

Application Managed Services (AMS) Provider Infrastructure Qualification Project

Clarkston recently partnered with a biopharmaceutical company developing, manufacturing, and marketing regenerative biologics utilizing human placental allografts for multiple sectors of healthcare. The client has over 45 placental tissue issued and allowed patents on their products and technologies, with over 90 pending applications at this time.

The organization was originally questioning their "audit ready" status of their business systems. 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 validation qualifications of the business systems and associated infrastructure housed at 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 traceability back to vendor settings, ability to troubleshoot, ability to regression test, and ability to upgrade.

Life Sciences Case Study

PROJECT OVERVIEW



INDUSTRY



Biopharma

PRODUCTS AND SERVICES



Regenerative Biologics

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 systems housed at the AMS, including ERP, Manufacturing, and the company's application integration platform (MOM)
- Execute an IQ and create an "audit ready" packet of IQ 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, as varying levels of documentation existed and Infrastructure Qualification (IQ) documentation needed to be updated to a "audit ready" state
- Review of the Hosting agreement identified a discrepancy with the Responsibility Matrix that needs to be resolved
- Review of the Data Center Hosting Provider documentation determined that additional work instructions need to be developed
- Review of non-AMS hosted applications should also be undertaken
- Recommendation to start with company Clinical Trial System (OpenClinica) due to likelihood of scrutiny during BLA submission

KEY BENEFITS

- Traceability back to vendor settings
- Ability to troubleshoot
- Ability to regression test
- Ability to upgrade

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