



FDA 21 CFR Part 11 Compliance Support

Assessment and Remediation Leveraging

Client:	Fortune 100 Corporation - (CIO for Large Sub-group of companies)
Project:	FDA 21 CFR Part 11 Assessment and Remediation Leveraging
Industry:	Pharmaceutical
Solution Focus:	Facilitating Regulatory Information Interchange Throughout Organization
Technologies:	WebEx, eRoom, Part 11 Software Solutions, Lab Equipment, Instron Devices/Software, MS Office Products

Executive Summary

A large sub-group (>50 affiliates/facilities worldwide) of a Fortune 100 International Healthcare Company faced large expenditures to comply with FDA 21 CFR Part 11. The Chief Information Officer (CIO) of that sub-group recognized a need to obtain assistance to aid in leveraging solutions to reduce the effort and cost needed to achieve Part 11 compliance.

Business Situation

The CIO contracted with Churchill & Harriman to work on a variety of 21 CFR Part 11-related tasks. Churchill & Harriman's responsibilities have focused on supporting the client's strategic initiative to make Information Management Regulatory Compliance a strategic and competitive advantage, including compliance with 21 CFR Part 11. The main thrust of these activities has been to leverage opportunities that allow the client's franchises to achieve regulatory compliance consistency while minimizing cost, saving calendar time and maintaining quality.

Solution

Churchill & Harriman's work on the project has on the following:

◆ **Information Collection and Dissemination:**

Existing 21 CFR Part 11 assessment and remediation documentation was collected from the different affiliates and analyzed. Based on this analysis numerous successful Tele-Workshops were organized seeking to leverage opportunities within the client's organization. Approximately 220 professionals participated; representing 13 of the client's affiliates where 21 CFR Part 11 is expected to have the strongest impact.

Result: Estimated savings to client of >\$200,000 by avoiding travel time and cost through setting up and conducting meetings with internal personnel and vendors.

◆ **FDA 21 CFR Part 11 Solutions:**

Served as the central contact with 21 CFR Part 11 solution providers to leverage client's efforts in identifying and learning the capabilities of commercially available Part 11 solutions and improving expertise in utilizing these solutions.

Result: Estimated savings of >\$400K in the purchase of these solutions and their installation and maintenance through leveraging procurement. Additional savings of >\$150K in annual maintenance/upgrade costs is also likely.

◆ **Laboratory Information Management Systems (LIMS):**

Inventoried the client's LIMS 21 CFR Part 11 solutions and remaining needs to facilitate leveraging the client's overall LIMS knowledge and expertise.

Result: Estimated savings of >\$250,000 on purchase prices plus >\$40,000/year in annual maintenance costs to the client's affiliates through purchasing agreements with LIMS solution vendors. There are also opportunities to avoid redundant effort within the affiliates and save calendar time.

◆ **Part 11 Collaborative Workspace:**

Developed and maintained a Collaborative Workspace on client's intranet to facilitate information sharing, including the preparation of a 21 CFR Part 11 FAQ's document and researching specific FDA Part 11 Warning Letters to be placed on the Workspace.

Result: Estimated immediate savings of >\$100,000 plus annual savings of >\$60,000 in personnel time, evaluation costs and calendar time as well as producing increased regulatory consistency.

◆ **Training:**

Facilitating the review, selection and/or development of recommended 21 CFR Part 11 and other regulatory training materials. Once selected/developed, the appropriate training materials will be made available to the client's affiliates via the intranet and/or classroom. Previously, each franchise had investigated and arranged its own regulatory training.

Result: Save the client >\$1 Million one-time and \$250K annually by reducing per person 21 CFR Part 11 training costs in addition to personnel and calendar time spent in redundant training course evaluation, development and annual updating.

Conclusion

Churchill & Harriman was able to provide the client with a consistent approach to FDA 21 CFR Part 11 compliance and substantial savings in internal efforts and external purchase costs. In addition, an improved atmosphere for exchanging information was established which should continue to provide cost reductions through future leveraging.