

Electronic Approvals and Electronic Signatures (Part 11 Complaint Digital signatures)

A Case Study

The client wanted to have both Electronic Approvals while using their internal electronic forms and Electronic Signatures that were 21 CFR Part 11 compliant when PDF files were created and circulated for signatures. Because the application of Electronic signatures is only required by FDA in specific cases, the client was comfortable with using electronic approvals that do not require a Digital Signature.

The time required to process SOPs, Deviations or Change Requests, even using PDF files, was a time consuming process and limited by where the signer was at the time they were requested to sign. That process required the signer to print, manually sign, scan and email the new file back to the sender. If there was no printer and no scanner then their approval would have to wait.



Dynamic Compliance Solutions, **QMSuite** uses our configurable eForms to enable rapid and simple electronic approvals by authenticating the user and allowing only the defined reviewer to complete that review. Multiple reviewers are a completely normal part of the process. The Document Coordinator simply selects the reviewers and sends the eForm off for Review using the configurable workflow. Each reviewer receives a Task to assure that they complete the review and then the Coordinator is notified when the Task is complete. Reviews can be done serially or in parallel.

Upon completion of the review process the eForm can be converted into a PDF and circulated for a fully compliant Digital Signature if necessary. The configurable workflows enable the Coordinator to select the Approver(s), convert the document to PDF and apply Watermarks, Effective Dates and Signature boxes prior to circulating the final document for Signature.

QMSuite is unique in the way that it makes use of the SharePoint platform and Adobe's Signature capability to enable Compliant solutions to today's Quality Business.

