

# DARQA JUBILEE CONFERENCE 2016

May 26 - Amersfoort, NL

# Be Prepared

CONFERENCE PROGRAMME

MAY 26

On May 26<sup>th</sup> DARQA celebrates its 35 years of activities with a Jubilee conference. The venue for the conference is 'De Veerensmederij' in Amersfoort, The Netherlands. The conference theme is 'Be prepared'.

The conference provides insights into the future of quality and system thinking. The carefully planned programme is intended to bridge the theory of the 'the fathers of quality' to daily practices so that delegates can build on that in their own work environments.

There is no question that the worlds of R&D and production/ services are fundamentally changing. Worldwide industries and service providers are in the midst of the 4th industrial revolution, also known as the 'industrial Internet'. This equally applies to DARQA's constituency; life sciences, food/feed and healthcare. As this revolution evolves, quality assurance personnel, managers and inspectors/investigators will witness their work processes & methods transform drastically.

Managing new complexities requires a different mind-set and another skill set: quality thinking and systems thinking. This conference will help you to get there. By attending this conference you can capitalise on the knowledge and skills from a rocket science environment such as NASA (featured speaker Bill Bellows is employed by Aerojet Rocketdyne, a propulsion system contractor to NASA) and petrochemical

giant Shell. (featured speaker James Haug is employed by Shell). The presented ideas and case histories give you a unique and direct insight into these worlds. You learn how to directly apply and implement the theory of quality thinking and system thinking in life sciences, healthcare and other complex industry sectors. Moreover insight in the regulatory expectations in 2016 and beyond by a former FDA investigator. You will be better prepared for the future by attending and becoming conversant with the theme of the conference.

Quality thinking and systems thinking is universally applicable, therefore the preconference welcomes delegates from ALL quality driven sectors including; the chemical & energy industry, ICT, aviation/aeronautics, aerospace, automotive, lithography, education, agriculture and financial institutions. So take full advantage of this unique opportunity to learn from the experts and ask your questions during the panel discussions by preparing questions and sending cases with your registration.

Be inspired and enriched by James Haug (Shell), Martin Browning (EduQuest) and Bill Bellows (In2:InThinking Network) & Kit Roes (University Hospital Utrecht).



**DARQA**  
the quality improvement network

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## FEES

Registration fees Pre-conference; 35 euro\* for DARQA members and 195 euro for non- members. Fees include refreshments, lunch, network & Tapas dinner and parking. Website: [www.darqa.org](http://www.darqa.org)

## SPEAKERS

### JAMES HAUG - SHELL - VP OF QUALITY AND CONTINUOUS IMPROVEMENT

James Haug has been the VP of Quality & Continuous Improvement and the Global Head of Quality Engineering for Shell since November 2014. He has 20 years of experience, primarily in engineering and management within the aerospace industry. James spent 10 years as a project engineer at Boeing (Rocketdyne Propulsion and Power business unit), developing the world's largest hydrogen-fueled rocket engine for space launch applications. He also led mission assurance for major missile defence programs and other critical projects at Raytheon Missile Systems. Prior to joining Shell, James was the Chief Engineer of Quality for Bechtel. He has a bachelor's degree in Chemical Engineering from the University of California at Davis and an MBA in Finance from UCLA Anderson School of Management.

### BILL BELLOWS - PRESIDENT IN2:INTHINKING NETWORK

Bill Bellows is an Associate Fellow in the InThinking Network at Aerojet Rocketdyne in Canoga Park, California, where he is known for his efforts to provide insights to the advantages of thinking together, learning together, and working together. While integrating the thinking of W. Edwards Deming into Genichi Taguchi's design system, he's been a pioneer in developing ideas that include Mixed Model Management, Macro System Models, Micro System Models, Purposeful Resource Leadership, Category & Continuum Thinking, and Investment Thinking. Audiences for his presentations and classes have also reached after-school programs in elementary schools, graduate students at Northwestern University, as well as corporate, university, and public classes across the

United Kingdom. Bill earned his BS, MS, and Ph.D. in Mechanical Engineering from Rensselaer Polytechnic Institute in Troy, NY. Away from work, Bill serves as president of the In2:InThinking Network ([www.in2in.org](http://www.in2in.org)), and as a board member of the W. Edwards Deming Institute ([www.deming.org](http://www.deming.org)), and the Volunteers of America - Los Angeles chapter ([www.voala.org](http://www.voala.org)). He also serves on the editorial board of the Lean Management Journal ([www.leanmj.com](http://www.leanmj.com))

### MARTIN BROWNING - PRESIDENT EDUQUEST / FDA INVESTGATOR

Martin Browning has over 35 years of experience at the U.S. Food and Drug Administration and industries regulated by the FDA. He offers EduQuest clients extensive expertise in FDA compliance, Part 11 and Annex 11 interpretation and compliance, quality systems, software and systems engineering, inspection preparedness, and auditing of internal systems and suppliers. His specific experience also includes quality systems design and documentation, verification and validation of production processes and software and responding to FDA enforcement actions. While at FDA, Martin served as Vice Chair of the Electronic Record and Signature Working Group, which drafted the 21 CFR Part 11 regulations. He also served as Chair of the U.S. Government ISO-9000 committee; on the Global Harmonization Task Force; and on the committee that developed the medical device good manufacturing practice regulations, otherwise known as the Quality System Regulation (QSR) 21 CFR 820.

### KIT ROES - DIRECTOR QUALITY AND PATIENT SAFETY OF THE UNIVERSITY MEDICAL CENTER UTRECHT

Kit Roes is Director Quality and Patient Safety of the University Medical Center Utrecht and Professor of Biostatistics at the Julius Center. He joined the UMC Utrecht in 2009, after a career in industry. His experience includes over 15 years in research and development in the pharmaceutical industry and life sciences research and 10 years of experience in industrial statistics. He has been responsible for statistics, data management and medical writing in multiple global drug development projects and regulatory filings.

\*DARQA member prior to February 1st, 2016

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## PRESENTATIONS

James Haug will speak about Shell's perspectives on quality and continuous improvement in relation to long term sustainability.

Martin Browning will speak about current and future FDA expectations from a regulatory standpoint. He will discuss quality and continuous improvement expectations for 2016 and beyond for food/feed, pharmaceutical products, and medical devices. He will also talk about software quality assurance (SQA) with regards to the development life cycle for software applications and computerised systems.

Bill Bellows will speak in-depth about the 4 fathers of quality (Phillip Crosby, W. Edwards Deming, Joseph Juran, Genichi Taguchi) and leading systems theorist Russell Ackoff and how their theories led to contemporary artefacts such as Toyota (TPS), lean and lean six sigma. He will explain how an integration of these theories was successfully adopted in rocket science domains, like NASA and Aerojet Rocketdyne.

Kit Roes will talk about integrity of Patient & Research data during Investigator Initiated GCP Studies.

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### • Welcome & Opening

Frans Leijse - DARQA / Director ITC Validation Consultants

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### • Shell's global perspectives on Quality and continuous improvement

James Haug - Shell Vice President Quality & Continuous improvement

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### • Brief History of Quality: The Good and The Bad

Bill Bellows - President In2:InThinking Network / Board Member of the W.E Deming Institute

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### • FDA current and future expectations on Data Integrity, Medical Applications and Supplier Assessments

Martin Browning - President EduQuest / former FDA Investigator

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### • A Systems View of Quality for the 21st Century

Bill Bellows - President In2:InThinking Network / Board Member of the W.E Deming Institute

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### • Integrity of (Research) Data in Healthcare

Kit Roes - Director Quality and Patient safety at the University Medical Centre Utrecht

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### • Interactive Panel Discussion

James Haug - Bill Bellows - Martin Browning - Kit Roes

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### • Tapas Dinner & Networking

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