Eliminating paper-based processes during manufacturing with a fit-for-purpose digital tool

Andrius Ramanauskas
Odyssey Validation Compliance, Ireland, ramanauskasa@odysseyvc.com

Eliminating paper-based processes during manufacturing with a fit-for-purpose digital tool

Author:

Andrius Ramanauskas

Projects and Operations Lead at Odyssey VC

Abstract:

Digital transformation has been a growing priority in the Life Sciences industry, and with Covid it never has been more necessary. This paper presents a technical solution which eliminates paper-based processes during manufacturing with a fit-for-purpose digital tool.

Introduction

If digital transformation has been a growing priority in the Life Sciences industry until now, the past year has made it a necessity. In recent years there has been a strong desire to move away from the heavy reliance on paper and manual processes that can potentially hinder advancement and rapidly move to digitization to support innovation. The challenge for companies working in the Life Sciences industry - or those digital companies wishing to supply and support Life Sciences - pertains to the ability to demonstrate that the integrated digital solution complies with strict regulations such as FDA 21 CFR Part 11 or EMA Annex 11. That challenge has only grown in urgency since the Covid-19 pandemic emphasised just how much our old processes and working models require radical upheaval.

We have all had to adapt in some way. At Odyssey VC, for example, we have implemented a comprehensive digital transformation program internally to better deliver our value proposition to our customers through our web presence and to accelerate the delivery of our professional services in a digital first model.

We have also, by way of contingency planning for the future, modified our working model to a hybrid and remote-first model to ensure that our business processes are robust and scalable for a global delivery strategy. This means we are now better placed to deliver our critical products & services to a global audience.

This is a stark contrast to the very traditional models that our primary target market segment has operated under for a long period of time due to the perceived risk of the critical quality & compliance services we provide.

In a recent assignment Odyssey VC were tasked with executing a key digital objective for one of the world's leading biopharmaceutical companies. This leading biopharmaceutical company wanted to substantially reduce its dependence on paper-based activity with a view to reducing the cycle time of developing and delivering new treatments.

The Problem

Our client's problem statement was this: "We want to benefit from implementing digital solutions to replace our paper-based manual activity. In our search for innovative compliant digital solutions, we have struggled to find tools that can be quickly deployed, easily configured, intuitively maintained and cost-effectively scaled across our global network."

There were numerous industry trends contributing to our client's motivation:

- manual activities which are prone to human error
- the move to computerised systems
- the drive from leading regulatory authorities to deal with legacy systems and paper-based processes and adopt modern systems for advancement. MHRA (Medicines and Healthcare product Regulatory Agency) Data Integrity Guidance states that "continued use of the legacy system may be justified by documented evidence that a compliant solution is being sought".

The ability to analyse and report on data was not possible within our client's existing paper-based process. Our client urgently wanted to resolve this by having the capability to explore their data in a meaningful way which would allow decision-makers to take action to enhance productivity and business gain.

Our client wished to benefit from the reduction in paper-based human error with a "right first time" digital approach, with faster and more accurate responses during audits as well as an overall reduction in manual workload. Our solution to their problem statement was to undertake a services project which would deliver a right-sized, fit-for-purpose, scalable and cost-effective digital tool to eliminate a critical paper-based process during manufacturing.

The Solution

The solution provided a single standardised and validated electronic workflow for the management of critical paper-based processes during manufacturing. The solution was built on one of our partners' Business Process Management (BPM) workflow tools and hosted internally by the client, featuring a web-based user access for the client sites globally.

Odyssey VC's role was to provide a turn-key project solution, where the Odyssey VC project management team took over control of the majority aspects of the project including internal, customer and third party software provider resource management to ensure project delivery on time, on scope and within the allocated budget.

This was a global cross-functional project, delivered utilising remote teams, which took place across the US, India, UK, Ireland and Canada. The team consisted of; Odyssey VC Project Management, Validation and Application Specialists; Client Compliance, Quality, Business, IT, and Senior Management representatives; third party software vendor and partner.

In terms of processes and governance, a hybrid project approach was utilised to deliver this complex GxP software project. The Agile approach was used for the software build and configuration while the waterfall approach was used for the validation part of the project, to ensure end user requirements are met and software is delivered in a compliant manner (See Fig. 1 below).

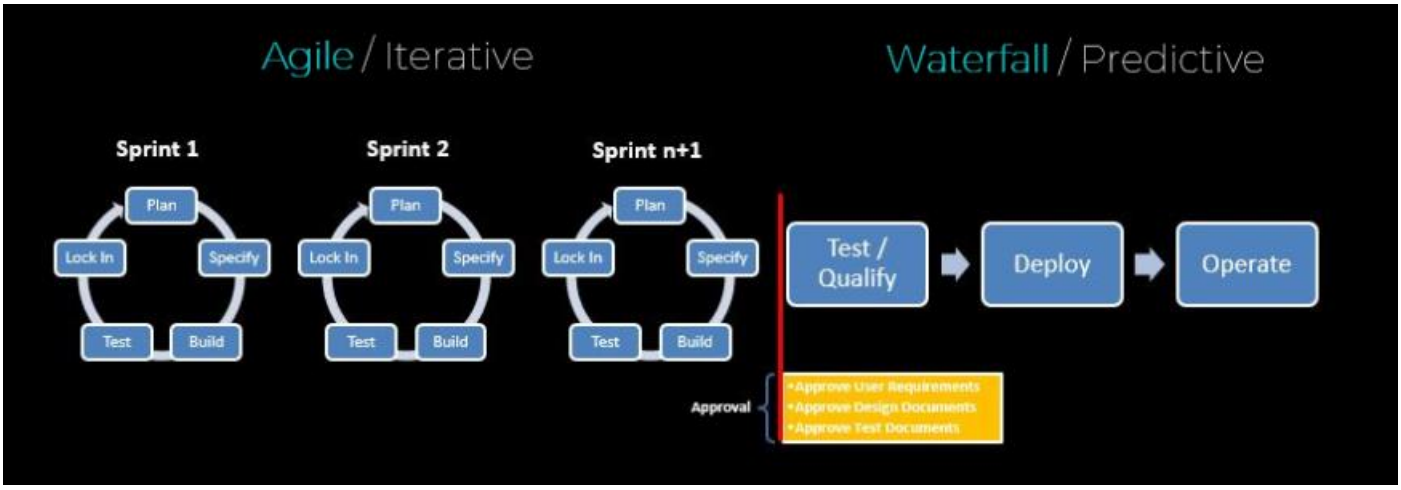

Fig. 1: Project Development Methodologies

The software product was configured and customised by the Odyssey VC team to suit a unique customer use case. It was delivered in a revolutionary way, by validating the process (authoring, reviewing, approving in the production environment) and not the outcome (ready-to-use in the production environment), which allows users to create thousands of electronic logbooks in a production environment in a compliant way, without the additional and costly validation overhead.

The technology used included web-based integrated project management tools (ZOHO projects + ZOHO Sprints) to manage a hybrid of agile + waterfall project management approaches. For collaboration and communication, we utilised MS teams. A new approach was utilised for web-based interactive RAID log, to ensure proactive and interactive

Risk, Issue, Assumption and Decision management, avoiding out-dated and rarely-used (by non-project management team) Excel spreadsheets.

Summary

There were many benefits realised by the customer. These included a greater than 35% reduction in the cost of managing the paper-based process, a substantial reduction in the use of paper, significant reduction in errors associated with poor documentation behaviours, easily retrievable data for trend and metrics reporting, always accessible data via web-based dashboards, reduction in paper review cycles and paper administration, and the identification of further cost reductions through future feature enhancements.

Odyssey VC, est. 2015, is a compliance and digital innovations company committed to accelerating the adoption of compliant digital solutions in the Life Sciences industry. At Odyssey we combine our innate ability to interpret and solve complex digital compliant-related challenges with our innovative thought leadership ability to deliver best-fit compliant digital solutions for our customers. To find out more visit www.odysseyvc.com