

This International Conference

will be of interest to:

Engineering Directors
Operations Managers
Managing Directors
Production Managers
Project Engineers & Specifiers
Instrumentation & Control Engineers
Design Consultants & Design Office
Project Managers
Engineering Managers
QA/QC Managers
Construction Managers
Validation Managers & Specialists
Maintenance Managers
Procurement Managers

PAPER BRIEFS

Calibration Strategies in a Regulated Environment

Mr. Vincent Cantwell Tyco Healthcare

Vincent will demonstrate, in detail through practical examples, how a calibration strategy was implemented and optimised in a heavily regulated pharmaceutical bulk production facility. Industry is constantly striving to achieve an optimum balance between compliance and commercial practicalities. Calibration should be used as an analytical tool, which when properly integrated into plant performance metrics can be used to optimise the production process. Calibration should be the process that measures, analyses and seeks to minimise errors and variances in plant systems.

Cleanroom Environment and the FDA

Mr. John Power Schering Plough, Brinny

The ongoing evaluation of Environmental Monitoring (EM) data is a key component in ensuring correct conditions are maintained within the cleanroom. This evaluation forms the basis for product release, investigation of adverse trends, and identification of corrective action plans. Examples will be given of routine operations which can be problematic, and how to avoid or resolve them. The regulatory requirements for cleanrooms in Biotechnology/Pharmaceutical Operations will be discussed, with an emphasis on Aseptic Processing. The role of EM programs in the Validation, and routine operation, of cleanrooms will be highlighted.

PAPER BRIEFS

Design & Operation of Clean Rooms

Mr. Declan Fleming Schering Plough, Brinny

Declan will present an overview of and the challenges encountered in the design, construction, validation and ongoing operation of a clean room with emphasis on the application requirements of the Biotechnology/Pharmaceutical Industries. You must apply the correct specifications during the front end design stage, during Declan's presentation, he will focus on such topics as HVAC Components, Building Management Systems, Environmental Conditions, Balancing/Commissioning, typical problems which are encountered, and new features which would be beneficial in future designs.

Electronic Batch Tracking

Mr. John Coughlan Pfizer Ireland Pharmaceuticals

John's paper will focus on the efficiencies that their Material Tracking System (MTS) has brought to OSP4, from a production perspective. There are many steps involved in changing to an Electronic Batch Tracking system such as has been implemented in OSP4. He will give an outline of what was required before the MTS to record/track materials, primarily a paper-based system, versus what OSP4 has in place today. This will clearly demonstrate the trend away from paper to a more electronic, real-time system.

E-Purchasing is Here

Mr. Gregg Brandyberry GlaxoSmithKline

"For thousands of years man has bartered, negotiated, bought/sold goods and services... Electronic reverse auctions are truly different and suddenly I recognise that Procurement will never be the same. They have fundamentally changed the competitive forces in the bidding process. It's 10.00am on a Tuesday morning and I'm in Brussels, watching GlaxoSmithKline Capital and Construction Procurement run an on-line reverse auction for office furniture on my Laptop. The process brings the best suppliers to the buyer... only the best will be able to compete; the suppliers that focus on first time quality, lean processes and innovation resulting in low cost/high quality goods and services."

Together in Excellence

Mr. Andrew Dunne Yamanouchi Ireland Corp. Ltd.

TiE (Together in Excellence) is a partnership programme, which seeks to dovetail the relationship, practices, procedures and standards of Yamouchi Ireland with those of our supporting contractors, service providers and suppliers. The aim is to ensure that all YICL personnel, maintenance craftspeople and operatives, service providers, contractors and suppliers who support the Maintenance Engineering function, receive adequate training and awareness in order to carry out their duties in a safe and efficient manner, and to document and record those activities in a logical and legible fashion, which complies with all current legislative and regulatory requirements, while ensuring traceability. *"Together we can make a difference."*



**ISA—The Instrumentation, Systems,
and Automation Society**

Striving for Perfection in a Regulated Environment -An End User View



**Tuesday 18th February, 2003.
Maryborough House Hotel,
Douglas, Cork, Ireland.**

OBJECTIVES

The conference is a platform to introduce and discuss upcoming challenges and their effects within industry. Presentations will explore in some detail the views of leading professionals in their respective fields. Speakers will call on practical experience, highlighting how these challenges can be overcome.

As with all conferences, participation is key to its success. We anticipate a sharing of ideas and have allocated a generous amount of time for discussion after each paper.

www.iol.ie/~isaire

SCHEDULE

8.45	Registration, Tea & Coffee	12.40	Lunch
9.15	Introductions by Mr. Alan Edwards President of ISA Ireland Section	1.40	Together in Excellence by Mr. Andrew Dunne Maintenance Management Yamanouchi Ireland Corp. Ltd.
9.20	Chairperson Address by Mr. Cormac Callaghan Director Global Engineering Bristol Myers Squibb	2.25	Questions & Answers
9.30	Design & Operation of Clean Rooms by Mr. Declan Fleming Manager-Maintenance Pharmaceutical Manufacturing Schering Plough, Brinny	2.35	Calibration Strategies in a Regulated Environment by Mr. Vincent Cantwell Senior Instrument Engineer Tyco Healthcare
10.15	Questions & Answers	3.20	Questions & Answers
10.25	Tea & Coffee	3.30	Tea & Coffee
10.35	Electronic Batch Tracking by Mr. John Coughlan Team Leader OSP4 Pfizer Ireland Pharmaceuticals	3.40	Cleanroom Environment and the FDA by Mr. John Power Manager Manufacturing, Microbiology and GMP Support Schering Plough Brinny
11.20	Questions & Answers	4.25	Open Session Questions & Answers
11.30	E-Purchasing is Here by Mr. Gregg Brandyberry Director Global Systems & Processes GlaxoSmithKline	4.45	Chairperson Summary & Closing
12.30	Questions & Answers		

SPEAKERS

Mr. John Power **Schering Plough, Brinny**

John has over 16 years experience of Aseptic manufacturing and has for 12 years been responsible for the QC Microbiology and In Process Control Department at Brinny. John's current role involves the evaluation of manufacturing practices, and implementing changes or improvements which enhance product protection. This role included responsibility for the Environmental (microbial, particulate etc.) control and Qualification of Cleanrooms and Controlled areas in Fermentation, Purification and Sterile Manufacturing facilities.

SPEAKERS

Mr. Declan Fleming **Schering Plough, Brinny**

Declan has over 13 years experience at Schering Plough, Brinny. He has been responsible for the Sterile Manufacturing Production Equipment, Site Utilities and all aspects of Cleanroom Utilities. Declan is currently responsible for the Operation and Maintenance of Schering's BMS/HVAC systems supplying the Purification and Sterile Manufacturing Production areas. In addition, Declan has been involved in the design, commissioning & regulatory submissions associated with BMS/HVAC system in new facilities.

Mr. John Coughlan **Pfizer Ireland Pharmaceuticals**

John is a Chartered Chemical Engineer with over 14 years experience. He joined Pfizer in 1998 and his career to date has seen him spend time in Production and Engineering. He was Lead Systems Engineer on the recent Pfizer multi-million pound OSP4 Project. He presently works as a Team Leader in OSP4.

Mr. Gregg Brandyberry **GlaxoSmithKline**

Gregg has been a Director of Global Systems and Processes at GlaxoSmithKline since 1999, having joined in 1993 as a Quality Manager in Procurement. He has held various roles in line management and procurement support. Prior to joining GSK, Gregg worked for Gates Corporation. He holds a diploma in biology and is a member of the National Association of Procurement Professionals.

Mr. Andrew Dunne **Yamanouchi Ireland Corp. Ltd.**

Andrew is a time served Electrician who has gained a BSc in Electrical Engineering and completed an MSc in Maintenance Management & Systems. He has worked in senior maintenance management for over 12 years with experience in a range of industries from Light Engineering, Polymers, Computer, Paper, PCB, Pharma and Contract Engineering. "As a company in one of the most regulated industries, it is essential that YOU are in a position at all times to prove to your regulators that you insist on the same practices and standards from third parties as they expect from their own staff."

Mr. Vincent Cantwell **Tyco Healthcare**

Vincent has had primary responsibility for the design, start up, validation and commissioning of the Instrumentation systems at this green field facility. He has 18 years experience in the Industrial Automation field. The last 10 years have been spent working as Senior Instrument Engineer at the Tyco Healthcare facility in Dublin. Vincent is currently pursuing an MSc in Process Automation through the Universities of Sheffield and Newcastle. "In today's heavily regulated world, industry is constantly striving to achieve an optimum balance between regulatory compliance and commercial practicalities."



International Conference

ISA IRELAND SECTION

Striving for Perfection
in a Regulated Environment
- An End User View

Tuesday 18th February, 2003.

Maryborough House Hotel, Douglas, Cork, Ireland.

NAME:	_____
COMPANY:	_____
POSITION:	_____
ADDRESS:	_____ _____ _____
TEL:	_____
FAX:	_____
E-Mail:	_____
Name 2:	_____
Name 3:	_____

Costs: ISA / ISPE Member €200.00
Non-Member €280.00 (INCLUDES ONE YEARS SUBSCRIPTION TO ISA)

Please reserve place(s). I enclose a payment/cheque for € made payable to ISA Ireland.

Mail completed form to: Mr. Billy Walsh, ISA Ireland Section,
PO Box 203, Eglinton St., Cork, Ireland.
Tel: -353-21-4902144
Fax: -353-21-4276398
E-mail: info@isa.ie
Website: www.iol.ie/~isaire

Please note: Numbers are limited and bookings will only be accepted when accompanied by full payment.

THIS COURSE IS APPROVED BY FAS TO RECEIVE GRANT AID
SUBJECT TO THE AVAILABILITY OF FUNDS.