

# PRESS RELEASE

## Surviving the Backlash of the Meningitis Outbreak

*Chemical Management Systems help provide a means to survive the increased scrutiny resulting from the NECC Fungal Meningitis Outbreak*

**November 19, 2012:** In the aftermath of this year's fungal meningitis outbreak caused by unsterile conditions at the NECC Massachusetts facility, the FDA has been under a Congressional microscope. The message from Congress to the FDA is: (1) why did the FDA not do more to prevent the outbreak; and (2) what new legislation should be passed to prevent this from happening again.

Clearly feeling the heat from the investigation, the FDA is asking for an increase in its authority<sup>1</sup> and is going to be increasingly diligent in discovering violations within companies which fall under its jurisdiction. Pharmaceutical companies should be prepared for tougher scrutiny and put systems in place for not only record keeping but evidence of ways to detect and prevent the manufacture of bad batches.

In response to the strict regulations faced by pharmaceutical manufacturing, Valdata's Manufacturing Execution System has implemented features which can help pharmaceutical companies meet these tougher guidelines. Within the manufacturing execution system are protocols which "police" manufacturing activities preventing: (1) use of wrong or expired material; (2) use of equipment which has not been cleaned/sterilized; (3) use of equipment which has passed calibration or maintenance dates; (4) unauthorized adjustments to batches.



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<sup>1</sup> "The head of the Food and Drug Administration asked Congress Wednesday for more authority...", Matthew Perrone, AP, November 14, 2012

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A valuable feature of the CMS (Chemical Management System) software is the complete digital audit trail of every transaction which impacts inventory – from receipt through packaging.

Such systems have a proven track record of preventing mistakes before they happen, protecting both the company and the end user.

### **About Valdata Systems**

Headquartered in Fairfield, NJ, Valdata Systems is a premier provider of Chemical Management solutions specifically targeting the Pharmaceutical, Flavor & Fragrance, Nutraceutical and Chemical Manufacturing industries.

For more information on Chemical Management Systems, Inventory Control Systems, Recipe Manager and other products provided by Valdata Systems please visit: [www.valdatasystems.com](http://www.valdatasystems.com)

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