

Case Study: Maximo & Fingertip help medical tech blue-chip with FDA & HSPA compliance



IBM Maximo & Fingertip
Calibration Module enable
seamless calibrations and
inspections in the field.

Guerbet is a global leader in medical imaging, based in France. They manufacture products and solutions for diagnostic and interventional radiology.

As part of this work, they use IBM Maximo software to manage their assets, helping them to improve productivity, ensure health & safety compliance and high-quality standards are maintained throughout their organisation.

This involves managing their assets safely and efficiently in hazardous environments.

Reducing the paper trail

Guerbet contacted Peacock Engineering because their current version of Maximo was outdated, and they wanted a more supportable version with all the latest features. This additional functionality was required to further improve asset management within their hazardous environments.

They specified that this new solution needed to be:

- Safe to use in hazardous environments
- Able to send 'work orders' when faults detected
- Entirely paperless
- Accessible on a mobile device, on or off-line
- Compliant with industry standards & ATEX regulations
- Easy to use, read & understand for all staff

Peacock Engineering worked with Guerbet to get a clear sense of what they planned to use this new solution for. That way, we were able to make an informed, useful recommendation that maintained their ability to comply with FDA and HPRRA regulations.

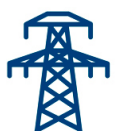
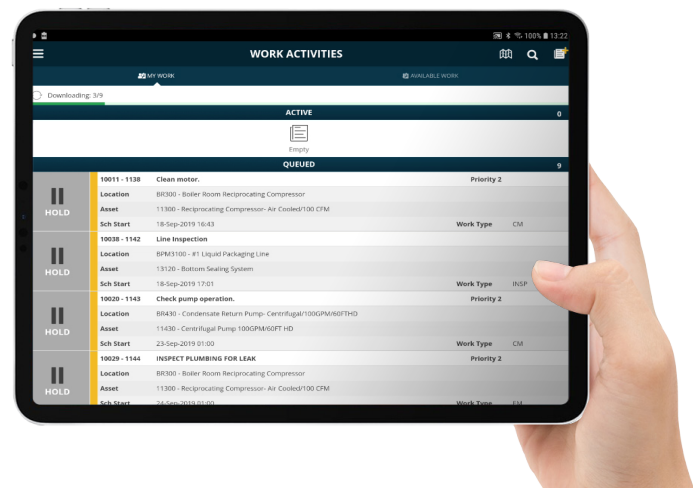
Improving efficiency

The project target was to upgrade to the very latest version of Maximo. As part of this, our Fingertip solution was selected, therefore providing industry-leading benefits that they could not get anywhere else.

We worked with Guerbet to implement this Fingertip solution for Maximo. It is now:

- Installed with mobile forms, ensuring work processes are followed
- Paperless, mobile calibration and work-orders
- Off-line mobile use, allowing safe use in hazardous environments (ATEX, zone 1 & DSEA)
- High data quality ensured
- Easy-to-use, with audit trail

As a result of Fingertip's accessibility, Guerbet technicians can now carry out Instrument Calibrations & Inspections with optimum efficiency. They receive automated updates every time a work order is completed.



Guerbet also decided to deploy the IBM Cognos solution, which enables their team to have real-time, business intelligence (BI) reporting.

Validation

A critical objective of the project was to ensure that self-certification was in complete compliance with all appropriate regulatory requirements (see box at right).

Coordinating go-live across the world

As part of this project, Peacock Engineering worked with many of Guerbet's discipline teams across the world, including India, France, Ireland, USA and the UK. The system was deployed quickly, safely and in compliance with all regulations.

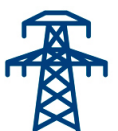
Result: efficient, accurate, compliant and cost-effective
The upgraded and enhanced solution allows Guerbet to maintain its assets more cost-effectively, more efficiently, with a high level of accuracy, ensuring the integrity of its calibration & inspection programmes.

Technical & Validation Specifications

- Major Upgrade from IBM Maximo v7.1 to v7.6
- Fingertip Mobile Solution from Peacock
- Fingertip deployed on ATEX zone 1 handheld devices
- Fingertip Calibration Module was implemented to support Guerbet's complex business processes
- IBM Cognos Analytics business intelligence and reporting tool
- Used Peacock's tried & tested validation process to meet stringent requirements

Software validation to give compliance with:

- FDA Title 21 CFR part 11
- Health Products and Regulatory Authority (HPRA)
- EU Annexe 11
- Irish Health Products Regulatory Authority
- International Society of Pharmaceutical Engineers (ISPE) Good Automated Manufacturing Practice (GAMP 5) regulations, rules and guidance.



What the client said:

Brian Doyle of Hazardous Risk Solutions, who is leading the development of Guerbet's Maximo System and project managing the implementation of Maximo 7.6 and the deployment of Fingertip explains:-

"In my opinion, a critical attribute of any Asset Maintenance Management system is that all asset related information is stored within one single database.

To effectively manage and report on asset performance, it is essential that information is not spread over different independent systems. Unfortunately, too often we see companies who have ended up with multiple databases. They have ATEX compliance information, calibration program data and routine maintenance data spread across different independent systems. It makes planning resources and managing costs much more complicated and leads to inefficiencies.

What sets Fingertip Inspections and Calibrations apart from any existing mobile system is that it is fully integrated into Maximo. This is a key product differentiator as the data is being captured as the maintenance task is being done. This data is immediately available to all system users including those responsible for managing asset integrity.

This fully integrated system enables better management and control of maintenance costs". "Incidentally, Fingertip runs on the intrinsically safe Aegex10™ Windows enabled tablet at Guerbet (Dublin)"

More information:

To find out more about how IBM Maximo and Fingertip EAM solutions can help your organisation, please contact us:

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