Life Sciences Case Study

PROJECT OVERVIEW

Business System FDA Readiness Project

Clarkston recently partnered with a client that is a biopharmaceutical company developing, manufacturing and marketing regenerative biologics for multiple sectors of healthcare.

The organization was questioning the "audit ready" status of their business systems in advance of a new product launch. They determined an assessment of their validation documentation for the business systems and associated infrastructure housed at their third-party data center provider was the appropriate action to take.

Clarkston Consulting collaborated with the client to perform an assessment of their validation documentation and retrospective qualification of the business systems and associated infrastructure housed with their third-party data center provider. The client wanted to create an “audit ready” packet of validation documentation to ensure compliance with industry standards. The benefits of this approach provided the client with defensible documentation of computer system validation, traceability back to vendor settings, ability to troubleshoot, ability to regression test, and ability to upgrade.

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CLARKSTON CONSULTING

COMPANY:

Medical Device Company

INDUSTRY:

Life Sciences

EMPLOYEES:

650 +

REVENUE:

$ 325MM

PRIMARY OBJECTIVES:

- Perform an assessment and retrospective Installation Qualification for the business systems and associated infrastructure housed at their third-party data center provider.
  - There are various business systems housed with their third-party data center provider including ERP, Manufacturing, and the company's proprietary application integration platform.
- Create an "audit ready" packet of computer system validation documentation to ensure compliance with industry standards, as well as to receive benefit from appropriately documenting their system implementations.
- Perform a GAMP 5 Assessment including the configuration documentation for all in-scope systems.
  - Original Risk Assessment; Val Plan, URS, FRS, IQ / OQ / PQ, Val Summary; Trace Matrices

RESOLUTION:

- Supporting documentation for systems was reviewed and gaps were identified. Varying levels of documentation were in existence but needed to be improved. Infrastructure Qualification (IQ) documentation needs to be updated to a "audit ready" state.
- Review of the Hosting agreement identified a discrepancy with the Responsibility Matrix which needs to be resolved.
- Review of the Data Center Hosting Provider documentation determined that additional work instructions need to be developed.
- Recommendation to review non-hosted applications for audit readiness starting with the company's Clinical Trial System due to likelihood of scrutiny during BLA submission.

KEY BENEFITS:

- Defensible documentation of FDA Computer System Validation for critical business systems.
- Traceability back to vendor settings
- Ability to troubleshoot
- Ability to regression test
- Ability to upgrade

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