

Kallik's AMS360 Helps Medical Devices Manufacturers Meet Looming UDI Compliance

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- Labelling content & Artwork management leader Kallik's AMS360™ software (<http://www.kallik.com/>) is proving vital for medical devices firms who need to meet critical compliance directives –

Tamworth, UK April 14, 2014 – Labelling Content & Artwork management leader Kallik has announced it is offering an advanced labelling and packaging solution to help organisations in the medical devices sector meet a 'perfect storm' of compliance changes.

The news is significant as much of the market is believed to be lagging in preparing for regulatory changes, including the US Food and Drug Administration's imminent unique device identifier (UDI) product identification standard. To be included on product labels, UDI will make individual items easier to trace as they move through the supply chain and beyond. The FDA requires UDI compliance in the US by as soon as September 2014, with Europe to follow within the next 2-3 years, then China and the rest of the world.

The solution has been shown to help firms get set for UDI – as well as improve internal systems, help customers meet their regulatory requirements and improve profitability at blue chip sector customers such as Colloplast, BSN, and many others.

Apart from UDI, 2014 is going to be dominated by pressure from buyers for higher quality at lower costs, increased M&A/consolidation activity, accompanied by more and more need for internationalised/global products and marketing solutions – all of which means an integrated approach to Labelling and Artwork Management is critical.

Medical device manufacturers will benefit from a robust, transparent process in place to deal with these pressures, say experts.

For Neil Gleghorn, Chief Executive Officer of Kallik, "Rather than thinking of UDI labelling as a challenge, think of it as an opportunity to improve all your labelling processes.

"By centralising and automating the way all forms of product packaging, labelling and customer documentation gets created, approved, delivered and managed, we are helping customers consistently deliver significant benefits of cost, time and risk reductions.

"It also increases visibility, ensures labelling accuracy – while also making it much easier and faster to make changes to labelling output as requirements change."

About Kallik

Kallik is a global provider of software solutions that simplify complex artwork management, generation and approval challenges for regulated industries.

Kallik's systems help these organisations to reduce the risk of product recall, guarantee product and brand consistency, mitigate risk and reduce costs.

Based on technologies using a structured data-centric approach, Kallik's solutions leverage and repurpose content to automatically generate artwork. This enables businesses to remove duplication, track content and rapidly change messaging to respond to new market and regulatory challenges.

Formed in 2001, Kallik's founders and senior management team have a rich heritage in the packaging and labelling industry. The flagship AMS360™ Automated Artwork Management solution was devised based on this insider knowledge of the sector and today underpins the businesses of companies including Sealed Air, Estee Lauder, Coloplast, Integra, Mary Kay and Unilever.

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