Veeva Vault

Vault Mobile – Computer Systems Validation (CSV) Considerations

Executive Summary

This White Paper is designed to provide guidance to any customer who is using the Vault Mobile application in support of GxP activities.

Within this white paper, Veeva will outline the recommended CSV considerations for users of Vault Mobile as stated above.

As both expected and required when deploying systems, services or technology in support of GXP functions, each customer should confer with their internal regulatory, quality and information technology policies, SOP's and other relevant controlled documents.

Vault Mobile Architecture Overview

Computer systems validation applicability is commonly rooted in the system use in the development of regulated products as well as the design or architecture.

Consider the following facts about Vault Mobile and how these could drive into a decision of CSV applicability.

- Vault Mobile is not a separate Vault application family

- Noting that Vault Mobile is not configurable, (i.e. there are no mobile-specific business processes that the customers can build or customize) there should be no additional CSV activities beyond the provided Veeva validation documentation

- End-users access Vault Mobile using the same credentials and Vault account that they use to access Vault through a computer

- The Vault Mobile app uses the same security model as the Vault platform and thus all interactions between the app and the Vault platform are secured by the users' security permissions. Additionally, all network traffic between the app and the Vault platform is securely encrypted

- Vault Mobile development adheres to the same validation process as all other Vault applications. The validation documentation will be published with the other compliance documents

Conclusion

Vault Mobile is not a separate application that processes GXP data. It offers an entry and view into your existing Vault product(s).

A sound risk-based approach, accompanied by a documented regulatory assessment, GxP risk assessment or other document should deem Vault Mobile the lower of risk categories and not require a separate CSV effort.

For any questions please contact:

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About Veeva Systems

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