Process Industries Division

PHARMACEUTICAL MANUFACTURING SURVIVAL IN THE 21ST CENTURY

Institution of MECHANICAL ENGINEERS

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cogent Skills for Science Based Industries

The National Skills Academy PROCESS INDUSTRIES

12 May 2010
One Birdcage Walk, London
Book now:
www.imeche.org/events/s1430

ATTENDING THIS EVENT WILL HELP YOU:

- Benefit from lessons of best practice, recognise the signs of success and help prevent failure
- Learn principles that help build a competitive edge
- Reduce manufacturing overheads
- Develop efficiency enhancements
- Apply practical risk reduction to improve operational reliability
- Learn about Process Analytical Technologies (PAT) and how they can be of great benefit
- Understand how innovative thinking can benefit your organisation
- Successfully manage the human factors of manufacturing
- Understand why outsourcing to India or the Far East is not as effective as we might think
- Meet, greet and network with key industry players
- Find collaborators for future projects

Improving the world through engineering

PHARMACEUTICAL MANUFACTURING SURVIVAL IN THE 21ST CENTURY

While regulatory compliance in the UK pharmaceutical manufacturing industry is generally very high, manufacturing efficiency is often lacking.

Ever-increasing cost pressures mean that a number of companies have moved their manufacturing operations to countries with lower labour costs.

However, it doesn't have to be this way, not if established world-class methodologies, principles and innovative thinking are applied to pharmaceutical plants.

Many examples of best practice in other industries may be easily applied in the pharmaceutical industry, and companies that have done so have seen very significant improvements in operational efficiency.

What are the pitfalls? How do you prevent or address misunderstandings of the concepts? And how to you safeguard cGMP compliance?

This event will answer these questions and offer advice, solutions and best practice to tackle excessive lead times, high inventory, inefficient staffing, poor process control and supply-chain reliability. Benefit from the lessons of best practice, recognise the signs of success and help prevent failure.

THIS EVENT WILL ATTRACT:

Anyone in the pharmaceutical and related industries, eg biotech, medical devices, healthcare, contracting services, equipment and control systems supply, with responsibility for or interest in manufacturing, performance, quality and related fields. General engineers, senior managers, departmental heads, directors and senior technical staff from manufacturing, engineering and quality disciplines will all find this seminar invaluable.

"IT IS VERY ATTRACTIVE TO ATTEND SUCH AN EVENT WHERE YOU CAN SEE THAT YOUR CURRENT KNOWLEDGE CAN ONLY BE COMPLEMENTED BY THE REAL-LIFE EXPERIENCE."

MS KRISZTINA KOVACS-SCHREINER
SPEAKING ABOUT
PHARMACEUTICAL ENGINEERING DESIGN FOR COMPLIANCE SEMINAR 2008

TECHNICAL ADVANTAGES:

- Understand how to apply operational excellence and improve customer satisfaction
- See how to apply new technologies
- Maintain and improve regulatory compliance
- Relate risk based approaches to commissioning and validation
- Appreciate changing competitive Dynamics within the industry
- Learn how to encourage innovation
- Recognise how innovation can impact business sustainability
- Identify opportunities for optimising plant operations

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SUPPORTING ORGANISATIONS

cogent Skills for Science Based Industries

The National Skills Academy PROCESS INDUSTRIES

IChemE Pharma Subject Group

ISPE United Kingdom Affiliate ENGINEERING PHARMACEUTICAL INNOVATION

THE WOLFSON CENTRE for Bulk Solids Handling Technology at The University of Greenwich

PHARMACEUTICAL MANUFACTURING SURVIVAL IN THE 21ST CENTURY
12 MAY 2010
INSTITUTION OF MECHANICAL ENGINEERS

09:00 REGISTRATION, TEA AND COFFEE

09.30 CHAIR'S WELCOME

09.35 KEYNOTE ADDRESS – OPERATIONAL EXCELLENCE/ CUSTOMER SATISFACTION

Roger Benson, Honorary President, CPACT

10.05 THE IMPACT OF SKILLS ON THE FUTURE OF THE UK PHARMACEUTICAL INDUSTRY

- From hands-on manufacturing to laboratory based innovation the pharmaceutical sector must re-skill and up-skill the workforce for the "Factory of the Future"
- Describe the Cogent Gold Standard a training framework for world-class skills
- The Gold Standard will address not just technical competence and compliance but also business improvement and behavioural skills

John Holton, Strategic Development Director, Cogent Sector Skills Council

After completing a DPhil in Chemistry John Holton joined ICI where he held a number of senior management positions. In the early 90's he joined EVC, an ICI/Enichem joint venture based in Brussels and after a spell as Group Strategic Planning Manager John launched, and then as Managing Director, led Inovyl, a new global business venture involved in speciality chemicals and technology licensing. In 2005 John joined Cogent as Strategy Development Director where his responsibilities include the development of the employer engagement strategy to enable Cogent to fulfil its objective of improving business performance through skills.

10.35 DISCUSSION

10.50 TEA, COFFEE

11.15 IMPACT OF INNOVATION ON PHARMACEUTICAL BUSINESS SUSTAINABILITY

- How challenges faced by manufacturers are magnified by stringent regulations
- Why fear of non-compliance can adversely affect business viability
- Why current conditions call for methodical consideration of innovation to maintain businesses
- Exploration of the impact of innovation on pharmaceutical business sustainability

Eddy Azad, CEO, Parsec Automation Corporation

Eddy Azad is the founder and CEO of Parsec Automation Corporation, which is a software development company that specialises in developing specific solutions for improving manufacturing operations and productivity. During the past 25 years Eddy, has been deeply involved with developing technologies with practical applications to measurably improve business performance in life sciences and consumer packaged products industries. He founded Parsec in 1987 to focus on delivery of consulting and implementation services to more effectively help customers realise the value of their investment in assets and resources. As a recognised subject matter expert, Eddy regularly contributes articles to trade magazines, speaks at global forums, and assists manufacturing companies in defining effective strategies for continuous improvement and operational excellence. Eddy holds a masters degree in engineering from Stanford University.

11.40 PRACTICAL APPLICATION OF A SCIENCE AND RISK-BASED APPROACH TO COMMISSIONING AND QUALIFICATION

- Why change my current systems to a science and risk-based approach?
- Understand the principles of the science and risk-based approach related to ASTM E2500-07 and ICH Q9 Quality Risk Management
- What support systems are needed to execute this process?
- Successfully choose an appropriate risk methodology

Robert Adamson, Manager, Pharmaceutical Compliance and Validation Pharmaceuticals, Foster Wheeler Energy

Robert Adamson is Manager of Pharmaceutical Compliance with Foster Wheeler in Reading, where he is responsible for all compliance and validation services. Robert has spent 39 years in the pharmaceutical industry, holding positions with Glaxo and Beecham (both now GSK). He is a Fellow of the Royal Society for Chemistry and a Chartered Chemical Engineer. His early career with Glaxo and Beecham included R&D and production management of API and steriles manufacture.

At Foster Wheeler his recent experience has included compliance and regulatory topics, validation of oral and sterile dosage forms, biotechnology and API facilities to meet EU, FDA and JMHLW requirements. He has worked with a wide variety of clients and on occasions has represented them at FDA meetings.

Robert is Chair of ISPE UK Affiliate and has written and presented a number of papers and contributed to a number of books. He has been involved with ISPE's commissioning and qualification initiative since its conception. He was the Co-Chair of the ISPE Communities of Practice for Commissioning and Qualification for two years, and was a member of the task team that wrote the new ASTM E2500 Standard for Commissioning and Qualification. He is ISPE's project manager for the completion of the Baseline Guide Volume 12.

12.05 THE EVOLVING D&M BUSINESS MODEL OF THE PHARMACEUTICAL INDUSTRY

- Research productivity has declined dramatically
- Competitive dynamics of the industry are changing
- Process development alongside manufacturing is a key trend
- Speed to market is key
- PAT, QbD and Real-Time Release are part of the new paradigm
- Successful role models

Barry O'Dowd, Senior Vice President, Pharmaceuticals and Biotechnology Department, IDA Ireland

Barry Dowd has been head of IDA Ireland's Pharmaceuticals and Biotechnology Department since mid-2005. IDA is the lead agency responsible for inward investment from overseas pharmaceutical and biotechnology companies.

Barry worked from 2002 to 2005 in Organon BioSciences International's headquarters based in Roseland New Jersey, where he worked on both business development and strategic corporate projects. He has an MSc from Trinity College Dublin and is a barrister.

12.30 LUNCH

13.30 OPTIMISING PHARMACEUTICAL PLANT OPERATIONS FOR EFFICIENCY AND PRODUCT QUALITY

- Impact on process reliability of vessel design – common mistakes
- Minimising variability in assay as a result of a loss of homogeneity – measurement and minimisation through design
- Obtaining consistency of dose weight and composition through metering device and interface design

Richard Farnish, Consulting Engineer, The Wolfson Centre for Bulk Solids Handling Technology

Richard is a consulting engineer at The Wolfson Centre for Bulk Solids Handling Technology, University of Greenwich where he has worked since 1996. The majority of his time at The Wolfson Centre he spent undertaking consultancy activities for a wide range of industrial sectors. A large proportion of his work is linked to trouble-shooting bulk particulate processes that are under-performing as a result of equipment design issues or product quality problems (segregation, agglomeration, attrition etc). His research specialism relates to techniques for improving the filling efficiency of sachets or closed vessel with fine powders.

13.55 CATALYSING INNOVATION

- How can you harness and invigorate the latent innovation capability in your organisation?
- Open or networked innovation, what does it really mean, when and how should we look outside the business?
- Common barriers to successful innovation and how you can overcome them

Matthew White, Director of Innovation & Intellectual Property, Sagentia

Matthew White is a scientist with a broad technical background. He champions Sagentia's innovation activities across all industry sectors. Over the last 11 years he has led innovation programmes and facilitated creative processes from initial strategy, opportunity discovery and concept creation through to product and service development.

14.20 SCALABLE TECHNOLOGY FOR THE EXTRACTION OF PHARMACEUTICALS (STEP)

- Demonstrate how ingenious mechanical engineering solutions create mixing and settling zones between immiscible liquids
- The application of a 'Magic' tube
- How a research programme funded by TSB and industry helped develop the technology
- Discuss the hurdles to be overcome in introducing new technology in the pharmaceutical industry

Ian Sutherland, Director, Brunel Institute for Bioengineering, Brunel University

In the last ten years Professor Sutherland has been developing new technology for extracting new active compounds from natural products, including Chinese medicinal herbs. The Brunel Institute for Bioengineering, along with GSK, Pfizer and a SME company, Dynamic Extractions, has just started a research programme entitled Scalable Technology for the Extraction of Pharmaceuticals (STEP) as part of the Government's Technology Strategy Board's (TSB) new high-value manufacturing initiative.

Keith Freebairn, Director in the Chemical Department, GlaxoSmithKline

Keith Freebairn joined GlaxoSmithKline in 1988 and is currently a Director in Chemical Development. His interests include the application of process analytics to continuous processing, the development of automated high-performance separation systems, sensor technology, online analysis and building intelligence into analytical instruments.

14.45 DISCUSSION

15.00 AFTERNOON TEA

Process Industries Division

Organising Committee:

Karen Stevenson, Validation Manager, Patheon
Eur Ing Robert J Hayes, SeerPharma (UK)
Eur Ing Paul Merrick, Consultant

15.30 CONTINUOUS PROCESSING IN THE PHARMACEUTICAL INDUSTRY – CONTINUOUS VS BATCH PROCESSING

- Review current technologies for continuous tablet manufacturing process
- Merits and limitation of batch and continuous processing approach
- Flexible batch granulation using roller compaction
- Recent developments in continuous manufacturing processes
- Scaling and flexibility

Bindhu Gururajan, Senior Scientist (Process Engineering), AstraZeneca

Dr Bindhu Gururajan did his Master degree in Chemical Engineering from the Indian Institute of Technology, Delhi and his PhD in Formulation and Process Engineering from the University of Birmingham. During his PhD thesis research he worked on the dry granulation of pharmaceutical powders with Merck Sharp and Dohme Pharmaceutical R&D Fellowship. He carried out post-doctoral research in Pharmaceutical Sciences at the Pfizer Research Centre, and is currently working at AstraZeneca as Senior Scientist (Process Engineering) and involved in formulation and process development, scale-up and technology transfer. He is an active committee member of Particle Technology Subject Group, Institution of Chemical Engineers.

15.55 PRACTICAL METHODS TO REDUCE RISK AND IMPROVE OPERATIONAL RELIABILITY AND INTEGRITY IN PRIMARY PHARMACEUTICAL PRODUCTION

- Maintenance and reliability – gap analysis and identification of best practice
- Operational safety and integrity – risk assessment and mitigation
- Criticality and vulnerability assessment – for HSE and production assurance
- Cost benefits of improved reliability and integrity assurance

Ken Bell, Principal Consultant, ABB Engineering Services

Ken Ball is a Principal Consultant with ABB Global Consulting. He is a Chartered Chemical Engineer with 39 years' experience in process optimisation, mainly in the oil and gas, chemical and pharmaceutical industries. His areas of consultancy include process development, operational improvement, competence development and assurance and compliance in health, safety and environment.

16.20 DISCUSSION

16.35 CLOSING STATEMENT BY CHAIRMAN

16.40 CLOSE OF SEMINAR

This programme is subject to change.

FORWARD THINKING.

For more information about any of these events, please contact Diane Lorenzelli on +44 (0)20 7304 6837 or management@imeche.org

16 MARCH, 13 APRIL AND 27 APRIL 2010: LONDON
USE LEAN PRODUCT DEVELOPMENT TO RECOVER FROM RECESSION
These interactive workshops will analyse the business processes, tools and techniques that the world's leading product developers use to do just that – and teach you how to apply them to your own business.
www.imeche.org/events/w1448

21-24 APRIL 2010: KEELE UNIVERSITY, STAFFORDSHIRE
ESSENTIAL MANAGEMENT SKILLS FOR ENGINEERS
This four-day conference will focus on leadership, innovation, negotiation, problem-solving, motivation and communication. It will teach delegates tools and techniques that can be used in the workplace and shared with colleagues.
This event is best suited to developing, motivated professionals with the capacity for leadership. Essential Management Skills 2010 is the perfect platform to add value to your company; it will help delegates acquire new engineering and management skills while building on existing ones.
www.imeche.org/events/c1310

19 APRIL 2010: ABERDEEN
TRIZ – RAPID INNOVATIVE PROBLEM SOLVING
TRIZ is a proven process for solving problems, generating new ideas and developing systems more quickly, cheaply and inventively than raditional methods. The TRIZ thinking tools are a rigorous and systematic approach for nderstanding and solving any problem; its principal tools enable you to uncover the most effective route to practical solutions, as well as the development of your next generation of products.
www.imeche.org/events/w1454

24 JUNE 2010: ONE BIRDCAGE WALK, LONDON
ATEX/DSEAR COMPLIANCE IN BULK MATERIALS HANDLING
Compliance with the ATEX directives has been mandatory for new equipment since June 2003, and for existing equipment since July 2006. There is still a great deal of uncertainty surrounding this legislation and its impact on design, testing, certification and operation of equipment in potentially explosive atmospheres for both users and manufacturers. This seminar will re-visit the legislation and discuss topics that still cause concerns, including: zoning, legal responsibility, old machinery, second hand machines and small vessels. It will also look at the future of ATEX and how it may develop in the coming years.
www.imeche.org/events/S1484

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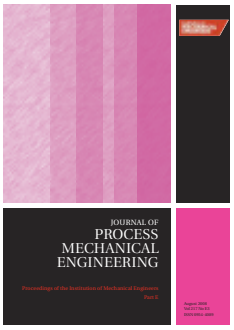

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PHARMACEUTICAL MANUFACTURING SURVIVAL IN THE 21ST CENTURY

BOOKING FORM EVENT S1430 12/5/10

One form per person only (forms may be photocopied)

For added convenience, you can also book online at www.imeche.org/events/s1430

Registration (please complete in CAPITALS)

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First Name | Job Title

Membership No | Institution

Name of Organisation (for name badge)

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Contact Telephone | Fax

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Do you have any special requirements?

How did you hear about this event? Direct Mail ☐ Website ☐ Colleague ☐ Other ☐ _____

Fees and Charges (please complete the appropriate box)

Registration fees include entry to the sessions, refreshments, lunch and a copy of the event proceedings

	Fee	VAT	Total	£
Institution of Mechanical Engineers Member	£210.00	£36.75	£246.75	_____
Member of Supporting Organisation	£210.00	£36.75	£246.75	_____
Non-Member	£260.00	£45.50	£305.50	_____
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Extra Items				
Invoice Charging (if applicable)	£10.00	£1.75	£11.75	_____
			Total	_____

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By submitting this registration form, you will be indicating your consent to periodically receiving information on our events and publications, unless you indicate an objection to receiving such information by ticking this box ☐

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Conditions of Booking
Completed application forms should be returned to the address below, along with the correct payment. Attendance at the event will be confirmed on receipt of the full balance. All participants are advised to bring a copy of their confirmation with them on the day, to ensure the fastest possible entry.

Special Requirements
Please inform us of any special requirements ie dietary or access, on the relevant section of this form.

Cancellation
For a refund (minus £25 + VAT admin charge), cancellations must be received at least 14 days prior to the event. Replacement delegates are welcome at any time.

Supporting Organisations
Members of the following organisations can register at our members' rates: The Wolfson Centre for Bulk Solids Handling, IChemE, ISPE, Cogent and National Skills Academy

Venue
This event will be held at
One Birdcage Walk, Westminster,
London SW1H 9JJ.
Details will be sent upon registration.

Insurance
The organisers do not accept liability for any injuries or losses of any nature incurred by delegates and/or accompanying persons, nor for loss or damage to their luggage and/or personal belongings.

Accommodation
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