Transforming your Waters Empower 3 Enterprise into the Digital Lab of the Future

Digital transformation is quickly becoming the new watchword for the 21st Century. Innovative digital technologies are pushing the boundaries and capabilities of the status quo swiftly into the future. Pressures in the marketplace to deliver products and services at an accelerated pace are driving the need for gaining efficiencies at every level of operations within a business. This rings particularly true for the scientific laboratory at a time where the development of vaccines and novel therapies are being fast tracked in the race to combat the global COVID-19 pandemic.

The digital transformation journey of your laboratory starts with the Waters Empower 3 Enterprise at the foundation of your digital lab of the future! Waters Empower 3 software is the leading chromatography data software (CDS) on the market today. Empower 3 effectively manages all of the chromatography needs within the laboratory from designing a customized, turn-key workflow, the automated analysis of results, developing custom report templates, and data management, to meeting all necessary security and compliance requirements. But that is only the tip of the iceberg!

With the need for connectivity across global sites, external business partnerships, along with remote work capabilities, it is imperative not only to remove paper-based processes from your workflow but also to deploy your network of applications within a cloud enterprise.

Cloud Computing in the Digital Lab

The digital lab of the 21st century resides in a virtual environment. With the need for connectivity across global sites, external business partnerships, along with remote work capabilities, it is imperative not only to remove paper-based processes from your workflow but also to deploy your network of applications within a cloud enterprise. Innovative technologies such as artificial intelligence (AI), machine learning (ML) and data science have the ability to further automate and transform processes within the laboratory. AI learns from existing data, identifies patterns in the new data, and offers the ability to make decisions in real time. Combining cloud technology with AI/ML can perform more complex tasks with less centralized hardware.

Empower Cloud combines Empower 3 CDS, with Amazon Web Services (AWS), the world's most secure cloud services platform. This combination offers computing power, database storage, content delivery, and other functionality to help you scale and adjust to business requirements. Empower Cloud for Infrastructure as a Service (IaaS) leverages the internet to procure technology, drive operational efficiency, and provides a low-cost solution for scaling IT capacity by replacing up-front capital costs with low variable costs to replace on premise installations. Empower Cloud is deployed from the AWS Marketplace onto your own Virtual Private Cloud (VPC) within your organization's AWS account. AWS Workspaces are provisioned manually with each

Empower client providing dedicated computing resources giving a desktop-like user connection. LAC/E acquisition stations remain on-premises and physically attached to the instrumentation. Connectivity to on-premise infrastructure is achieved by provisioning a secured, high-speed circuit (AWS Direct Connect) from your location into your organization's VPC. Empower Cloud provides global companies with the speed and agility to bring all their locations online, allowing them to focus on science and not the infrastructure.

Waters Chromatography Data Systems for LC and LC-MS enable streamlined workflows for end-to-end compliance from sample to result. Software assisted Quality by Design algorithms and attribute-based analysis for biopharmaceuticals accelerate the drug development process by leveraging advanced analytics and artificial intelligence modalities. With the exponentially increasing volume and complexity of chromatographic data generated in the laboratory, the need for employing cutting edge technologies in the realm of AI and ML is a critical component for developing your digital lab of the future. The connectivity of the Waters Empower Cloud computing environment enables unlimited access to transformative technologies such AI and ML applications within your virtual workflow.

Disaster Recovery and Business Continuity Planning

With all of this digital technology at our fingertips, cybersecurity considerations must be in lock-step as you proceed down the path of your digital transformation journey. Cyber-breaches, such as the recent "NotPetya" attack on a global pharmaceutical company have resulted in critical disruptions including the ceasing of all business operations for long periods of time, ultimately affecting supply chains and resulting in nearly a billion dollars in losses[1]. In the wake of these catastrophic events, cybersecurity is emerging as one of the top areas of concern for many pharmaceutical companies and research laboratories which are heavily investing in cyber security measures within their informatics roadmap.

Having a disaster recovery plan in place is critical in preparing your laboratory to continue operations in the event of a cyberattack. Water Empower Business Continuity (BC) LAC/E with SecureSync™ provides the protection needed to allow you to continue operating your Empower system offline, completely disconnected from the for as long as the disruption lasts.

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Benefits of Empower BC LAC/E with SecureSync™

- **Prepare proactively to minimize disruption**
- **Controlled switching with one device and full traceability**
- **Synchronize relevant data from Empower Enterprise to the bench in advance**
- **Continue your lab operations until connectivity is restored**

While Empower BC LAC/E offers uninterrupted system access in the occurrence of a cyber-event, additional protection for your operations can be achieved through the use of Oracle Data Guard within the Empower Enterprise. The structure of the Data Guard setup maintains standby database copies of the production database. These standby databases can be located at remote sites or the same site as the production data center. If the production database becomes unavailable because of a planned or an unplanned outage, Data Guard can switch any standby database to the production role, thereby minimizing the downtime associated with the outage, and preventing any data loss or system inaccessibility.
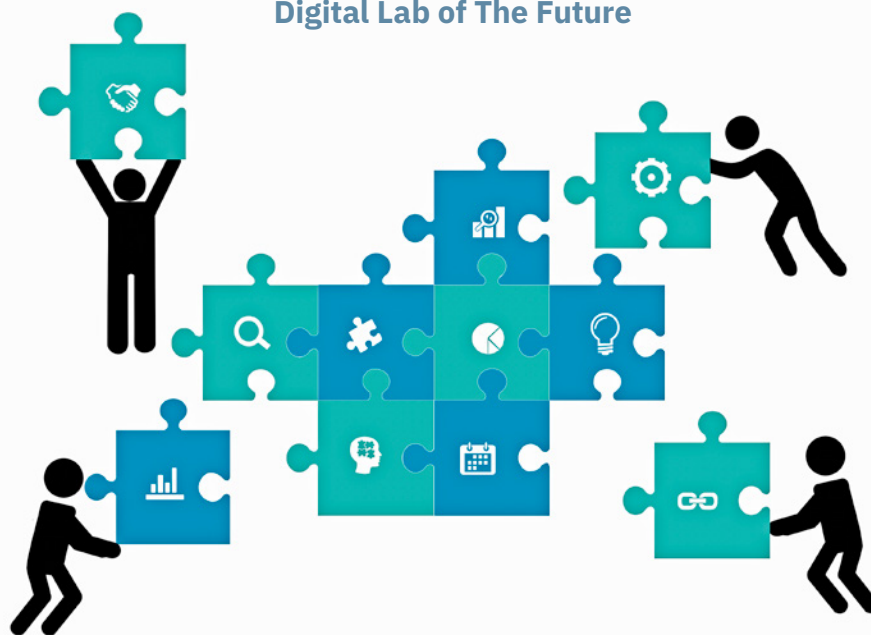
ASTRIX TECHNOLOGY GROUP
Trusted informatics partner can provide you with the scientific expertise and demonstrated industry best practices to guide you through every step on your way to achieving a successful transformation to your digital lab of the future

AUTOMATED CALCULATIONS
Implementing Custom Fields and All-In-One Reports allows more data to be managed and reviewed electronically, which will provide a number of important quality and productivity benefits for your organization

Waters Empower 3 Digital Lab of The Future

BUSINESS CONTINUITY
High availability protection for your operations can be achieved through the use of Oracle Data Guard.

Additionally, with the implementation of BC LAC/E, you have continued operations while disconnected from the network during prolonged outages and have automated data synchronization to server following disaster recovery

EMPOWER CLOUD
Secured and Scalable Cloud deployed Empower 3 CDS with AWS hosting

Optimizing your Waters Empower 3 Enterprise

The Digital Lab of the Future requires the need to drive efficiencies within all of the processes within the laboratory. The removal of manual processes, pre-optimized workflows, connectivity between systems, and the speed of access to data and results are essential to maximizing the efficiency of your laboratory informatics platform.

Multi-vendor instrument support:

Empower connects to a multitude of third-party instruments giving the ability to control a wide range of systems without requiring multiple CDS and providing more possibilities for the lab expansion. Waters partners collaboratively with a variety of analytical instrumentation suppliers to provide multi-vendor instrument control in Empower to enable business flexibility and productivity within your laboratory.

Empower inventory viewer:

This comprehensive, automatic inventory mapping tool for your Empower Enterprise allows you to obtain fast and accurate visibility to critical information such as driver versions, firmware versions, serial numbers, configuration, and status for each system. Empower Inventory Viewer allows you to view a visual map of the systems and modules that are installed on your Empower Enterprise so that a clear overview can be displayed when planning upgrades or changes to your Empower environment.

Custom Fields and Empower Reporting ability:

Custom Fields are a combination of input fields and calculations that allow the user to input minimal data and receive an output of a calculated value utilizing Empower database field data. Manually transcribing the data from Empower 3 to an external system can present huge risks from a data integrity perspective.

Waters Empower 3 has a number of on board tools that address compliance and data integrity concerns such as electronic signatures and audit trails to maximize their results and automate the data review process. Implementing Custom Fields and All-In-One Reports allows more data to be managed and reviewed electronically, which will provide a number of important benefits for your organization:

- **QUALITY CONTROL** – significant reduction in transcription errors, investigations and data integrity observations related to Empower.

- **SAVED TIME** – reduction in time spent on review cycle, report creation, user training, test method orientation, etc.

- **OPERATIONAL EFFICIENCY** – increases in the number of products tested and reported per analyst in Empower, along with number of tested products reviewed by reviewer in Empower.

Result Audit Viewer:

Empower 3 Results Audit Viewer allows you to review the audit trail information associated with a Result Set by bringing the complete information history into one window rather than going to all of the individual audit trail windows. When reviewing the audit trail information associated with a Result Set, it looks at a number of things including the Project Audit Trail, the Processing Method Audit Trail, and the Sample Set Audit Trail. Having all aspects of the Audit Trail information in a single comprehensive view can really simplify compliance requirements for the GxP Laboratory.

Create the Right Team to Support your Digital Transformation Journey

For a digital transformation initiative to succeed, it requires a team with subject matter, IT and business analysis expertise, along with expertise in laboratory informatics systems. It also requires active support by a visionary executive leadership team that works to build a corporate culture that will welcome significant organizational change. In addition, the leadership team needs to clearly communicate business goals and empower those within the organization in key transformational roles, while embracing outside expertise when necessary.

Astrix's Services for Waters Empower 3 Include:

- Assessment of existing architecture and design of the future system architectural model

- System installation and upgrades of the network infrastructure

- Development and Validation of Custom Fields and Reports

- Data Integrity Assessments

- Development of SOP procedures and Computer System Validation deliverables for regulated environments

- Business Continuity Plan

- Integrations with external systems such as LIMS and NuGenesis

A third-party laboratory informatics consultant can be an invaluable partner in your digital transformation journey. A qualified consultant will have expertise with hundreds of different informatics systems and experience facilitating digital transformation with many different organizations. This will allow them to understand what is possible for your organization and thus provide the guidance that will help you realize the full potential of your transformation initiative.

Conclusion

With the rapid acceleration of technological advancements at the forefront of the competitive landscape on today's scientific laboratory, the need to adopt a transformative approach in your laboratory's operations is essential to achieve the digital lab of the future. The ever-increasing need for on-demand data, scalable scientific computing solutions, secure cloud-based connectivity and automation of routine processes are driving the search for innovative solutions across the laboratory computing enterprise options available in the market.

Waters Empower 3 Chromatography Data System provides the foundation for the digital transformation of your laboratory with best-in-class tools for all your chromatography needs. The Empower 3 Enterprise provides a powerful suite of solutions for instrument control, scientific data management, secure cloud computing and compliance management to streamline analytical processes across your entire informatics workflow aligned with modern data integrity requirements.

A system with this many features and possibilities for implementation can impose complex and overwhelming challenges that might create a significant burden for IT and laboratory personnel during the implementation process. Laboratories can be at varying stages of their digital transformation journey, and it is important to leverage a trusted informatics partner from the initial planning stages through progressing scale up efforts. A reliable informatics partner can help you get the most out of these systems, and additionally provide you with scientific knowledge and proven industry best practices to guide you every step of the way to achieve a successful transformation in your digital lab of the future.

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[1] D. Voreacos, et al., "Merck Cyberattack's $1.3 Billion Question: Was It an Act of War?," Bloomberg Markets, www.bloomberg.com/news/features/2019-12-03/merck-cyberattack-s-1-3-billion-question-was-it-an-act-of-war, accessed Aug. 31, 2020

About Astrix:

Astrix Technology Group has been helping scientific organizations implement and integrate new informatics systems in the laboratory since 1995. Our experienced team of expert informatics consultants bring together technical, strategic, regulatory and content knowledge to provide the most effective solutions to problems faced by scientific organizations. Our domain experts have helped dozens of companies effectively navigate their digital transformation journey. With our proven, comprehensive methodology (the Astrix Approach™), we help organizations turn data into knowledge, increase organizational efficiency, improve quality and facilitate regulatory compliance. If you have any questions about Astrix Technology Group services, or if you would like to have an initial consultation with an Astrix informatics expert to explore how to optimize your digital transformation strategy, don't hesitate to visit our website (www.astrixinc.com) and contact us.