



8 September 2011

Dear Sir or Madam,

Factorytalk is very pleased to invite you to a seminar on Supporting PIC/S Inspections and Audits using Electronic Quality Management Systems (eQMS). This event offers educational seminars and case studies to detail regulatory requirements (PIC/S) and expectations for Audits and Inspections to give you expert practical guidance, valuable tools and compliant systems that support best practices. The program will include a live system demonstration of key functions of an eQMS in the areas of Document Control, Training Management, Quality Events and Audit and Inspection.

Factorytalk, headquartered since 2004 in Thailand has executed 100's of successful assignments and projects in over 15 countries across the US, Europe and Asia. Factorytalk provides both regional and international Pharmaceutical and Biotech manufactures with a suite of compliance services and tools to ensure that Best Practices are built in to your organization and are sustainable. Our Compliance Consulting team specializes in helping pharmaceutical firms establish efficient, cost effective quality systems that will pass inspection and produce high quality products. We also review current systems to make them more efficient and robust enough to stand up to current regulatory challenges.

SEMINAR

Supporting PIC/S Inspections and Audits with Electronic Quality Management Systems (eQMS)

Date: Friday 30th September 2011

Time: 9:00-14:00

Ratanakosin Room (2nd floor), Four Seasons Hotel, Bangkok

Thank you for taking the time to read this letter. We look forward to hosting you to our event and please don't hesitate to contact us if you have any questions.

Yours sincerely,

David Margetts, Managing Director
Factorytalk Co., Ltd.

AGENDA

Supporting PIC/S Inspections and Audits with Electronic Quality Management Systems (eQMS)

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Time: 9:00-14:00

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9:00 Start

Welcome and introductions

9:15 Session 1 – Best practices for handling PIC/S inspections and supplier audits. By Dr. Tony Margetts including;

- Regulatory expectations
- Preparation for Inspection
- Important tools for inspections and audits
- Key points for audit management

10:00 Session 2 – Case study: The US FDA's implementation of MasterControl eQMS. By Mr. John Yarborough including;

- How MasterControl ensures best practices and compliant Quality Management for the US FDA
- Key benefits of eQMS for audit and inspection support
- New developments in eQMS

10:45 Coffee Break

11:15 Session 3 – eQMS demonstration and highlights. By Ms. Chompunut Apinan

- Live demo of eQMS for handling audit processes and integration to quality events, documents and training management.

12:00 Lunch Break

13:00 Session 4 – Case study: Project approach for the first MasterControl eQMS implementation in Thailand. By Mr David Margetts

- Project approach
- Validation
- Timelines
- Benefits

13:30 Session 5 – Wrap-up, Q&A

14:00 Closure

SPEAKERS BIOGRAPHY

DR ANTHONY MARGETTS BIO

Dr Tony Margetts recently re-located to South East Asia and operates as an Associate Consultant for Factorytalk Co., Ltd. During the 1990's he managed the introduction of new world-wide validation procedures and was the Chairman of a UK Pharmaceutical Industry Group charged with writing a Guideline on Computer Systems Validation which evolved over a number of editions and expanded from UK through Europe, USA and Japan and is now called the Good Automated Manufacturing Practice (GAMP) Guide. Dr Margetts was chairman for the editorial review of the latest version of the GAMP series, GAMP 5, published in 2008 which is considered the world reference for Computer Validation for the Regulated Industries. He has also been involved in producing several of the GAMP/ISPE good practice guides including A Risk Management Approach to Compliant Electronic Records and Signatures.

JOHN YARBOROUGH BIO

John Yarbrough, Senior Vice President-Business Development, is a seasoned sales executive with more than 20 years' experience in sales, business development, management and marketing in the software industry. Yarbrough is responsible for building MasterControl's worldwide sales partner program.

Yarbrough has an extensive track record in building and leading successful sales organizations for software companies. He has served as Vice President of Sales for TopTier (SAP) and subsequently served as vice president of sales for MetricStream, Inc. and Pilgrim Software and vice president of worldwide sales for EtQ Management, Inc. He holds an MBA from California Coast University with a concentration in management.

DAVID MARGETTS BIO

David Margetts is the Managing Director and Co-Founder of Factorytalk and acts as a trusted Advisor and Consultant to the Pharmaceutical and Biotech industries. He oversees a widely experienced and rapidly growing business and team of experts who apply compliance, technology and operational improvement solutions into practice across Asia, US and Europe.

Margetts' technical background spans shop floor control through manufacturing execution to the corporate level and the application of operational excellence and regulatory compliance initiatives.

Before moving to Asia in 2004, Margetts worked in Engineering and Validation for Industrial Technology Systems Ltd and AstraZeneca PLC. He is an ISPE certified trainer for Computer Validation (GAMP5) and studied Systems Engineering at Bristol UK.

CHOMPUNUT APINAN BIO

Chompunut Apinan is a Compliance Consultant at Factorytalk and is the technical manager for all MasterControl projects including the first eQMS implementation in Thailand. Apinan has a great depth and range to her expertise and has led consulting assignments in all areas of support for PIC/S compliance and held key technical and quality roles in the implementation of large scale IT projects.

Apinan previously worked as an Analyst for Advanced Info Systems PLC and as a group leader in Quality Assurance for Ajinomoto Ltd. She holds a Masters in IT from KMUTT University Thailand and Bachelors in Biotechnology from Mahidol University Thailand.

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Register online at <http://www.factory-talk.com/form.htm> or fill and return this form to:

Ms. Jutamas E-mail: jsu@factory-talk.com or fax to 02-650-4527

REGISTRATION FORM

Please complete one form for each registrant • PLEASE USE BLOCK LETTERS

Title (Prof, Dr, Mr, Mrs, etc) _____ Full Name _____

Position _____

Organisation _____

Address _____

Telephone _____ Facsimile _____

Mobile _____

Email _____

WHY YOU SHOULD ATTEND

The seminar is a practical, the seminar describes how PIC/S requirements for inspections and audits can be managed using an electronic Quality Management System and will provide practical information covering best practices with case studies and demonstrations which focus on Owners, Managers, Production, QA, QC staff from Pharmaceutical Companies

TERMS & CONDITIONS

Please fill in and return this form **no later than 27 Sep 2011**

Reservations are on a "first come, first serve" basis. This seminar is **FREE OF CHARGE**

Cancellation policy: All cancellations must be noticed within 7 working days prior to the seminar day