



NEWS RELEASE

Veeva Expands Veeva Vault Regulatory Capabilities for Medical Device and Diagnostics

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Modern cloud technology enables device and diagnostics manufacturers to keep pace with changing regulations and growing complexity

BARCELONA, Spain--(BUSINESS WIRE)-- **Veeva Systems** (NYSE:VEEV) today announced new capabilities in **Veeva Vault RIM** for medical devices and diagnostics to manage regulatory documents and processes. Organizations can unify product registrations, health authority correspondence and commitments, and submissions documents on a single cloud platform for one global authoritative source of regulatory information.

Regulatory requirements are rapidly changing, especially with the European MDR going into effect in 2020. Regulatory activities are largely manual, making it difficult to manage the complexity of global submission dossiers and ensure consistency across the end-to-end process.

“Device and diagnostics companies face greater regulatory scrutiny and complexity than ever before,” said Michael Morton, RAC, member of Regulatory Affairs Professional Society (RAPS) board of directors and former vice president of corporate regulatory affairs at Medtronic. “Traditional, manual approaches no longer work. If companies don’t change their model and upgrade to modern technologies, they will struggle to stay compliant and delay getting their products to market.”

Vault RIM now includes new medical device capabilities to streamline processes and drive greater efficiency. Medical device product registration data is modeled to conform with US and EU UDI guidelines. Vault RIM has also expanded to support industry-standard submissions formats such as STED, IMDRF, and 510(k) to improve collaboration and execution across global stakeholders.



Vault RIM applications in the **Veeva Vault Medical Device Suite** include Vault Registrations for simplified planning, tracking, and reporting on product registrations and health authority correspondence; Vault Submissions for easier authoring and submissions assembly; and Vault Submissions Archive for global access to a complete history of submissions.

Several medical device companies, including a top 20, are among the early customers adopting Vault Medical Device RIM applications to eliminate manual handoffs and fragmented processes globally. Veeva's entry into RIM for the medical device market builds upon the company's success in regulatory. More than 180 biopharmaceutical companies use Vault RIM applications for efficient submissions development and greater visibility across end-to-end regulatory processes.

"The addition of RIM to the Veeva Vault Medical Device Suite gives manufacturers tailored applications to manage evolving regulatory requirements and increase collaboration globally," said Annemien Pullen, director of strategy for medical device and diagnostics at Veeva Europe. "Our regulatory applications allow companies to get ahead of these changes and bring their products to market faster."

The Veeva Vault Medical Device Suite includes commercial, clinical, quality, and regulatory applications to provide manufacturers with greater visibility, collaboration, and speed across the product development lifecycle. More than 70 medical device and diagnostics companies, including 8 of the 10 largest, are now using Vault Medical Device Suite applications.

Earlier this month, Veeva announced that **Alcon**, a global medical device company specializing in surgical and vision care products, chose Veeva Vault Clinical Data Management System (CDMS) as its enterprise clinical data management system for electronic data capture (EDC).

Learn how Vault RIM applications in the Veeva Vault Medical Device Suite are helping manufacturers keep pace with new regulations by registering for the **Veeva 2019 R&D Summit** in Philadelphia, 8-10 September, 2019. Also, hear more at other industry events, including the **RAPS Regulatory Convergence** in Philadelphia, 23-24 September, 2019, the **MedTech Conference** in Boston, 23-25 September, 2019, and the **TOPRA Medical Devices Symposium** in Dublin, Ireland, 1-2 October, 2019.

Additional Information

For more information on Veeva Vault Medical Device Suite, visit: veeva.com/eu/MedDevice

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About Veeva Systems

Veeva Systems Inc. is the leader in cloud-based software for the global life sciences industry. Committed to innovation, product excellence, and customer success, Veeva serves more than 775 customers, ranging from the world's largest pharmaceutical and medical device companies to emerging biotechs. Veeva is headquartered in the San Francisco Bay Area, with offices throughout North America, Europe, Asia, and Latin America. For more information, visit veeva.com/eu.

Forward-looking Statements

This release contains forward-looking statements, including the market demand for and acceptance of Veeva's products and services, the results from use of Veeva's products and services, and general business conditions, particularly in the life sciences industry. Any forward-looking statements contained in this press release are based upon Veeva's historical performance and its current plans, estimates, and expectations, and are not a representation that such plans, estimates, or expectations will be achieved. These forward-looking statements represent Veeva's expectations as of the date of this press announcement. Subsequent events may cause these expectations to change, and Veeva disclaims any obligation to update the forward-looking statements in the future. These forward-looking statements are subject to known and unknown risks and uncertainties that may cause actual results to differ materially. Additional risks and uncertainties that could affect Veeva's financial results are included under the captions, "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," in the company's filing on Form 10-Q for the period ended April 30, 2019. This is available on the company's website at veeva.com under the Investors section and on the SEC's website at sec.gov. Further information on potential risks that could affect actual results will be included in other filings Veeva makes with the SEC from time to time.

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