CASE STUDY GLP Validation Success Through Specialization

Background: After initially outsourcing all of its GLP safety work, a large pharmaceutical company decided to bring GLP studies back "in-house" in order to reduce costs. They planned to begin with a safety pharmacology study that required the GLP validation of their Ponemah software systems used in such studies.

The Challenge. Under ideal circumstances, the pharmaceutical company (client) would have conducted the GLP validation of their Ponemah systems using their own staff. However, they faced some particularly challenging issues:

- They wanted to begin their study within four months
- They had several telemetry systems that needed validation
- They needed in-depth knowledge of the Ponemah system in order to validate quickly

The Solution. The client company commissioned DSI Scientific Services to assist in the GLP validation of their Ponemah systems. To ensure that the client's timeline could be met, DSI's Validation Specialist:

- Scheduled the necessary activities in advance
- Pre-arranged time with the client's staff members to sign-off on procedures
- Spent three weeks on-site guiding the client through the validation process

In addition to the validation of the client's safety pharmacology systems, unforeseen gaps in the compliance processes for other areas, including Toxicology, were discovered, thanks to DSI's expertise.

The Outcome. With DSI's help, the client company was able to complete the GLP validation of their safety pharmacology systems in less than three months from the date of their initial inquiry. With the on-time validation of their complex systems, the client company:

- Was able to begin their study on-time
- Averted several critical issues in other research areas
- Achieved the validation of their systems for about 1/5 of the cost and 1/3 of the time required to validate using internal resources alone.[1]

Because of the success they experienced with this validation, the client company has ordered additional validation services for the validation of another software system.

This case study demonstrates the value of DSI's validation services as a cost and time-saving solution for GLP validation to help researchers complete the process quickly while ensuring the integrity of their most important studies.

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[1]Cambridge Healthtech Associates. (2011) Part One Final Report: Providing Pre-Packaged Validation Services for DSI's Software Suite.