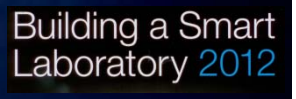
businessreview webinars

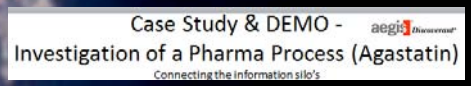
Q & A

QbD & PAT

The Scientist Is No Longer In The Laboratory, But Integrated In The Overall Quality Process

Relevant white papers download





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PaperlessLab Forum

Webinar: QbD & PAT - The Scientist Is No Longer In The Laboratory, But Integrated In The Overall Quality Process

Sponsored by: Industrial Lab Automation

Focused on:

Date: 4 October Days old: 1

Time: 3PM London / 10AM New York

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Economic Pressures to Reduce Effort on Compliance and Improve Quality have Accelerated the Adoption of Quality by Design and PAT

The industry is looking at more holistic approaches to improve processes of bringing new products to market that can accelerate product development and lower operational costs. Quality by Design (QbD) has come relatively late to the pharmaceutical industry. In terms of quantifiable benefits, the main QbD value comes from four main areas; (1) a reduction of Cost of Goods Sold (COGS) and capital expense, (2) increased technical development productivity, (3) improved quality and lower risk, and (4) increased sales.

During this practical webinar learn how QbD principles combined with PAT technologies will facilitate and implement a robust pharmaceutical quality system according to ICH Q10 in the development and manufacturing. Practical examples will show how QbD will enable you to gain the benefits of establishing and maintaining a state of control, continual improvement, enhancing regulatory compliance and meeting quality objectives.

Leadership, outstanding processes, and culture are the ingredients for making companies successful. Technologies are just enablers to achieve that goal. This webinar explores the journey and its role in driving QbD and Pat adoption within Pharma and gives answers of some of the concepts behind the QbD concept.

Presented by

Peter J. Boogaard,
Director

Peter Boogaard is a customer first, results-driven innovated senior executive with over 25 years of significant contributions to knowledge management automation. He is founder of Industrial Lab Automation which provides services to address harmonization, integration and consolidation of business processes in Life Science development and manufacturing enabling cross-functional collaboration between research, development, quality assurance and manufacturing corporations to achieve Quality by Design (QbD) initiatives. Strong demands to help companies optimizing their processes to break their barriers across development and manufacturing resulted in teaming up with Vialis AG. Vialis is the leading provider of paperless lab for the chemical and pharmaceutical industries. Peter has published several white papers and contributes in several industry advisory boards.

Industrial Lab Automation

Key Learning Objectives

- Introduction to QbD concept and update on ICH Q10 and QbD Pharmaceutical Quality Systems guideline
- Overview of PAT technologies and industry examples in both development and manufacturing
- Introductory overview of Product Quality Lifecycle Implementation (PC and Introduction to the 4 Product Quality System elements (PQS)
- Introduction to paperless lab initiativ to help you eliminate the informatics information silo's

Audience

- CEO/President/Chairman/Executive Director
- Senior Technical Directors
- Senior Heads of Quality Compliance
- Process Development Scientists
- Senior PAT and QbD Specialists an experts
- Project Managers
- Senior Scientific Advisors and Inspectors
- Senior Scientists

QUICKPOLL

QbD is here to stay

Please select one:

- Yes, but in development only
- Yes, but in manufacturing only
- Yes, can be applied in the whole product life cycle
- No. Will be replaced by something simpler
- No. We continue as we do now

Poll Results (single answer required):

Yes, but in development only	10%
Yes, but in manufacturing only	0%
Yes, can be applied in the whole product life cycle	85%
No. Will be replaced by something simpler	0%
No. We continue as we do now	5%

QUICKPOLL

The future of PAT relies on…

Please select one:

- ○ Acceptance by regulators
- ○ Availability of more PAT applications
- ○ Availability of cheaper sensors and instrumentation
- ○ Availability of skilled multi-disciplinary resources
- ○ Wishful thinking. It is over the top

Poll Results (single answer required):

Acceptance by regulators	6%
Availability of more PAT applications	29%
Availability of cheaper sensors and instrumentation	29%
Availability of skilled multi-disciplinary resources	29%
Wishful thinking. It is over the top	6%

QUICKPOLL

The principle of a paperless process will…

Please select one:

- ○ Establish a self-documenting processes
- ○ Eliminate manual entries and transfers
- ○ Create more paper
- ○ Enable cross-functional collaboration between internal silo'
- ○ Never happen

Poll Results (single answer required):

Establish a self-documenting processes	42%
Eliminate manual entries and transfers	32%
Create more paper	5%
Enable cross-functional collaboration between internal silo'	21%
Never happen	0%