VERISTA

AmplifyBio Advances Compliance and Their Digital Strategy

One Step Closer to Realizing Pharma 4.0

CASE STUDY

BLUEmountain QUALITY RESOURCES

Veeva

amplifybio

CLIENT

AmplifyBio is a drug development and commercialization partner for advanced therapies. They provide industry-leading preclinical toxicology, safety, and pharmacology testing, along with expert drug discovery, optimization, characterization, and manufacturing services. This development ecosystem allows clients to harness decades of experience in drug development, safety testing, and manufacturing support services from concept to commercialization, significantly reducing costs and timelines.

PROBLEM STATEMENT

AmplifyBio sought to identify areas of their operation where digitalization of their processes would deliver an ROI in a short amount of time. Digitizing everyday activities like harmonizing regulatory asset management, streamlining calibration and maintenance, and making every spreadsheet 21 CFR Part 11 compliant with a click of a button were attractive areas to optimize. As a result, AmplifyBio wanted to replace their paper-based systems with a single 21 CFR Part 11 compliant electronic system that would eliminate manual touches, and thereby mitigate regulatory, quality, compliance and data integrity risks while improving efficiency.

GOALS

As a startup, AmplifyBio adopted a Pharma 4.0 strategy early on and sought to implement a workflow driven, digital eco-system with zero paper and manual touches. This would significantly reduce human intervention; minimize quality, regulatory and data integrity risk exposure; and improve efficiencies.

STRATEGY

Due to the complexity of the project, AmplifyBio, Verista and Blue Mountain jointly took a holistic strategy and implemented well-established guidelines that aligned with Pharma 4.0 and consisted of four elements – strategy, technology, process and people – all functioning in a well-orchestrated concert, seamlessly with no boundaries.

The team evaluated where AmplifyBio's operations were on the Digital Maturity Model (Figure 1). Having made strides in stages 1 and 2, AmplifyBio was at stage 3, focusing on eliminating silos via the integration between automated and manual processes.

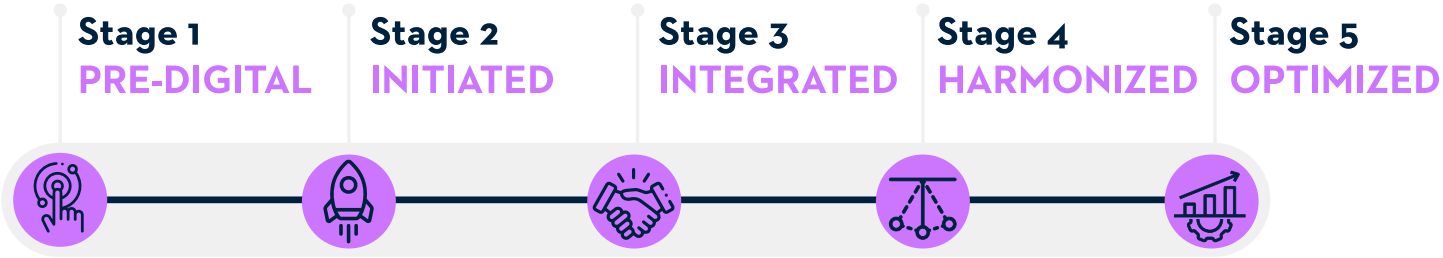

Figure 1: Digital Maturity Model

VISION

- Zero manual touches and paper
- Workflow and data-driven
- Cloud based
- Near zero customization… out-of-the-box wherever possible

DESIRED VALUE

Value to AmplifyBio

- ✓ Minimum on-premise footprint – lower cost
- ✓ Faster time to launch
- ✓ Optimized and digitized process improvements
- ✓ Reduced compliance, regulatory and data integrity risks
- ✓ Paperless and automated Computer System Validation (CSV) and Commissioning, Qualification and Validation (CQV)

VERISTA SERVICES

Verista SMEs reviewed the work plan to launch Blue Mountain RAM at AmplifyBio and suggested a strategy to minimize redundancies and maximize on efficiencies.

The Verista team advocated continuous improvement strategies through the transition from the paper-based to the fully regulated asset management Blue Mountain system.

Working closely with the Blue Mountain team, Verista reviewed job aids, workflows, SOPs, and day-to-day tasks to be carried out by the various departments at AmplifyBio and came up with discrete sets of training guidelines and best practices to be honed and perfected with repetition.

Verista SMEs collaborated with AmplifyBio staff to help with post go-live activities and handle any issues or Blue Mountain RAM questions. Working hand-in-hand with Blue Mountain and AmplifyBio, Verista created knowledge-base like articles which would act as a deep learning reference point.

VALUE DELIVERED TO AMPLIFYBIO

1. New digitized, automated workflow and data driven system, eliminating all manual touches and paper-based activities, thereby minimizing compliance and regulatory risk.
2. Simplified, out-of-the-box, cloud-based solution that doesn't require in-house technology expertise and customizations, yet facilitates effective change management.
3. Optimized sub-optimal processes, increasing efficiency, reducing cycle time, and providing the ability to add functionality for ongoing continuous improvement, thereby allowing faster time to market.
4. Scalability: with the ability to reuse digital templates, processes and SOPs, AmplifyBio only needs to make minimal changes (vs. creating them from scratch) for new use cases – i.e., a validation plan for a piece of equipment.

5. High quality and efficient regulatory compliance: centralized electronic audit trails for all processes, SOPs, documents, equipment validation e.g., calibration, preventative maintenance, updates, etc.
6. Controlled and validated spreadsheets: using eInfoTree and XL Validator helped establish a 21 CFR Part 11 compliant "fence" around existing spreadsheets and the development of new ones with the control and validation process for anything and everything related to access, audit trail and change management on spreadsheets, along with enabling an e-signature-based process.

In addition to implementing Blue Mountain RAM for calibration and maintenance management, AmplifyBio and Verista also moved their eQMS platform to Veeva to reap the benefits of an electronic document management system, greatly reducing quality and compliance risk. The key with this move was to eliminate manual touches and establish a workflow-based seamless system to handle any type of documentation or procedure. By implementing an out-of-the-box solution, AmplifyBio avoided costly and time consuming customization, focusing on configuration instead, so the go-live time to implement and validate the Veeva system was considerably shortened.

A key aspect of digital transformation efforts is the plug and play capabilities as each new system becomes part of the overall organization's system architecture. The Verista team partnered with AmplifyBio SMEs to identify and streamline the interactions between the Blue Mountain RAM and the Veeva QMS environments. This provided clarity on what system would serve what purpose and when it would be needed in the workflows.

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