# VEEVA IS BUILDING THE OPERATING SYSTEM FOR LIFE SCIENCES
## TRANSFORMING QUALITY, A TOP PRIORITY FOR CUSTOMERS AT VEEVA SUMMIT 2019
By: Daniel R. Matlis, President

## INTRODUCTION

Veeva has become a strategic technology partner to more than 775 customers across the globe, ranging from the world's largest pharmaceutical companies to emerging biotechs.

I had the opportunity to cover the 2019 Veeva R&D Summit in Philadelphia, PA in September.  The event brought together more than 1,700 life science professionals and experts to share the latest market trends in the industry, experience innovative technology, and share best practices. The annual event has experienced 25% attendance growth compared to 2018.



*Image Courtesy of Veeva Systems*

With more than 75 sessions by leading life sciences companies, the R&D Summit showcased the latest advancements in Veeva's Development Cloud, which includes clinical data management, clinical operations, quality, regulatory, and safety.

This brief focuses on my first-hand interactions with leading industry executives leveraging Veeva's quality offerings to modernize quality management in the cloud.

The following executives shared how they are leveraging modern cloud-based solutions to transform quality management:

- James Choi, VP and CIO at Samsung BioLogics, on his vision for modernizing manufacturing quality.
- Chris Lamont, Director, Global QMS Programs at Bristol-Myers Squibb on the company's journey to achieve enterprise quality with Vault QMS.
- Jennifer Trundle, Associate Director, Quality Management Systems at Gilead on the successful expansion of Vault QualityDocs across the global enterprise.

## VEEVA AS THE OPERATING SYSTEM FOR LIFE SCIENCES

Speed continues to be one of Veeva's core values. However, my interactions with industry executives at the summit show that that Veeva is not simply operating at the right speed, but at high velocity. For a more detailed analysis of Veeva's Speed vs. Velocity paradigm, see Veeva is Building the Life Sciences Cloud with High Speed and Velocity

"We are building the industry cloud for life sciences. The vision is for the industry cloud to be the operating system for life sciences; interconnected across your companies, industry, CRO and one day patients and hospitals" said Peter Gassner, President and CEO of Veeva during his keynote. "We want the industry and your company to be more efficient and effective – supporting your journey to improve and extend human life," Gassner added.



Image Courtesy of Veeva Systems

Moving at a high velocity, Veeva provides the industry with modern, mature, preconfigured out-of-the-box (OOTB) cloud-based Quality Management solutions.

## VEEVA VAULT QUALITY CONTINUES TO MAKE SIGNIFICANT INROADS

"Modernizing quality is becoming a top priority for life science companies," commented Gassner. "Vault Quality has gained significant market share by replacing paper-based or legacy on-premises solutions at over 200 Vault QualityDocs customers, over 100 Vault QMS customers and 18 training customers –ranging from emerging biotechs to top 10 pharmaceutical companies in just a few years," he added.



Image Courtesy of Veeva Systems

Veeva continues to make significant inroads in the Quality Management System market. In fact, almost a third of conference attendees (450+) were Veeva Quality clients. "Veeva has seen a 33% increase in Vault Quality customers and has doubled the number of quality users to 346,000 in the last year," disclosed Mike Jovanis, Vice President Vault Quality, Veeva Systems.

"Veeva provides a unified suite of quality applications that helps organizations eliminate silos and drive efficient and effective end-to-end business processes across product development, quality, and manufacturing," said Jovanis. To this end, Veeva continues to grow the number of offerings in its unified quality suite, which now includes Vault QMS, Vault Quality Docs, Vault Station Manager and Vault Training. Simply put, Veeva provides a single source of truth across quality processes and content.



**Image Courtesy of Veeva Systems**

Vault Quality Suite offers a unified and connected suite of applications that cover:

- Deviations
- Internal and external audits
- Complaints
- Lab investigations
- Change control
- CAPAs
- Supplier qualification
- Proactive initiatives
- Training
- Document management
- Quality Risk Management

## CLOUD FIRST APPROACH FOR QUALITY GAINS MOMENTUM

A number of forces are converging to accelerate the move of QMS in the cloud.   Axendia's research "Soaring to the Cloud in Support of Quality and Compliance"  shows that life science companies are taking a cloud-first approach as they continue to globalize and outsource.

Process modernization and the need to reduce the complexity are driving consolidation of siloed solutions onto a single cloud platform.

In addition, life science companies are looking to streamline processes with consistent and standard OOTB solutions that are based on industry best practices, allowing seamless communication with other critical applications, facilitating standard metrics and reporting.

Veeva's Quality customers echoed these themes during their presentations and discussions. These included:

- The benefits of using integrated end-to-end quality processes in a modern cloud QMS platform.
- The improved efficiency in execution of QMS processes
- The ability to respond to changing business and regulatory landscape
- The ability to achieve seamless collaboration with internal and external partners

Veeva's modern cloud QMS also made it possible to manage externally generated data to support development and manufacturing activities.

## SAMSUNG BIOLOGICS: VISION FOR MODERNIZING MANUFACTURING QUALITY

During the event I had the opportunity to sit down and reconnect with James Choi, VP and CIO, Samsung BioLogics, to discuss his vision for modernizing manufacturing quality. Samsung BioLogics is a world-class contract development and manufacturing organization (CDMO) located in Songdo, South Korea.  The company was founded in 2011 and today has the largest total plant Cell Culture Capacity in the world from a single location:  364,000 L. Samsung BioLogics employs more than 2500 employees including 100+ global expats from 12 countries.

**SAMSUNG MANUFACTURING PORTFOLIO**
Three plants completed validation and in operations

| Plant No. 1 *"Industry Standard"* | Plant No. 2 *"The Largest Single Plant"* | Plant No. 3 *"The Most Competitive Plant"* |
|---|---|---|
| Cell Culture Capacity **30,000L** | Cell Culture Capacity **150,000L** | Cell Culture Capacity **180,000L** |
| Fill Finish **Liquid & Lyo vials** | Fill Finish **Liquid vials** | Fill Finish **Leverage Plant 1 & 2** |
| Regulatory Approval **FDA, EMA, PMDA and Health Canada** | Regulatory Approval **FDA, EMA** | Regulatory Approval **TBD** |

**Largest CMO Capacity as of 2018**

*Source: 2019 Veeva R&D Summit Session*

To date, the company has had a 100% drug substance batch success rate. It has also undergone more than 20 regulatory inspections and 29 approvals in 4 years.

## MANAGING CONTENT ON SAMSUNG'S SHOP FLOOR

Custom applications and paper binders make it difficult to find, update, and track work instructions and procedures, as well as to verify that the right versions are being used.

When Samsung BioLogics was looking for a way to deliver the right content to the right station for a connected shop floor, it partnered with Veeva to develop Vault Station Manager, an easy-to-use mobile application in the Veeva Vault Quality Suite. Vault Station Manager provides manufacturing operators up-to-date content directly on the manufacturing floor. It delivers documents and videos, including critical work instructions and procedures, from Veeva Vault QualityDocs to tablets located at shop floor stations.

Vault Station Manager allows Samsung BioLogics to connect to the shop floor making manufacturing operations more agile and adaptable to changing business requirements with greater velocity.

"It's challenging," revealed Choi "to manage and maintain information on the manufacturing floor and ensure operators are working from the latest procedures.

Delivering content directly to manufacturing stations through a mobile application makes it faster for teams to stay up-to-date."

With Vault Station Manager, manufacturers can increase efficiency and reduce compliance risk by keeping content current and providing operators the information they need to perform their jobs. Vault Station Manager automatically synchronizes content on station tablets and makes it available for operators, including for offline viewing. Administrators can centrally manage, distribute and track the content being used at each facility, station, or device gaining complete visibility into the documents and videos manufacturing teams are leveraging.

According to Mike Jovanis, "Veeva is modernizing manufacturing operations in life sciences with an advanced mobile application to connect the shop floor. Veeva Vault Station Manager is making it easier for operators to do their jobs and enable continuous operations across the manufacturing organization."

## WHAT'S NEXT FOR SAMSUNG?

Samsung Biologics is built on Samsung's innovation DNA as well as its core skills in engineering and operational excellence. However, noted Choi, "We don't implement technology for the sake of technology, we implement innovation that drives business value based on a unified IT vision approach.



Source: 2019 Veeva R&D Summit Session

The company's IT directional focus is guided by three value drivers:

- ▲ Provide quality and efficiency of development and manufacturing services
- ▲ Deliver blockbuster scalability and operational resilience
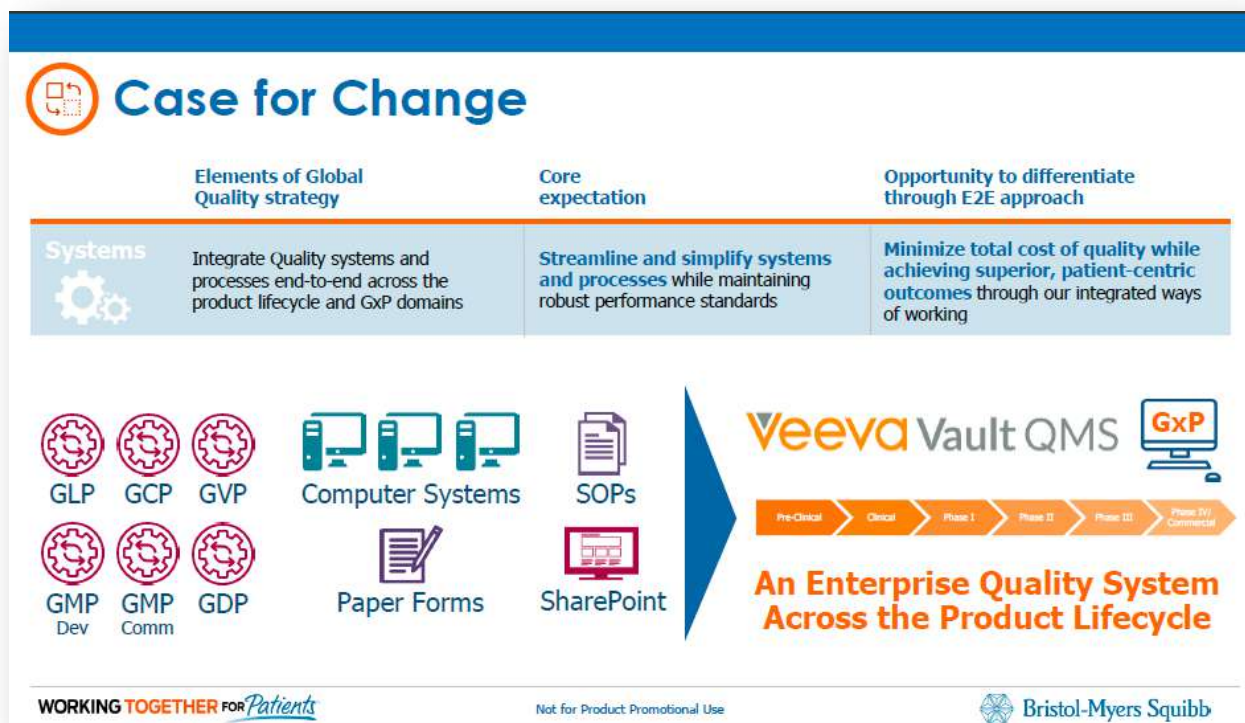- ▲ Build partnership value and trust

Based on this unified IT vision approach, the company is evaluating the use of technologies such as:

- ▲ Internet of Things (IoT)
- ▲ Block chain
- ▲ Big data
- ▲ Cloud BI and data lake
- ▲ Biometric e-signatures
- ▲ Paperless validation

## BMS: ACHIEVING ENTERPRISE QUALITY WITH VAULT QMS

Chris Lamont, Director, Global QMS Programs at Bristol-Myers Squibb, discussed the company's journey to achieve enterprise quality with Vault QMS.

BMS is implementing Vault QMS to modernize their quality management.  The goal is to minimize total cost of quality while achieving superior, patient-centric outcomes through integrated ways of working.  To this end, BMS is integrating quality systems and processes across the product lifecycle and all GxP domains.  BMS also recognizes the need to streamline and simplify systems and processes while maintaining robust performance standards.



Source:  2019 Veeva R&D Summit Session

To drive positive change in its global quality strategy, BMS adopted the following principles:

- Integrated and simplified end-to-end quality processes in a single electronic platform
- Improved efficiency in execution of QMS processes by reducing waste and cycle times
- Improved ability to respond to changing business and regulatory landscape via configuration changes
- Improved collaboration with external partners

BMS went live with Vault QMS on May 29th, 2019.  The initial system rollout included more than 1700+ users and over 800 records supporting change management, GCP and GVP audits and action tracking.  As a result, BMS eliminated over 50 procedures and has saved 17,000 hours of cycle time and 90 hours/record in lead time.

Lamont also shared the following key learning from this project:

- Optimize/simplify your process BEFORE you configure your system
- Establish process design guidelines
- Evaluate the change agility of the user community early in the process
- Define stakeholders as early as possible
- Communicate often with all stakeholders
- Determine testing strategy early in the design phase
- Minimize configuration complexity to make future enhancements easier

As a result of the implementation of Vault QMS across the enterprise, BMS reported enhanced user experience through improved transparency of quality system performance supporting improved decision-making

## GILEAD: EXPANDING QUALITY DOCS ACROSS THE GLOBAL ENTERPRISE

Jennifer Trundle, Assoc. Director, Quality Management Systems at Gilead, discussed the successful expansion of Vault QualityDocs across the global enterprise.

In 2015, Gilead implemented QualityDocs to support CxO partner collaboration and contractor manuals.
The initial implementation included:

- 21 doc types, 17 lifecycles
- Over 100 CxO partners
- 120,000 documents
- 700 internal users
- 400 external users
- Customized functionality for external partner security, contractor manual binders

In 2017, the company embarked on a project to rollout Vault QualityDocs across the global enterprise to replace its legacy document management system.  The legacy system was out-of-support making it difficult to maintain or adapt to meet business needs. In addition, inconsistent processes and a document control-centric design led to complex document types and a suboptimal user experience.

In 2019 Gilead went live with Veeva Vault QualityDocs globally.  This involved the migration and rollout across the entire organization for quality controlled documents including:

- 75 doc types,
- 4 lifecycles (with variations)
- 4 security categories
- 190,000 documents
- 18,000 internal users
- 6 system interfaces
- 1 customization

Gilead credited the use of the following guiding principles to the success of the project:

- Simplified, harmonized, and consolidated
- Self-service, easy to use
- Ease of navigation, improved find ability
- Establish document owner accountability
- Used out-of-box as much as possible

As a result of expanding the rollout of QualityDocs across the enterprise, Gilead reported improved approval efficiency, technical and authoring support, and user satisfaction.


## IN BRIEF


Veeva continues to build on its 12-year track record of delivering cloud-based software solutions that enable the life sciences industry to develop and commercialize lifesaving products that improve and extend human life. As a result, Veeva has become a strategic technology partner to more than 775 customers across the globe, ranging from the world's largest pharmaceutical companies to emerging biotechs.

Today, Veeva provides a unified suite of applications that helps life science organizations eliminate silos and drive efficient and effective end-to-end business processes across product development, quality, and manufacturing.

As the cloud-first approach for quality management gains momentum in life sciences, Veeva is moving at high velocity to provide modern, mature, preconfigured out-of-the-box cloud-based Quality Management solutions quickly and effectively. To this end, the company continues to grow the number of quality management offerings, which now includes Vault QMS, Vault Quality Docs, Vault Station Manager and Vault Training.

Discussions with industry executives at the Summit reiterated the need for simplification and standardization, and the shift from traditional, on premises, custom systems to preconfigured OOTB applications built on standard approaches.

My firsthand interactions with industry executives at the Summit highlighted that the implementation of Veeva's Vault Quality platform has improved the efficiency to execute QMS processes, the ability to respond to changing business and regulatory landscape, as well as the ability to achieve seamless collaboration with internal and external partners.

We will continue to monitor and report how Veeva executes its vision to become the operating system for life sciences.

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