INSTRUMENT OF SUCCESS

Leading biotech company works with Dell ISG to launch medical device with best-in-class user interface



The origins of biotechnology can be traced as far back as 500BC, when the Chinese used soybeans as an antibiotic. Today, it's a US\$30 billion a year industry with 160 drugs and vaccines to its name. Research-intensive and innovative, the life sciences are also tightly regulated.

SOLUTIONS:

- STANDARDISATION
- INDUSTRY SOLUTIONS GROUP



CUSTOMER PROFILE

COMPANY: Trinity Biotech INDUSTRY: Pharmaceutical COUNTRY: Ireland

FOUNDED: 1992

EMPLOYEES: approximately 700 **WEBSITE:** www.trinitybiotech.com

CHALLENGE

Trinity Biotech wanted to launch a new haemostasis analyser. This required standardised hardware from a solution provider who understood the challenges of regulatory compliance.

SOLUTION

Dell OEM Industry Solutions Group (ISG) provided a desktop to support Trinity's custom-built software. As a Trinity approved supplier, Dell simplified the compliance process. Custom Factory Integration ensures a consistent build, while phased delivery helps minimise inventory costs.

BENEFITS

- Optimal desktop configuration defined in eight weeks
- Regulatory insight speeds time to market
- Approved vendor status cuts length and cost of approval process
- Local Dell consultants work with German manufacturing site
- Consistent configuration maintains compliance
 Global support covers global customer
- base
- Phased delivery of units minimises inventory costs
- Change management protects business continuity



Trinity Biotech is a global leader in the development, manufacture and marketing of diagnostic devices for hospitals and laboratories. It also provides raw materials to the life sciences industry. With over 700 staff, Trinity is headquartered in Ireland and also operates in the US, Sweden and Germany. It markets more than 500 products to customers in 80 countries and is listed on the NASDAQ Global Select Market.

Medical devices undergo rigorous testing to gain approval from regulatory bodies such as the US Food and Drug Administration (FDA) and Underwriters Laboratories (UL). This can take several months, so it influences time-to-market — which, in turn, affects return on investment. Non-approval may remove or delay the profitability of many months' research and development. Even the slightest change to a component means re-approval of the entire device. And for a global player like Trinity, regional variations in requirements are a consideration too.

The aim behind Trinity's Destiny Max – a highthroughput haemostasis analyser – was to improve the user-friendliness, evolve existing functionalities, increase the instrument sampling robustness and improve the throughput of the existing 'predicate' device. That is, an instrument with FDA-approval.

The predicate was a composite hardware/ software device. But for the Destiny Max, the company wanted a standalone desktop and a touch-screen monitor, capable of supporting a new state-of-the-art user interface.

All components were subject to approval and had to be identical. Emmet McGauran, instrument development team, Trinity Biotech, says: "The success and longevity of the Destiny Max depended on us working with an industrial solutions supplier – a partner who understood the demands of regulatory compliance." That partner had to guarantee uniform hardware throughout the product lifecycle, with identical images and configurations.



"WITH DELL'S INDUSTRY INSIGHT, DEFT APPROACH TO HARDWARE CONFIGURATION AND CHANGE-MANAGEMENT EXPERTISE, WE'VE DELIVERED A PRODUCT THAT REINFORCES OUR MARKET POSITION AND OUR REPUTATION AS AN INNOVATOR."

Emmet McGauran, instrument development team, Trinity Biotech

HOW IT WORKS

HARDWARE

- Dell[™] OptiPlex[™] 755 desktop
- Elo Accutouch 1715L Touchscreen

SERVICES

- Dell OEM Industry Solutions Group (ISG)
- Custom Factory Integration (CFI)
- Dell ProSupport for IT
 - Mission Critical
 - Fast Track Dispatch

Trinity also needed keyboards in a number of languages to support global distribution, multiple USB ports and a large hard drive for archiving data into local networks at customer sites

McGauran knew from past experience that the Dell OEM Industry Solutions Group (ISG) could be relied on to comply with the intricate requirements set by the regulators. ISG is a dedicated sales & support division of Dell that works solely with European customers that are Original Equipment Manufacturers (OEMs). It provides dedicated support for customers that bundle PCs, servers or peripherals as part of larger solution based on hardware from one or more suppliers.

Additionally, Dell is a pre-approved vendor. "I'd worked with Dell ISG consultants in previous roles and found them receptive to the needs of the healthcare industry. ISG consultants demonstrate a level of regulatory insight I've not seen in other solution providers."

ISG consultants recommended the Dell™
OptiPlex™ 755 desktop – a robust, mainstream
high specification PC able to support Trinity's
custom-built software, along with an Elo
TouchSystems 1000 screen and keyboards
in the required languages. An Ethernet
connection links the Dell OptiPlex with the
instrument. Custom Factory Integration
guarantees a consistent hardware and
software build for each desktop, preinstalled at
the Dell factory using a single master image.

McGauran valued Dell's ability to provide an off-the-shelf commercial desktop with individual components chosen to provide maximum long-term uniformity.



"AS A GLOBAL COMPANY, WE REALLY APPRECIATE DELL'S WORLDWIDE PRESENCE. BECAUSE OUR STAFF IN GERMANY WORK DIRECTLY WITH LOCAL GERMAN-SPEAKING INDUSTRY SOLUTIONS GROUP CONSULTANTS, WE'VE AVOIDED LANGUAGE BARRIERS AND TIME-CONSUMING, COMPLICATED CHAINS OF COMMUNICATION."

Emmet McGauran, instrument development team, Trinity Biotech

"Dell quickly matched our needs with the right desktop, and then helped us define the right level of customisation for our product. In just eight weeks, we had the specification defined down to the last detail."

Crucially, Dell ISG also provided a longterm roadmap that will help Trinity manage re-approval when the OptiPlex 755 becomes obsolete. Staff at Trinity's manufacturing site in Germany procure directly from local Dell contacts. This saves time and ensures that stock levels are aligned with demand, while phased delivery of units minimises inventory

NEW MEDICAL DEVICE LAUNCHED SUCCESSFULLY WITH DELL HARDWARE

The Destiny Max was successfully released onto the European market on schedule. Sales to Japan, Italy and Ireland were agreed within a month.

The launch sees Trinity breaking into the highthroughput segment of the laboratory-based haemostasis market. This represents around 50 per cent of the overall market, so the move has boosted Trinity's competitive edge.

What's more, the combined performance of Trinity software and Dell hardware offers customers a best-in-class graphical user interface with touch-screen technology. In this way, the project has cemented Trinity's reputation as an expert integrator of software and hardware.

"With Dell's industry insight, deft approach to hardware configuration and change-management expertise, we've delivered a product that reinforces our market position and our reputation as an innovator," says McGauran.

SIMPLIFIED COMPLIANCE SPEEDS TIME-TO-MARKET

Trinity reduced the time and costs associated with compliance thanks to Dell's pre-approved status. "Our Dell hardware arrived pre-approved, so all we had to do was run tests inhouse to ensure that it would still be compliant when combined with our technology," says McGauran.

Standardised technology is difficult for companies to acquire using commercial distribution routes, but with Dell ISG, Trinity has consistency guaranteed. "To meet FDA, UL and CE conformity, we have to use standardised hardware," McGauran says. "Dell ISG understands that even the slightest divergence from the initial configuration we agreed on would cost us time and money.

Dell Custom Factory Integration (CFI) ensures that each machine arrives configured to Trinity's specifications. Dell holds a customised master image and uploads it onto each desktop before delivery. There are no deviations, and compliance is maintained.

"Every desktop is identical and arrives preconfigured and imaged. All we have to do is load our custom software. That saves us time, and gives us peace of mind that we're complying with regulations and delivering a consistent PC configuration for use with the Destiny Max Instrument," McGauran explains.

CHANGE MANAGEMENT PROTECTS BUSINESS CONTINUITY

Dell ISG's lifecycle management expertise will help Trinity to stay compliant as regulations and hardware change. At the beginning of the project, ISG consultants gave Trinity a long-term roadmap to help manage obsolescence of the Dell OptiPlex 755 desktop.

In particular, ISG consultants set 150 OptiPlex 755 desktops aside to help McGauran and his team manage the transition to the OptiPlex 770. "Dell Industry Solutions Group told us exactly when the OptiPlex 755 would become obsolete and reserved 150 machines for us. This means we have time to validate the next model — without worrying about a gap in production and possible revenue loss. This is a huge benefit to us."

EXPERT LOGISTICS SUPPORT SUPPLY CHAIN MANAGEMENT AND INVENTORY CONTROL

Maintaining a tight rein on inventory levels is crucial for Trinity. McGauran and his team must ensure that stock levels match demand and reflect the sales cycle of the Destiny Max. Dell responded by organising phased delivery of the OptiPlex desktop and touch-screen monitor to Trinity's manufacturing plant in Germany, where the devices are assembled "Dell custom-builds and ships our hardware as it's needed," McGauran comments. "This flexibility helps us manage our supply chain effectively and reduces our instrumentation manufacturing inventory by around 10%. We buy according to our sales forecasts, rather than holding large volumes of stock."

Regular contact means that the two companies work together to manage the supply chain. Says McGauran: "Our Dell ISG account manager is proactive. He's in touch regularly to check that our sales figures match our forecasts and our inventory levels are correct."

In addition, Trinity staff at the manufacturing plant liaise directly with local ISG staff. "As a global company, we really appreciate Dell's worldwide presence," says McGauran. "Because our staff in Germany work directly with local German-speaking Industry Solutions Group consultants, we've avoided language

barriers and time-consuming, complicated chains of communication."

GLOBAL SUPPORT ENSURES CONSISTENT CUSTOMER EXPERIENCE

Dell ISG can support Trinity's products no matter where they are sold. With standardised global support and global warranties, the company knows that all its customers will receive the same quality hardware and service.

Trinity opted for the Fast Track Dispatch option within Dell ProSupport for IT. Dell ISG provided trained and certified Trinity's technicians to help them resolve customer queries efficiently and also to skip basic troubleshooting processes when escalating issues to Dell. Trinity can also use online dispatch to send a Dell service technician directly to the customer, relying on the standardised cover provided by Dell ProSupport for IT. This quarantees a four-hour on-site response in 150 countries. "We don't have to worry about the quality and endurance of Dell hardware - we can deliver our product to customers with confidence. But the reassurance of support is always important too, particularly in healthcare. With Dell ProSupport for IT, we know we can get fast expert support to our customers, wherever they are."

DEVISING THE FUTURE

McGauran and his colleagues are considering Dell as a standard provider for all medical devices lines. McGauran says: "Dell Industry Solutions Group has a thorough appreciation of industry requirements. We have standardised global hardware and services, and a partner that supports innovation with outstanding logistical and regulatory expertise."

For more information on this case study or to read additional case studies, go to www.dell.com/casestudies and www.dell.ie

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