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2014 ISPE Annual Meeting 12 - 15 October 2014 Caesars Palace, Las Vegas

The
Leading Edge
of Pharmaceutical
Innovation

Date / time & Venue:

15 October 2014 – 11:00 AM 2014 – Annual ISPE congress Ceaser Palace – Las Vegas

Stream: Informatics

IT Infrastructures in support of the Full Product Lifecycle

Title:

Paperless Lab to Support Quality by Design (QbD) Initiatives

<u>Outline</u>

QbD will be the norm within 10 years and manufacturing efficiency will be significantly improved. Adoption of an integrated Product Quality Lifecycle Process facilitates innovation, continual improvement and strengthens the link between pharmaceutical development and manufacturing activities. The power of a Paperless Laboratory is the ability to enable organizations to implement self-documenting processes that produces both non and GxP-compliant documentation which eliminates unnecessary tasks from the workflow, to result in a significant cost of noncompliance to support corporate Cost of Goods Sold (COGS) optimization. This presentation will highlight how QbD and Paperless Lab processes enables organizations to create start-to-finish knowledge management repository to adopt cross functional collaboration between management, scientists and engineers responsible for products in development and manufacturing, processes, equipment and facilities.

<u>Presentation will address informatics challenges:</u>

- 1- Enabling cross functional collaboration between management, scientists and engineers
- 2- The need for data and context standardization in our industry has never been higher. Presentation includes industry initiatives with pragmatic examples
- 3-Holistic start-to-finish mind shift breaking strategies and examples of how informatics can change reactive CAPA into pro-active, self-learning PACA processes. (Publication <u>Scientific World</u>)

Short Bio:

Peter Boogaard has extensive experience in laboratory management to enable cross-functional collaboration between research, development, quality assurance and manufacturing corporations. Peter is founder of Industrial Lab Automation and organizer of the Paperless Lab Academy congresses. He is publishing in <u>national</u> and <u>international</u> magazines and contributes in several industry advisory boards. Peter is Dutch citizen and studied analytical chemistry in Delft. Member of ISPE

Contact peter