

# Case Study

## Manufacturing | Pharmaceutical On Key Validation



### Client Background

Biovac is a Public-Private Partnership in the biotechnology and pharmaceutical sector. They manufacture and distribute human biologicals and vaccines. It has manufacturing, packaging and warehousing facilities in Cape Town and warehousing facilities in Johannesburg. Biovac's Cape Town facility currently has just over 1100 assets, inclusive of components for the successful production, in-process testing, labelling, stoppering, packing, visual inspection and goods distribution of vaccines. Therefore, control over the identity, location and status of assets as per EU, FDA, SA, MCC, PIC/S and WHO cGMP regulations for finished pharmaceuticals is what Biovac aims for in its management of assets for the successful manufacturing and distribution of vaccines throughout Africa.

### Key Challenges

- Biovac required a Computer System Validation for their first cloud-based system, which is a SaaS platform hosted by Pragma.
- According to the *FDA Guidance for Computer System Validation Final-Rule*: *"Software Validation is documented evidence that the software specifications conform to the Users needs and intended uses, and that the requirements implemented through software can be consistently fulfilled."*
- Therefore, when replacing the retired system at Biovac for the planning and scheduling of calibration and maintenance activities of assets with the On Key System, a risk-based approach was taken in the Validation of the new On Key Enterprise Asset Management System (EAMS).



### Value Add

While the computer system validation system, On Key EAMS, is still in its Performance Qualification (PQ) stage, its business benefit to Biovac is:

- Real-time planning
- Real-time scheduling
- Real-time management of resources
- Accurate Asset Register
- Asset Care Plans per asset
- Reporting.

The above ensures that maintenance and calibration activities get prioritised and performed correctly and on time. As custom development is possible in the On Key EAM System, the possible system improvements were identified during the execution of the PQ to initiate continuous improvements in the digitisation and accessibility of Maintenance and Calibration activities.

**“ The installation, qualification and validation of the cloud-based Pragma system is a major milestone for Biovac on our journey to transform our business digitally. Pragma will facilitate a fully compliant planned and preventative maintenance program at Biovac's manufacturing site. Congratulations to the entire team on this achievement - Mark MacNaughton, Biovac Chief Operations Officer**

### Pragma Intervention

Biovac chose the Pragma On Key EAMS as a primary business application for its Maintenance Management operations. To maintain their current good practices in the mitigation of data integrity risks, the software had to be validated before implementation and roll out.

The following documentation had to be provided or created by Pragma:

- Functional Design Specification
- Software and Hardware Design Specification
- Pragma Disaster Recovery Plan
- Pragma Business Continuity Plan
- Pragma ICT Biovac Network Structure

The following defines the Biovac Operational Qualification Protocol scope that was prepared, reviewed, executed, collated and approved by relevant Biovac and Pragma stakeholders: Supplier Positive, Negative, Unit and Integration Testing, Data Migration Verification Testing, System Software and Web-Interface Verification, System Security Testing, Data Integrity, Back-Up, Archival, Protection and Retention of Records, Disaster Recovery Plan and System Stress Testing.

### Tools and Technology

- On Key EAMS
- On Key Asset Register Administration
- On Key Maintenance Manager
- Standard and custom SSRS reports
- On Key Analytics
- Standardised Work Planning and Control implemented for improved maintenance management
- Standardised On Key training material for various roles