QAD

IN VITRO DIAGNOSTICS

TODAY'S CHALLENGES

In Vitro Diagnostic (IVD) medical device manufacturers and suppliers are facing significant disruptions to their business model, especially in the areas of technology and reimbursements.

The majority of new IVD products are heavily regulated and subject to a multi-step approval process that may slow or stall funding from investors.

Adoption and reimbursement risks for new IVD products are high. Consumers may not be reimbursed by their health insurance plans for a new product, reducing the likelihood of mass adoption.

With growing pressure for cost containment, proving the clinical utility of an IVD product is critical to its acceptance by clinicians and healthcare providers.

FUTURE TRENDS

When planning for future products, IVD manufacturers will need to consider factors such as worldwide health issues, testing methods, technology, delivery methods, reimbursement requirements and specialization.

There will be an increased adoption of "Anything-as-a-Service" with a shift from selling the device to selling diagnostic tests as a service.

Wearable devices and other emerging technologies will increase the availability of clinical diagnostic data. IVD manufacturers will need to determine the best methods for capturing and utilizing this valuable data and patient information.

As data becomes more readily available, patients will continue to be more informed, leading to a boom in personalized medicine and direct-to-customer distribution and ordering.

IMPERATIVES FOR KEY DECISION MAKERS

Successful COOs will bring IoT and other advanced technologies to the shop floor and warehousing operations to improve quality, deliver connected products and services and improve IT/OT integration.

CEOs need to ensure their company is agile enough to execute rapidly on key decisions, balancing cost, innovation, risk and investment.

CIOs will need to move from old, unsustainable, insecure systems to agile solutions, so their organization can rapidly adapt to their company's changing business model and to the turbulent external environment.

The VP of Purchasing must become more strategic, moving from price-centricity to viewing and managing the complete supply chain by improving visibility and applying best practices.

The VP of Regulatory and Quality must be constantly aware of new industry regulatory and compliance requirements and be able to quickly address them.

HOW CAN QAD HELP?

QAD has been a trusted solution partner to companies in the in vitro diagnostic device Industry for decades. We actively participate in global industry associations, like AdvaMed, to develop standards for quality, the supply chain and corporate responsibility. QAD incorporates the resulting practices into its solutions.

QAD Adaptive ERP provides a comprehensive yet flexible solution for global manufacturers, supporting the unique needs of each manufacturer and offering excellent fit out of the box. Our cloud-based, FDA-qualified environment reduces the effort required for software validation and 21 CFR Part 11 and Annex 11 compliance. It supports traceability, ISO 13485, FDA QSR and EU MDR to support ever-evolving compliance requirements.

QAD Enterprise Platform, the application platform for QAD Adaptive ERP, simplifies the need to be flexible in a rapidly changing industry. It also makes it easy to extend ERP through low/no code techniques which limit the need for costly and difficult to maintain customizations.

QAD is known for fast and dependable implementations in the QAD Cloud and around-the-clock global support.

QAD offers an integrated application portfolio, **QAD Adaptive Applications**, to support the distinct planning and manufacturing needs of IVD suppliers. Solution examples include **quality management,** warehousing, demand and supply chain planning and shop floor visibility.

For more information on how **QAD Adaptive ERP** can help your company, please contact QAD at +1-805-566-6100 or email info@qad.com.

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