Veeva R&D SUMMIT Europe

**Unify and Connect | 11 - 13 June 2019**
Palau de Congressoss de Catalunya, Barcelona

# Agenda at a Glance

## Tuesday, 11 June

*Agenda Subject to Change*
*12 June 2019*

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|---|---|
| **From 11:00** | **General Registration Opens** |
| **12:00 - 13:30** | **Partner Forum** (H2) *By Invitation Only* |
| **13:00 - 17:00** | **Executive Roundtables** (Clinical: B1, Quality: B2, Regulatory: B3) *By Invitation Only* |
| **18:30 - 20:30** | **Welcome Reception - Veeva Food Market** (Partner Pavilion) |

## Wednesday, 12 June

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| **08:00 - 08:45** | **General Registration** | | | |
| **08:00 - 08:45** | **Breakfast - Meet the Experts** (Partner Pavilion) | | | |
| **08:00 - 08:45** | **Medical Device & Diagnostics Community Breakfast** (K1) | | | |
| **09:00 - 10:40** | **Opening Keynote** | | | |
| **10:40 - 11:10** | **Break - Meet the Experts** (Partner Pavilion) | | | |
| **11:00 - 17:45** | **CDMS Executive Roundtable** (Business Center 1) *By Invitation Only* | | | |
| | **Conference Sessions** | | | |
| **Track** | **Clinical Operations** (H3 & J) | **Quality** (H2) | **Regulatory** (H1) | **Vault Platform** (A) |
| **Theme** | **Optimizing Trial Performance with Unified Clinical** | **Modernizing Quality Management** | **Regulatory Transformation with Unified RIM** | **Vault as an Enterprise Platform** |
| **11:20 - 12:20** | **AstraZeneca: Our Future Reimagined with Unified Clinical**<br>Hear about AstraZeneca's clinical transformation and their vision for 2021. They'll detail their move to a unified suite, success criteria, and the considerations for a streamlined clinical landscape.<br>**Business & IT**<br>Debbie Brook, *Clinical Programme Manager, Global Medicines Development (GMD) Transformation* | **Novo Nordisk A/S: Simplifying Quality Content Management in a Complex World**<br>Novo Nordisk is leveraging Vault QualityDocs to simplify controlled content management across multiple departments and regions, and increase operational efficiencies. Hear how they are moving 50.000 users from a 20 year-old, fragmented, on premise system landscape to a single, modern solution – eliminating IT risks and gaining greater business value.<br>**Business & IT**<br>Sune Mouritzen, *Project Director*<br>Stine Adrian Møller, *Programme Director* | **GSK: An Agile Approach to Global Regulatory Processes**<br>By standardizing on a common RIM platform, GSK is driving global alignment across business units. Learn how they are using an agile approach to unify regulatory processes and generate value throughout their multi-year transformation.<br>**Business & IT**<br>Richard Eddershaw, *Head of Global Regulatory Operations - Pharma* | **Roadmap & Vision: Vault Platform**<br>Join us to explore what's new with Vault Platform and how your organization can leverage these capabilities. We'll look ahead at the roadmap and explore our plans for the next 12-24 months.<br>**Business & IT**<br>Andy Han, *VP Technology* |
| **12:20 - 13:10** | **Lunch - Meet the Experts** (Partner Pavilion) | | | |

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| | Conference Sessions | | | |
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| **13:20 - 14:05** | **GSK: Best Practices for Adopting a Modern eTMF Application**<br>GSK streamlines study processes and drives global synergies across divisions with Vault eTMF. Learn about the drivers and business case approach to leveraging eTMF as a strategic asset within the organization.<br>**Business & IT**<br>Astrid Beriaux, *Head of Trial Master File*<br>Hélène Kermarec, *TMF Business System Owner* | **UCB: Increasing Alignment for More Effective Partnerships**<br>UCB has implemented a single system to manage controlled content internally and also shared with contract manufacturing organizations and other partners. Learn how UCB deployed Vault QualityDocs to over 2000 external users, streamlining collaborative processes and gaining greater control and oversight.<br>**Business & IT**<br>Olivier Melis, *Quality Digital Partner*<br>Michel Van Nyvel, *Digital Partner QA* | **GE Healthcare: Lessons Learned from an End-to-end RIM Implementation**<br>Hear how GE Healthcare adopted Vault Registrations, Vault Submissions, and Vault Submissions Archive. We'll explore critical elements of the planning process, streamlining cross-functional business processes, and how the team has measured success.<br>**Business & IT**<br>James Hendry, *Head of Global Regulatory Operations - Pharma* | **Veeva Session: Vault Platform Security and Access Control Best Practices**<br>Learn how customers leverage Vault security capabilities such as dynamic access control, atomic security, and restricting access by user roles and lifecycle states to enable more control, greater scalability, and easier collaboration across sites and partners.<br>**Business & IT**<br>Kate Wilber, *Director, Product Management* |
| **14:15 - 15:00** | **Idorsia: Unifying Clinical with Vault CTMS and Vault eTMF**<br>Idorsia discusses their learnings after a year using Vault CTMS and Vault eTMF. Hear how they improved trial execution and are leveraging a complete view across trials.<br>**Business & IT**<br>Simone Mechler, *Associate Director, Clinical & Quality Systems* | **Johnson and Johnson: Global Journey to Harmonize Controlled Content Management**<br>Johnson and Johnson's single instance of Vault QualityDocs was initially rapidly adopted in more than 210 locations across 60 countries. As an enterprise-wide standard, the journey now continues with onboarding of the main pharma document management community. Learn how their journey of global harmonization continues with Vault QualityDocs.<br>**Business & IT**<br>Garrett Sayers, *Supply Chain Systems and Solutions Lead EMEA* | **BMS: Planning and Tracking Submission Content**<br>As part of a major transformation initiative, BMS adopted Vault Registrations to improve global visibility into submission content. Hear what advice they have for a smooth deployment and continued success two years post-launch.<br>**Business & IT**<br>Lianne Wolf, *Head of Regulatory Sciences Austria* | **Veeva Session: Scalable and Compliant Release Management**<br>With a scalable and robust release management process, companies can efficiently and effectively evaluate new releases. Learn best practices on managing new Vault releases and ways to validate new capabilities.<br>**IT**<br>Neelam Sidhu, *Manager, Customer Success Manager, Europe*<br>Akos Szottfried, *Practice Manager, Managed Services* |
| **15:00 - 15:30** | **Break - Meet the Experts** (Partner Pavilion) | | | |
| **15:40 - 16:25** | **Veeva Session: Evaluating the Tangible Benefits of Vault Clinical Suite**<br>Based on real-world scenarios and Veeva's value engineering model, learn how to identify areas for process improvement, key performance indicators, and the value realised from streamlining end-to-end clinical trial processes.<br>**Business & IT**<br>Michael Burton, *Director, Value Engineering*<br>James Reilly, *VP, Vault Clinical* | **Veeva Session: Accelerating Implementations with Vault Quality Essentials**<br>Vault Quality Essentials is a new Veeva services offering that delivers streamlined content management and quality processes tailored to the needs of small and medium-sized businesses. Hear how the Vault Quality applications can be deployed in weeks not months leveraging best practices in the Essentials package.<br>**Business & IT**<br>Rob Weisz, *Practice Manager, R&D* | **UCB: Unifying Submission Content Development**<br>UCB streamlined their business processes and unified submission content development across regulatory, clinical, and quality. Join this session to hear more about what challenges they faced, how they leverage Vault in their end-to-end labelling process improvements, and what plans they have for the future.<br>**Business & IT**<br>Mark Morris, *Director, Regulatory Knowledge Management* | **Veeva Session: Best Practices for Vault Lifecycles and Workflows**<br>Vault lifecycles and workflows are critical to supporting regulated processes. Hear case studies on key business challenges and how Vault was configured to solve them. We'll cover objects and documents, and take a first look at the new multi-document workflow.<br>**Business & IT**<br>Kate Wilber, *Director, Product Management*<br>Charles Bonnefoy, *Practice Director* |

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## Wednesday, 12 June

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| | Conference Sessions | | | |
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| **Track** | **Clinical Operations** (H3 & J) | **Quality** (H2) | **Regulatory** (H1) | **Vault Platform** (A) |
| **Theme** | **Optimizing Trial Performance with Unified Clinical** | **Modernizing Quality Management** | **Regulatory Transformation with Unified RIM** | **Vault as an Enterprise Platform** |
| **16:35 - 17:20** | **Accenture: The Beating Heart of a Living Business**<br>Large scale change management is not a core competence for most clinical operations teams. Accenture provides advice from their experience managing global transformation programs.<br>**Business & IT**<br>Andrew Finlayson, *Health Experiences Lead UK&I* | **Panel Discussion: SOPs of the Future - Reimagining Procedural Instructions**<br>Standard operating procedures are critically important to defining processes, establishing quality controls, and sustaining GxP compliance. However, with the complexity of today's working environments traditional multi-page SOPs may not be the most effective approach for managing, delivering, and consuming information. Join our panel discussion as we reimagine SOPs leveraging modern technologies.<br>**Business**<br>Heike Roeder, *VP, Corporate Quality – Head Process & Knowledge Management, Bayer Healthcare A/G*<br>Sophie Wehenkel, *Manager, PwC Germany*<br>Olivier Melis, *Quality Digital Partner, UCB*<br>Sune Mouritzen, *Project Director, Novo Nordisk A/S*<br>Stine Adrian Møller, *Programme Director, Novo Nordisk A/S*<br>Robert Gaertner, *Director Strategy, Vault Quality, Veeva Systems*<br>Garrett Sayers, *Supply Chain Systems and Solutions Lead EMEA, Johnson & Johnson* | **NNIT: Continuous Improvement through Unified RIM**<br>With unified RIM, regulatory teams benefit from greater transparency, improved data quality, and an enhanced user experience. More importantly, they gain a platform that stays current with regulatory requirements and releases new capabilities three times per year. In this session, we'll discuss how to transition to a unified RIM platform and leverage these release cycles to maximize your investment.<br>**Business & IT**<br>Rune Bergendorff, *Director of Life Sciences Advisory*<br>Gaurav Anand, *AVP Life Sciences Application Services* | **Valiance Partners: Applying Agile Principles to Veeva Vault Migrations**<br>A successful migration requires flawless planning and execution. Hear about recent experiences, best practices, and lessons learned from migrating from legacy systems to Veeva Vault.<br>**Business & IT**<br>Paul Crean, *Director – Delivery Services - Europe* |
| **17:30 - 18:15** | **LEO Pharma: Journey Towards a Unified Development Application Platform**<br>Get first-hand insights and recommendations for adopting Vault Development Cloud across R&D. LEO Pharma discusses the journey from ideation, to obtaining executive approvals, and proof of concepts that led to a unified platform programme.<br>**Business & IT**<br>Mika Välilä, *Senior Director, Digital Business Platforms*<br>Anders Helmø Larsen, *Business Relationship Manager* | **Horizon Therapeutics: Streamlining Quality Management in an Outsourced Business Model**<br>With a unified solution to manage quality content and key QMS processes such as deviations and CAPAs, and change control, quality teams at Horizon Therapeutics get a deeper understanding of quality events and how they are related. We will discuss potential insights gained for key quality processes and how to maximize impact to the business.<br>**Business & IT**<br>Jacintha O'Reilly, *Associate Director, Quality Systems* | **Norgine: The Role of RIM Innovation in Regulatory Transformation**<br>Join this session to hear Norgine discuss how RIM innovation has allowed them to streamline processes, better manage resources, and monitor change events by setting effectiveness checks and metrics.<br>**Business**<br>Segren Bernard, *Associate Director, Regulatory Information Management*<br>Jade Knight, *Partner Services Manager* | **Veeva Session: Enabling Data-Driven Decisions with Vault Reporting and Dashboards**<br>Make informed decisions with visibility into operational processes, application usage, and other management KPIs. See how to use reports and dashboards to determine information such as cycle times, overdue processes, and user access. We'll also explore what's coming on the product roadmap.<br>**Business & IT**<br>Kate Wilber, *Director, Product Management*<br>Adam Kohegyi, *Consultant* |
| **18:30 - 23:30** | **Evening Dinner Reception**<br>**Coaches will depart from the Fairmont lobby from 18:30 to 19:00.**<br>**Return coaches to the Fairmont Hotel will depart from 21:30, with the last coach departing at 23:30.** | | | |

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## Agenda at a Glance

## Thursday, 13 June

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| | | | | |
|---|---|---|---|---|
| **08:00 - 08:45** | **Breakfast - Meet the Experts** (Partner Pavilion) | | | |
| **09:00 - 12:00** | **Veeva Product Roadmap** (Clinical Operations: H3 & J, Quality: H2, Regulatory: H1, Vault Platform: A) | | | |
| | **Clinical Operations Roadmap** | **Quality Roadmap** | **Regulatory Roadmap** | **Vault Platform Roadmap** |
| **09:00 - 10:00** | **Unifying Clinical Operations with Veeva Vault**<br>Come and see how Veeva is unifying clinical operations with eTMF, study start-up, and CTMS.<br>■ Business & IT<br>Tom Dekker, *Senior Product Manager*<br>Lauren Garson, *Senior Director, Clinical Strategy* | **Vault QMS**<br>See Vault QMS in action and learn about recent and upcoming enhancements. Hear how Veeva is streamlining quality management and enabling greater insights.<br>■ Business & IT<br>Joby George, *Senior Product Manager, Vault Quality* | **Vault Registrations**<br>See how Vault Registrations can help you manage global complexity through bundling and splitting submissions and a new affiliate home page. Also, learn about recent progress in xEVMPD support as well as our plans for future IDMP capabilities.<br>■ Business & IT<br>Kate Wilber, *Director, Product Management*<br>Uri Reich, *VP Product Management, RIM* | **Roadmap & Vision: Vault Platform**<br>Join us to explore what's new with Vault Platform and how your organization can leverage these capabilities. We'll look ahead at the roadmap and explore our plans for the next 12-24 months.<br>■ Business & IT<br>Andy Han, *VP Technology* |
| **10:00 - 10:50** | **Breakfast - Meet the Experts** (Partner Pavilion) | | | |
| **11:00 - 12:00** | **Clinical Operations - Vault CTMS, Vault eTMF, and Vault Study Startup**<br>Learn about key enhancements for the clinical operations suite of applications including Vault CTMS, Vault eTMF, Vault Study Startup, and the Veeva Clinical Network.<br>■ Business & IT<br>Lauren Garson, *Senior Director, Clinical Strategy*<br>Tom Dekker, *Senior Product Manager*<br>Steve Harper, *VP Product Management* | **Vault QualityDocs, Vault Training, Vault Station Manager**<br>With a unified quality suite that includes blended learning assignments and a tablet application for the manufacturing floor, companies can make compliance easier. We'll review key enhancements from the last year, and take a look at the upcoming roadmap for a preview of what's to come.<br>■ Business & IT<br>Joby George, *Senior Product Manager, Vault Quality* | **Vault Submissions, Vault Submissions Archive, and Vault Submissions Publishing**<br>Learn about key Vault Submissions enhancements such as report-level content plans and advances in document linking and navigation. We'll also preview the Vault Submissions, Vault Submissions Archive, and Vault Submissions Publishing roadmaps including improvements for submission content plans, import and export of submissions, and future support for additional regional eCTD and validation criteria.<br>■ Business & IT<br>Uri Reich, *VP Product Management, RIM* | **Managing Vault Environments with Vault Tools**<br>Understand available tools and best practices for managing Vault environments to save time and reduce risk. Hear about approaches and tools used to streamline implementation, testing, and compliance. We'll also demonstrate features such as sandbox Vaults, datasets in configuration migration and reporting, and explore the roadmap for Vault environment management tools.<br>■ IT<br>Andy Han, *VP Technology*<br>John Tanner, *Senior Product Manager* |
| **12:15 - 13:00** | **Closing Keynote** \| Ice to Dust: Extreme Medicine (H3 & J)<br>Professor Mike Stroud OBE, MD, DSci | | | |
| **13:00 - 14:00** | **Lunch - Meet the Experts** (Partner Pavilion) | | | |
| **13:15 - 16:00** | **Veeva & U Communities** *By Invitation Only* | | | |
| | **Clinical** (H1) | **Quality** (A) | **Regulatory** (H2) | |