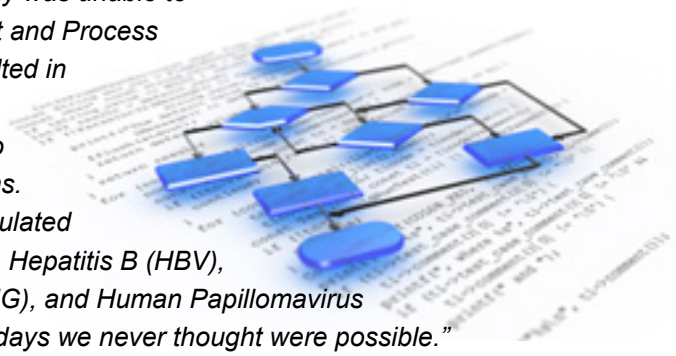
Regulatory Compliance and Validation Services

Spreadsheet Compliance Solution

Spreadsheet Development, Macro Development, Validation Services and DaCS™ Software (via ABB Consulting)

Client:	Molecular Diagnostics Market Leader
Location:	USA
Scope of Work:	Spreadsheet Development

"they provided us with technical expertise our company was unable to provide in the fields of Interfacing, Excel Development and Process Improvement. The recommended improvements resulted in considerable savings in time and completely changed the way we processed our data. We no longer have to transcribe data or cut and paste data between systems. The improvements have been applied to all of our regulated spreadsheets, including critical assays within our HIV, Hepatitis B (HBV), Hepatitis C (HCV), Chlamydia and Gonorrhoea (CT/NG), and Human Papillomavirus (HPV) spreadsheets. We have made savings in man days we never thought were possible."



Senior Technical Analyst

Background

Excel is the universal standard for data handling and data processing and the vast majority of companies use Excel for handling regulatory data. However, in many companies Excel spreadsheets are developed with little consideration of improving production efficiency and even fewer are developed with validation in mind. Spreadsheets have the capability to do much more than simply allow data input and perform a few calculations. A well designed spreadsheet can significantly improve your business throughput, saving operator time and identifying areas were improvements can occur. The key to maximising the spreadsheets performance is to integrate its use into your business processes rather than use it as a calculation or a reporting tool at the end.

Analysing the data from the Molecular Diagnostic machines was taking users up to 5 hours. In addition to this the spreadsheet outputs were being used to report on the validity of the data.

An external inspection by the FDA considered the analysis and the spreadsheets to be out of control. We helped automate the processes for analysis of the data, and secured the data within DaCS™ to provide validated spreadsheets within a secure environment.

The company wanted an automated and fully validated process for the HIV, HCV, HBV, CT/NG and HPV spreadsheets that fitted closely with their current QA and validation practices.

Solution

With each of the assays a full review was undertaken of the business process flow. We considered both business benefit and regulatory compliance an then recommended a balanced solution that provided real benefit and significant cost saving.

The manual process of analysing the data was replaced by validated macro processed within the spreadsheets. For each set of assays data processing time was cut to a fraction of the original workload, and there was no need for data transcription in the new process. The new outputs were modifiable, but only from within the secure and audit trailed DaCS™ environment .

We provided all validation documentation, both for the spreadsheets and macros, and also for the DaCS™ software.

"The key thing for us was to get a performance improvement in our analysis of the data. This we achieved by reducing the time taken from 5 hours to 5 minutes. Before the analysis of the data was very labour intensive and prone to operator errors".

QA/QC Vice President

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Project Benefits

- Full process automation from instrumentation through to final results spreadsheet
- Fully validated spreadsheets and macros removing future compliance concerns
- Full 21 CFR Part 11 compliance for all GxP critical spreadsheets
- An integrated and efficient business process that allowed continued use of Excel.
- Significant resource reduction in data import, data manipulation and data reporting practices
- Project was completed on time and in budget.

"The new process will provide cost savings in excess of $3 million over 5 years. These savings are on top of regulatory benefits now provided by having validated spreadsheets".

Spreadsheet Development Process

We have developed and validated 1000's of spreadsheets from most of the worlds top pharmaceutical companies.

Detailed user requirements understanding allow us to ensure your spreadsheets do what you need and maximise every possibility to improve business functionality.

cSV Compliance is the global leader in spreadsheet validation services for the Life Sciences and regulated industries. The cSV Compliance team supply spreadsheet validation and compliance services worldwide.