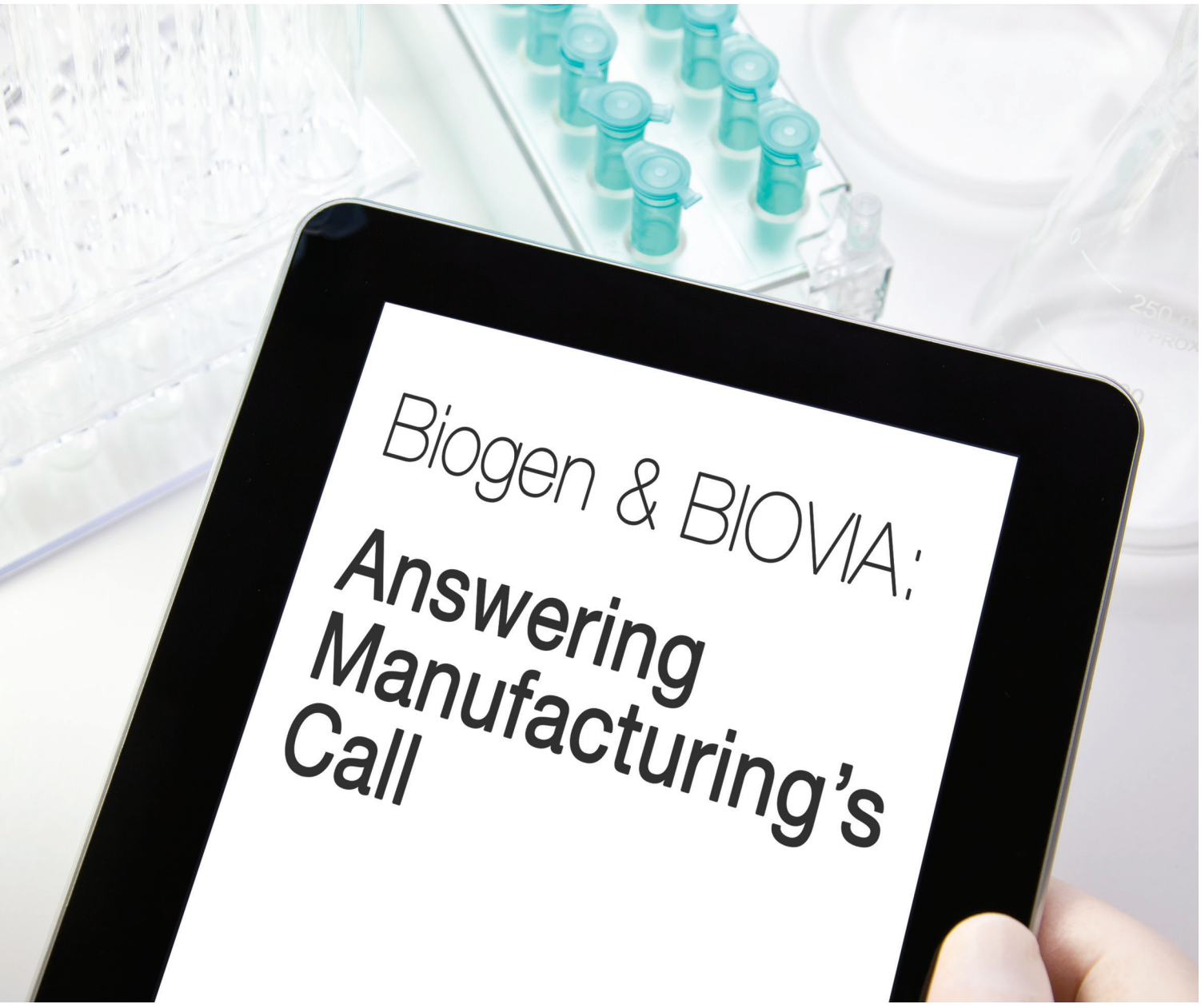
DASSAULT SYSTEMES

BIOVIA

BIOGEN AND BIOVIA: ANSWERING MANUFACTURING'S CALL

CUSTOMER STORY



Biogen

Challenge:
Improve the delivery of critical documentation to employees working in a clean environment

Solution:
BIOVIA QUMAS application for the iPad

Benefits:
- Saved time - over 1,575 hours per year
- Reduced labor costs by $110,000 per year
- Eliminated materials costs of over $3,300 per year
- Freed up counter space in manufacturing areas

ABOUT BIOGEN

Founded in 1978, Biogen is the world's oldest independent biotechnology company. The company discovers, develops and delivers to patient's worldwide innovative therapies for serious neurodegenerative diseases, autoimmune disorders and hematologic conditions.

Biogen's well-known products are AVONEX®, TYSABRI®, and RITUXAN®. In 2013, Biogen launched TECFIDERA®, a new first-line oral treatment for people with relapsing forms of multiple sclerosis (MS). In 2014, Biogen reinforced their commitment to addressing unmet medical needs with the approval of two new hemophilia therapies, ALPROLIX™ and ELOCTATE™.

Although their corporate office is located in Cambridge, Massachusetts, Biogen has facilities and offices worldwide in North America, South America, Europe, and Asia.

The corporate headquarters located in Cambridge, Massachusetts, includes a small scale manufacturing facility and serves as a test bed for new technologies in improving operational efficiencies.

Since 2002, Biogen has used an Electronic Document Management System called BIOVIA QUMAS EDMS to manage procedures, master records, forms, technical reports, risk assessments, and other department-controlled documents.

This case study focuses on how Biogen improved the delivery of critical documentation by leveraging BIOVIA Quality and Regulatory Compliance Management Software on Apple iPads.

THE BIOGEN CHALLENGE – IMPROVE "DELIVERY" OF CRUCIAL DOCUMENTATION

Inherent in a biotechnological and pharmaceutical manufacturing facility is a constant cycle of change, as well as the need for utmost control over the changes. Because the Standard Operating Procedures (SOP) are so crucial to the success of a product, there must be strict controls around the recording, storage, and communication of any modifications in the manufacturing facility.

Biogen's Cambridge Manufacturing Facility leaders assessed their paper-based SOP delivery system. Their findings were that their procedures were inefficient and costly. As a result, they established the following four goals for improving the process:

- **Compliance** – Provide operators with the effective version of the procedure
- **Time** – Significantly lessen the time it takes to deliver changed documentation
- **Labor Costs** – Decrease the labor cost from delivering paper documentation manually in a timely manner
- **Material Costs** – Decrease the materials costs associated with paper documentation and manual delivery

> "Our main objectives for this project was to have employees be able to view the most effective version of the documents for performing their tasks and to also reduce all the labor hours for doing all the manual updates in all the various locations in the manufacturing facility."
>
> — Gregory Chua, Senior Manufacturing Support Associate

Their solution to the inadequacies caused by the paper documentation was to move the access to the documentation and the method for delivering it to an electronic device.

THE SCOPE OF THE BIOGEN CHALLENGE

In the Cambridge manufacturing facility, there are three Good Manufacturing Practices (GMP) areas. Each area has its own procedures and forms that are subject to updates. The Cell Culture area has 233 procedures and 68 forms. The Dispensary area owns 179 procedures and 112 forms, and the Purification area has 252 procedures and 65 forms.

Updates must be delivered to many sites. Within each area there are a number of sites that must receive updates. The Cell Culture area has 18 sites, Dispensary has 13, and Purification has nine. This means that every time there is an update, the deliverer must visit 40 sites.

Also, the manufacturing floor is a clean environment. As a clean environment, a person, such as the deliverer of the paper updates, must put on a gown when entering the areas and must remove the gown when coming out. It is a time-consuming process, because it must be repeated so many times when updating the manuals.

The process of executing a paper update was labor-intensive and time-consuming. It took about six people to perform an update - one person to prepare the update and one to verify that the update was done correctly, and four different deliverers to perform and verify that the updated documents were placed at the correct site.

The old update process was the following:

- Each department/group received an email notification from Quality that provided a list of documents that required updating.
- Then, the department/group prepared those documents by filling out all of the forms to notify the user of the PRCD documents, the SOP documents, and the version numbers that will change. This took approximately an hour or two to prepare the list.
- Next, the department/group printed out the effective version of the documents, which took another hour.
- Once the documents are printed, a deliverer brought them to the manufacturing floor to distribute to the correct site within an area.
- When the deliverer brought the documents to an area, he verified that the document is correct according to the prepared list.
- The deliverer makes more copies, the correct number for the sites in the area.
- The deliverer then took five to ten minutes to put on a gown in order to enter the clean environment.
- The deliverer distributed all of the documents to the correct locations within the area.
- After that, the deliverer took another five to ten minutes to take off the gown.
- Finally, this routine was repeated two more times for the other areas.

At Biogen, frequently there are unscheduled updates throughout the week. Whenever there was an update, the process was repeated.

THE BIOGEN SOLUTION: A DECISION TO MAKE DOCUMENT UPDATING ELECTRONIC

The Biogen Manufacturing team in Cambridge decided that the solution to the inefficient updating of paper documentation was to use an electronic device for viewing documents and to view the documents via a BIOVIA application.

After a comparison of devices, Biogen in Cambridge selected the Apple iPad for its delivery vehicle. Certain iPad features stood out:

- It's portable.
- There are protective cases suitable for the manufacturing suite where it could get wet.
- There are ergonomic charging stations for multiple devices.
- The iPad allows for customization:
  - Restrictions were set so the user cannot download anything nonessential. Documents cannot be exported and printed because all of the other features for any installation of any applications on the iPad are turned off.
  - A user cannot modify an account.
  - iPad bookmarks and apps are synchronized: one iPad is configured and the others then have the same bookmarks and apps.
- With hyperlinks, documents are easy to find, and all users link to the same location on the same server to find their documents that are controlled by BIOVIA QUMAS EDMS.
- Users can see diagrams better. The quality of the screen is better than photocopies. In addition, the diagrams can be enlarged for easier reading.

THE BIOVIA CONTRIBUTION

After selecting the iPad, Biogen relied on their compliance and quality management partner, BIOVIA, to provide the interface that would allow them to make their documentation available on the iPad in a way that is faster and less costly.

- Although the BIOVIA application for the iPad is capable of SOP access, reviewing documents and approving documents; at this time, Biogen is focused only on SOP access. The app is called BIOVIA QUMAS Portal.
- For the BIOVIA QUMAS Portal, the customer governs the access to the site and the application, as well as access to the networks. At Biogen, the server is onsite and connection requires being on their secure network.
- BIOVIA QUMAS Portal adheres to all of the 21 CFR Part 11 and all of the general security requirements.
- The application retains a secure login. Users must still log in to retrieve documents. The documents are not stored on the iPad. The iPad is linked to the BIOVIA QUMAS Portal to view as needed.
- Documents are opened directly from the server, ensuring that the version displayed on the iPad is always the most current, effective version.
- Documents are shown in full-screen mode and display the version number. Additionally, the full screen mode feature can enable long time use.
- The application allows more than one document to be opened and viewed in separate tabs.

IMPLEMENTATION OF THE SOLUTION

Biogen implemented the solution over a year. Job aids were given to all of the employees involved. They created iPad ambassadors on the manufacturing floor to provide assistance and support to employees. In addition, employees received the following training :

- How to navigate the iPad
- How to connect to Biogen's WiFi system
- How to use the bookmark links to get to the hyperlinks for all of the documents
- How to use the search feature on the iPad to quickly find the step number in the SOP
- How to use BIOVIA QUMAS Portal on the iPad

Very importantly, a manual index with hyperlinks was created for each department. Via the index, users can go through the list of documents chronologically to find the document they need and open them without worrying about searching for them.

BIOGEN MEETS ITS GOALS WITH IMPRESSIVE RESULTS FROM THE BIOVIA/IPAD SOLUTION

Electronic delivery of documentation has resulted in significant saving to the company.

- **Saves time** - Manuals updated on screens eliminating the user delivering manuals to multiple sites, which was time-consuming. The savings is over 1,575 hours per year.
- There has been a **labor cost savings** of $110,000 per year by not having people run around to different areas to update documentation.
- **Saves materials** - Eliminated copying onto paper saving greater than $3,300 for paper, toner, and printers.
- **Saves space big and small** - On tables and in the manufacturing areas because the documents do not have to be stored.

There were additional important results, although these are less quantifiable. The BIOVIA QUMAS Portal/iPad solution was also well received by the users.

- Users believe that this solution is more convenient.
- Users found the solution easy to use, but familiarity with the technology was helpful.
- With zoom in and out, the documentation was easier to read.
- In the two years of its implementation, only one iPad needed to be replaced because it was submerged in water. Since the iPads are covered by Apple Care, the iPad was replaced.

NEXT STEPS

Based on the results that were achieved at the site in Cambridge, Massachusetts, Biogen is making plans to roll out the BIOVIA / iPad solution to its other manufacturing sites around the globe.

ABOUT BIOVIA

BIOVIA from Dassault Systèmes provides a scientific collaborative environment for advanced biological, chemical and materials experiences. The sophisticated enterprise system of modeling, simulation, laboratory, and quality management enables innovation for science-based industries. For Regulatory, Quality, and Compliance Management, BIOVIA QUMAS provides an integrated solution for all quality process and content activities from lab to commercialization, maintaining regulatory compliance with global mandates.

Dassault Systèmes, the 3DEXPERIENCE Company, provides business and people with virtual universes to imagine sustainable innovations. Its world-leading solutions transform the way products are designed, produced, and supported. Dassault Systèmes' collaborative solutions foster social innovation, expanding possibilities for the virtual world to improve the real world. The group brings value to over 190,000 customers of all sizes, in all industries, in more than 140 countries.

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