The largest benefit of the equipment monitoring system is that we are logging automatically now rather than manually, so it's saving us about 1,100 man hours per year. In addition to the benefits that Fujirebio now gets from EMS, the real advantage is what it can do in the future."

Josh Zimmer
Quality Engineer
Fujirebio Diagnostics, Inc.

Innovation Always Starts with an Idea

The project started when the personnel at the Malvern, Penn. campus identified a major opportunity to save time and paper, while still retaining compliance by automating the acquisition of equipment data and generating electronic reports for review and approval. The solution is called the Electronic Initiative and the first phase of the implementation is called the Equipment Monitoring System, or EMS.

"EMS provides us a way of archiving data and it allows us to trend the way our equipment is operating to make sure its staying within our specifications and up to our standards," said Josh Zimmer, Fujirebio quality engineer.

The EMS system at Fujirebio performs a number of very important functions such as:

- Enabling personnel to monitor equipment from their workstations
- Maintaining all temperature readings in electronic records
- Notifying authorised personnel in the event of adverse temperature trends

- Generating electronic Good Manufacturing Practice (GMP) reports for review by exception
- Providing authorised personnel electronic signature capabilities to approve reports

"Before the EMS went in, I was spending about 15 or more hours manually reviewing the GMP packs. After the system, I went from hours to minutes. The key benefits of the system are the electronic signatures with the review by exception, and not having to worry about missing papers or chart recorders. The system has just made my life a whole lot easier."

Rachael Vinjamuri
Lead Manufacturing Document Analyst/
Fujirebio Diagnostics, Inc.

Saving Time and Effort

Now that it's up and running, the employees at Fujirebio have more time to spend on other productive activities. The amount of time saved is significant and equates to:

Activity	Time Saved
Log Data	439 hours
Check Recorder Charts	230 hours
Change Charts	30 hours
Prep & Review Doc Pack	89 hours
Dept. Review Doc Pack	112 hours
QA Review Doc Pack	192 hours
Total	1,100 hours

"Going paperless has saved us a huge amount of time and it has freed us up to do other aspects of our job," said Cynthia Travia, Fujirebio quality assurance analyst. "I'm saving approximately two-thirds of my time, or about 10 hours a month, by using the EMS system."

What makes the solution unique is that it is a complete paperless system with electronic records and electronic signatures. It generates eighteen monthly department reports for review by exception, and routes reports for review and approval via AVEVA's Workflow software.

Workflow Management — the Heart of the EMS at Fujirebio

Workflow Management is at the heart of Fujirebio's EMS. What Workflow Management does is digitise and automate Fujirebio's manual processes that include people, equipment and systems, based on a sophisticated Business Process Management (BPM) foundation standard. This enables staff to generate electronic records and file them automatically.

Each day, companies such as Fujirebio execute complex work flows involving both people and systems. Consistent execution of critical work leads directly to better operating performance. With Workflow Management, Fujirebio is able to route critical reports for review and approval, ensuring that vital work flows are executed correctly every time. This drives accountability and better stewardship within the organisation.

Capabilities for Future Growth

Because of the way the EMS is architected, Fujirebio now has the flexibility to expand to other types of applications such as process automation, MOM/MES, operations improvement and ERP integration. The scalability of the solution will sustain all the innovation and future projects.

With the help of Wonderware by AVEVA, Fujirebio is sure to remain a trusted source of innovative clinical diagnostics solutions for another 20 years.

"Perhaps the key business metric of the EMS is the time saved as a result of going paperless, which is especially important in a regulated industry. With Workflow Management, Fujirebio is able to comply with 21 CFR Part 11 for electronic electronic records and electronic signatures."

Ken Kovacs
Quality Business Systems Manager
Fujirebio Diagnostics, Inc

Include image caption here. Photograph courtesy of Company name.

About AVEVA

AVEVA is a global leader in engineering and industrial software driving digital transformation across the entire asset and operational life cycle of capital-intensive industries. The company's engineering, planning and operations, asset performance, and monitoring and control solutions deliver proven results to over 16,000 customers across the globe. Its customers are supported by the largest industrial software ecosystem, including 4,200 partners and 5,700 certified developers. AVEVA is headquartered in Cambridge, UK, with over 4,400 employees at 80 locations in over 40 countries.