



Global MedTech Leader Enhances Asset Management with CompuCal's Digital Platform

CompuCal works with a global leader in the medical technology industry that offers high quality, innovative products and services that create cost-effective solutions to support more than 100 million patients worldwide each year. In the decade since initial integration with CompuCal, the MedTech company has not had a single system outage or breakdown causing work or other delays.

Challenge:

In the highly regulated world of medical device manufacturing, maintaining the accuracy and calibration of measurement instruments is critical. A robust solution is necessary to digitise and streamline the calibration and maintenance processes for its assets, which number over 100,000 globally. A comprehensive system is essential – to provide real-time insights, automate compliance procedures, and generate analytics to optimise the management of inspection and measurement instrumentation.

Solution:

CompuCal's Calibration & Asset Management software was chosen to address the calibration and maintenance of assets. CompuCal's software proved to be a game-changer for manufacturing operations. With over 20 sites already utilising the solution, CompuCal provided a unified platform for managing and digitising all measurement instruments and assets.

Key Benefits:

1. Regulatory Compliance:

CompuCal's software ensures that all calibration and maintenance activities are carried out in accordance with industry and regulatory requirements, including FDA's stringent guidelines for electronic records and signatures (ISO 17025, ISO13485 21CFR part 11, Annex 11 and GAMP 5). A key benefit is the system capacity to address audit requests as they arise, negating the need to print documents and ensuring that the audit process is not delayed.

2. Ease of Multi-System Integration:

CompuCal's cloud-based SaaS/AI infrastructure supports a seamless integration within a complex and dynamic environment which can include wide-ranging Enterprise Resource Planning systems (ERP), Manufacturing Execution System (MES) and Laboratory Information Management Systems (LIMS) as necessary. The effectiveness of the implementation plan and rollout minimises the burden on the manufacturers' resources.

3. Global Enterprise Solution:

Because CompuCal's cloud platform is validated, this greatly reduces the burden on internal validation teams as they roll out the platform to a global manufacturing base.

4. Real-time Insights:

The Enterprise-wide Asset Management SaaS/AI



platform delivers live and up-to-date information on the installed asset base, enabling management to make informed decisions about calibration and inspection intervals. There is also extensive scope to add as much detail for each asset as needed.

5. Business Intelligence Reporting:

CompuCal's BI reporting functionality provides management with a comprehensive overview of asset status across all manufacturing plants, streamlining decision-making processes.

6. Global Standardisation:

The cloud-based SaaS/AI platform ensures that all plants operate at the same high standards, reducing variations and ensuring consistent asset management practices.

7. Risk Mitigation:

By providing a complete digital record with an audit trail, CompuCal's platform minimises the risk of human error and ensures compliance with recordkeeping requirements.

8. Continuous Improvement Analytics and Trends:

CompuCal's analytics capabilities enable the manufacturing team to track asset performance against industry standards, identify key trends, and optimise asset efficiency. The adaptability of its reporting suite, enabling the analysis of recorded data, is an important tool in driving compliance, performance efficiency and cost-down initiatives and in the generation of adjustable, tailored KPIs.

9. Sustainability:

Operating within a digitally transformed, integrated enterprise asset management makes a sustainable, efficient, paperless environment that can scale with manufacturing demand.

10. Cost Effectiveness:

Value for money is one of the greatest benefits to this software.

Conclusion:

Implementation of CompuCal Calibration Management Software brings numerous enterprise-wide benefits to the MedTech company. In such a highly regulated environment, management of inspection and measurement instrumentation is a core contributor to quality metrics and compliance with regulations.

CompuCal works closely with the internal metrology team to define, adapt and deliver a tailored calibration package that meets their operational requirements:

- To consistently manage processes enterprise-wide, both for internal teams and service providers.
- To eliminate inefficiencies that stem from manual processes, siloed data, and inconsistent asset information.

Summary

CompuCal curates a rich data set, insights and analytics allowing easy management of all instrumentation effectively. The software provides a comprehensive view of all assets, standardises asset critical information, and incorporates automated workflows, streamlining processes and improving the overall efficiency and reliability of the company's assets. The digital transformation of the process has boosted sustainability, reduced manual recording of data, the risk of errors and delivered notable value and return on investment. The MedTech company transformed their enterprise asset management environment, by being an early adopter of a cloud - enabled, digital platform.