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## GMP, GCP & Quality Control

August 12-13, 2016 Toronto, Canada

## Food safety moderization act - What does it mean to a food plant?

Amandeep S Dhillon Michigan Milk Producers Association, USA

The FDA Food Safety Modernization Act (FSMA), the most sweeping reform of US food safety laws in more than 70 years, was signed into law by President Obama on January 4, 2011. It aims to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it. FDA Issued Final Preventive Controls Rules Under FSMA on September 10, 2015, the Food and Drug Administration released the final preventive controls rules to implement the FDA Food Safety Modernization Act (FSMA). They form the cornerstone of the law and will shape daily food manufacturing operations and FDA inspections for decades to come.

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## Keeping your body of work in living stasis

Mark Stevens Formpipe Life Science, UK

The need to retain information as accessible, searchable and useable goes far beyond the need to satisfy legal requirements of data longevity. There's also arguably more onus than ever before regarding the visibility over who's accessed what and when: Something that a paper-based, manually administrated system can struggle to provide. As many compliance conscious organizations migrate from a paper-based archiving system to an electronic alternative, Mark explores the common misconceptions surrounding the journey and provides guidance on how businesses can minimize the cost implications of keeping an ever-growing population of content electronically preserved. At the conclusion of this presentation, participants will have an enhanced understanding of: The pitfalls of paper, compatibility and accessibility, and the benefits of an electronic quality management system (EQMS), how to select and implement an EQMS, considering the complete journey between document creation and archiving, What's involved in migrating from paper to electronic from a cost, compliance and process perspective, The need to future-proof business critical documentation – advocating active preservation over mere safe-keeping. The options open to organizations when it comes to where to store archived digital data and who should be responsible for it, the security and accessibility challenges surrounding both off-site but internally managed systems, and fully outsourced solutions. The latest facts and figures surrounding achieve trends across multiple regulated industries.

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