

DaCS™ Spreadsheet Process Improvement / Compliance

Client: Leading Molecular Diagnostic Company
Location: USA



The Business Problem

- Production of sets of result data from automated testing equipment running assays for HIV, Hepatitis B, Hepatitis C, Chlamydia and Gonorrhoea, and Human Papillomavirus (HPV). Resultant data analysed in Microsoft Excel by the users manually.
- Lack of security
- Lack of Traceability
- Excessive amount of data manipulation
- No validation work carried out

How did we help?

- Automation of the data manipulation
- Removed the need for user interaction
- Removed the re-work effort
- Production of Validation Plan
- Production of Validation Summary Report
- Production of URS / FS / DS
- Production of IQ / OQ / PQ
- Execution of IQ / OQ / PQ
- Project Management
- User Training
- Administrator Training
- Installation of DaCS™
- Execution of DaCS™ IQ / OQ / PQ

Project Costs and Savings

Metrics for Manual Process

- Assays performed 10 times a week
- Manual process took 5 hours to complete
- Staff cost estimated at \$350 per day
- 8 hour working day

Project Costs

Year 1 – \$57,000 (includes licenses for DaCS™, installation and training)
Year 2 - \$45,000
Year 3 - \$40,000
Year 4 - \$40,000
Year 5 - \$50,000

Project Benefits

- Go-live with 4 assays
- Each assay comprised a number of spreadsheets
- First Spreadsheets run taking 2 mins (previous time to complete 5 hours)
- All 15 spreadsheets fully validated using proven ABB Validation Package
- Spreadsheets operating under GxP and 21 CFR Part 11 guidelines
- Cost savings over 5 years in excess of \$3 Million
- Increase in profit margin for the sale of the Assays
- Increased user productivity



“It used to take us 5 to 10 hours to analyse the data from the source. Now with the improved process we are able to obtain results from the raw data within minutes.”

Quality Control Supervisor

Cost Savings over 5 years

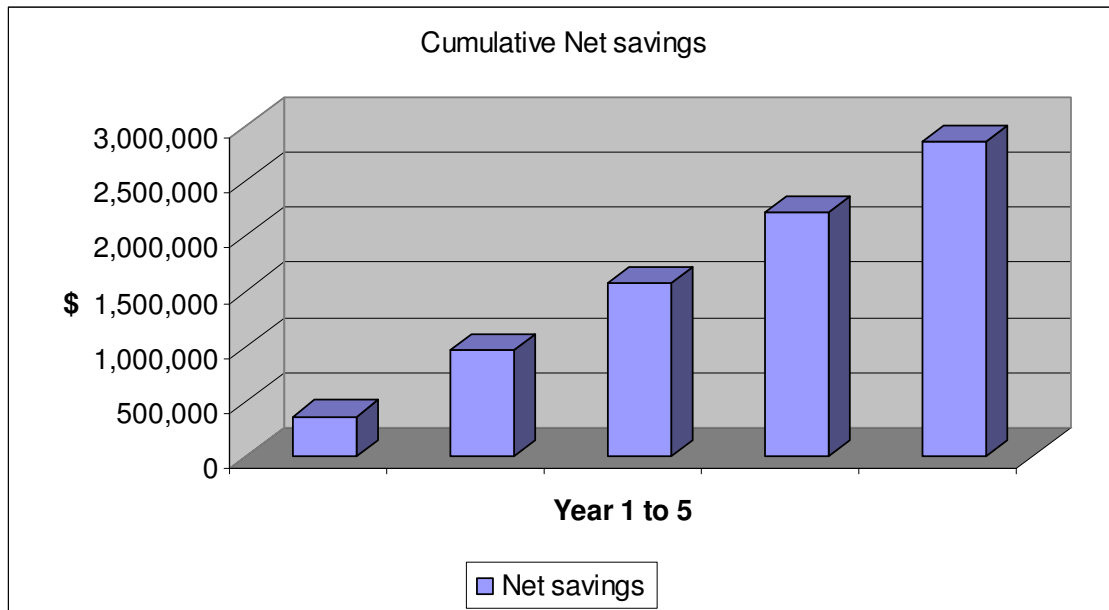


ABB Spreadsheet Validation Experience

ABB are the world leaders in spreadsheet validation. Use their experience to ensure a successful, efficient and scalable validation project.

- Use ABB's pre-developed process, or adapt their proven process into your own quality systems and validation practices.
- Why risk such a critical and resource intensive project to validation teams with little or no experience of validating spreadsheets?
- ABB are the industries key speakers on spreadsheet validation at conferences and providing white papers for journals. ABB present joint sessions with the FDA, Pfizer and Allergan as case studies.
- A scalable process, suitable for individual spreadsheets through to whole company or departmental inventories.
- A scalable consultancy service that can provide a complete turn-key solution with minimal end user input or ABB can provide training on the whole process and leave you to undertake your own project.



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