



## CUSTOMER CASE STUDY

# Fujirebio Diagnostics implements paperless electronic initiative for biomarker manufacturing

Fujirebio Diagnostics, Inc  
Industry - Life Sciences

## Goals

- To enhance collaboration and enable swifter vaccine manufacturing
- To replace an existing paper-based record system and manual process

## Challenges

- A significant amount of 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 regulations

## Results

- The electronic initiative helps produce 75 million tests
- The equipment monitoring system saves about 1,100 man hours per year
- 67% reduction in time spent on quality assurance
- Data reviewing time is reduced from 15+ hours to just minutes

## Solutions

- AVEVA™ System Platform
- AVEVA™ InTouch HMI
- AVEVA™ Historian
- AVEVA™ Work Tasks

With a more than 20-year reputation 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 partner of choice among leading diagnostics companies around the world. Being in the life sciences industry, Fujirebio adheres to a strict manufacturing process. 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," said Mike Koch, Vice President of Supply Chain, Fujirebio Diagnostics.

### **An 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 an FDA-registered facility that is 21 CFR Part 11 compliant, and is both ISO 9001 and ISO 13485 certified for quality systems.

A major milestone was achieved at Fujirebio on July 1, 2013 when its manual, paper-based process of periodically recording temperature readings for specific manufacturing equipment was officially replaced by a new computerized system.

"At Fujirebio, we are looking to take advantage of our electronic systems," Koch said. "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."

### **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.

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**"EMS provides us a way of archiving data and it allows us to trend the way our equipment is operating to make sure it's staying within our specifications and up to our standards,"**

**- Josh Zimmer**

Quality Engineer, Fujirebio Diagnostics

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 authorized personnel in the event of adverse temperature trends
- Generating electronic Good Manufacturing Practice (GMP) reports for review by exception
- Providing authorized personnel electronic signature capabilities to approve reports

The solution is completely paperless and provides electronic record collection with electronic signatures while maintaining 21 CFR compliance and ISO 9001 and 13485 certification.

"Before the EMS system went in, I was spending about 15 or more hours manually reviewing the GMP packs. After the system, I went from hours to minutes," said Rachael Vinjamuri, Lead Manufacturing Document Analyst at Fujirebio. "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."

### **Saving time and effort with AVEVA**

Now that it's up and running, the employees at Fujirebio have more time to spend on other productive activities. The new EMS has relieved staff of the tasks related to manually logging equipment parameters and reviewing paper logs and charts on a daily basis. The amount of time saved equates to:

Activity	Time saved
Logging Data	<b>439</b> hours
Check Recorder Charts	<b>230</b> hours
Change Charts	<b>30</b> hours
Prep and Review Doc Pack	<b>89</b> hours
Dept. Review Doc Pack	<b>112</b> hours
QA Review Doc Pack	<b>192</b> hours
<b>Total</b>	<b>1,100</b> 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 the AVEVA Work Tasks workflow solution software.

“At Fujirebio we’re looking to take advantage of our electronic systems. We installed the equipment monitoring system to electronically capture data from our temperature-controlled areas. But it also provides us with infrastructure for other electronic data capture projects as we go forward.”

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**Mike Koch**  
 Vice President of Supply Chain, Fujirebio Diagnostics

## AVEVA Work Tasks – the heart of the EMS at Fujirebio

What AVEVA Work Tasks does is digitize and automate Fujirebio’s manual processes that include people, equipment and systems, based on a sophisticated Business Process Management (BPM) foundation standard. AVEVA Work Tasks is integrated into AVEVA System Platform.

The combined functionality of AVEVA Work Tasks with AVEVA System Platform enables Fujirebio to model, execute, analyze, and improve work processes, enhancing collaboration, productivity, and innovation.

Each day, companies such as Fujirebio execute complex workflows involving both people and systems.

Consistent execution of critical work leads directly to better operating performance. With AVEVA Work Tasks, Fujirebio is able to route critical reports for review and approval, ensuring that vital workflows are executed correctly every time. This drives accountability and better stewardship within the organization.

“With AVEVA Work Tasks, our staff is able to generate electronic records and then file them automatically.”

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**Ken Kovacs**  
 Quality business systems manager, Fujirebio Diagnostics

“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 AVEVA Work Tasks, Fujirebio is able to comply with 21 CFR Part 11 for electronic records and electronic signatures.

AVEVA Work Tasks also enables Fujirebio staff to successfully model entire workflows involving people and systems, as well as the proper task sequencing and dependencies. The application tracks each work step and records the outcome so Fujirebio staff has the detail it needs to properly evaluate work performance and fine tune workflows. Overall, AVEVA Work Tasks improves operational consistencies at Fujirebio, and in turn enhances productivity and reduces operational costs.



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“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.”

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**Josh Zimmer**

Quality Engineer, Fujirebio Diagnostics

## Capabilities for future growth

Because of the way the system 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 support future projects.

The future looks bright for Fujirebio as it continues to help healthcare professionals and patients manage disease. Every day, thousands of people all over the world are living a better life because of the products Fujirebio manufactures. With the help of AVEVA, Fujirebio is sure to remain a trusted source of innovative clinical diagnostics solutions for another 20 years.