Who Should Attend?

- 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

Objectives

The conference is a platform to introduce and discuss upcoming challenges and their effects within the Pharma/Bio 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.

Paper Brief

Fluidised Bed Incineration Technology - Ms. Laura Burke

Indaver Ireland is preparing a planning application for an Industrial/Municipal Waste Incinerator for the treatment of Hazardous and Non-Hazardous Waste in Ireland.

Laura's paper will give details on the proposal for the disposal of Industrial Waste in a Fluidised Bed Incinerator.

Fluidisation is the term applied to the process whereby a fixed bed of fine solids is transformed into a liquid-like state by contact with an upward flowing gas.

Paper Brief

Advantages of Plant Modular Construction - Mr. John Sweeney

John's paper will discuss the facility design strategies and automation system designs used to facilitate the delivery of the modular manufacturing building.

In our highly competitive pharmaceutical manufacturing sector, where in addition to GMP requirements, speed to market and facility life cycle costs are key to a company's success as a manufacturer of medicines, novel methods of facility delivery pose great opportunities in achieving these goals.

Eli Lilly S.A. who have been manufacturing medicines in Ireland for over 20 years took the decision to attempt to reduce facility delivery costs and schedule for their newest manufacturing facility through the use of modular construction techniques.

Paper Brief

Managing Environmental Risk - Environmental Due Diligence - Dr. Graham Parry

Using case studies, Dr. Parry's paper will describe how your environmental liabilities can be assessed as manageable business risks. These risks can then be imported into economic models. He will describe the process of assessment including identification of liabilities arising from your plants historic uses and issues relating to your current activities and processes.

The concept of materiality will be discussed and how the results of environmental due diligence can be used to prevent excessive discounting and assist in maintenance of value.

Environmental issues have become a standard feature of Due Diligence in transactions of all sizes. Purchasers and sellers recognise the broad range of industries where this has to be considered.

Paper Brief

Containment Technologies for Pharmaceutical and Biotech Applications - Mr. Gregg Herman

The technology of containment is one of the fastest developing design issues faced by the Industry. Your demands today of producing product are greater and more complex than ever before. The challenges placed on you to research and develop the next generation of wonder drugs is only matched by the challenges placed on your Design and Production Teams to produce these drugs.

Gregg will outline how you could meet these demands, how you may overcome the issues, how you could set new standards for your Designer and Producer. The concept of Manufacturing in a safe environment is as old as the practice of medicine. However, Operator Environment Safety, Product Containment, Facility Cost, Equipment availability and delivery are all issues that face us today.

Paper Brief

Environmental Regulation in Ireland - from IPC to IPPC - Mr. John Feehan

This presentation will look at the background to IPC Licensing, its implementation to date and a look forward to the implications of IPPC.

The EPA is responsible for the licensing and regulation of large/complex industrial and other processes with significant polluting potential on the basis of Integrated Pollution Control (IPC), and having regard to the best available technologies for these purposes.

The Environmental Protection Agency Act, 1992, established a new institutional framework for the control of environmental pollution in Ireland.

ISA–The Instrumentation, Systems, and Automation Society

FLUOR DANIEL EEL

Meeting the Challenges within the Pharma/Bio industry, 2001

SPEAKER QUOTES

" Your demands today of producing product are greater and more complex than ever before"

" Environmental issues have become a standard feature of Due Diligence"

"You have different approaches open to you in the validation of your biotechnology facility"

"Background to IPC Licensing, its implementation to date and a look forward to the implications of IPPC"

" Operator Environment Safety, Product Containment, Facility Cost, Equipment availability and delivery are all issues that face us today"

"Speed to market and facility life cycle costs are key to a company's success as a manufacturer of medicines"

" Your environmental liabilities can be assessed as manageable business risks"

Wednesday 3rd October, 2001.
Great Southern Hotel,
Cork Airport, Ireland.

Registration will begin at 9.30am including Tea & Coffee.

10.00 **Opening Address**
Mr. Tony Mahon
(President of the ISA Ireland Section)

10.10 **Chairperson**
Mr. Donal Loughrey
(Elan Corporation)

10.15 **Containment Technologies for Pharmaceutical & Biotech Applications**
Mr. Greg Herman
(Fluor Daniel Inc. USA)

11.00 **Advantages of Plant Modular Costruction**
Mr. John Sweeney (Eli Lilly)

11.30 **Questions & Answers**

11.40 **Tea/Coffee**

11.55 **Approaches to the Validation of a Biotechnology Facility**
Mr. Trevor Deeks
(Fluor Limited UK)

12.40 **Questions & Answers**

12.50 **Lunch**

14.00 **Fluidised Bed Incineration Technology**
Ms. Laura Burke
(Indaver Ireland)

14.30 **Managing Environmental Risk - Environmental Due Diligence**
Dr. Graham Parry
(RPS England)

15.20 **Questions and Answers**

15.30 **Tea/Coffee**

15.45 **Policy Document Requirements for Future Products**
Mr. John Feehan
(EPA)

16.15 **Seminar Questions & Answers**

16.35 **Chairperson Summary**

16.45 **Close by Mr. Liam Cosgrave**
(Fluor Daniel EEL)

Speaker: Mr. Gregg Herman *(Fluor Daniel Inc. USA)*
Mr. Gregg Herman has 28 years experience in the Pharmaceutical and Biotechnology Industry Globally. He has extensive international experience in Formulation Process Development, Packaging, Process Start-up for Solid Liquid, Parenteral and Bulk Products. Mr. Gregg Herman is a well known speaker on containment technology and is a Senior Containment Specialist in the United States.

Speaker: Dr. Graham Parry *(Exec. Director, RPS Group Plc.)*
Dr. Parry is a Director of RPS Group Plc. RPS is the largest independent environmental consultancy in Europe. Dr. Parry has over 25 years experience in environmental management in the public and private sectors. For the past 12 years he has been responsible for the development of the Risk Management division of the group.

Speaker: Mr. John Sweeney *(Eli Lilly)*
Mr. John Sweeney is an IE16 Lead Automation Engineer for Eli Lilly in Co. Cork. He is a graduate of Applied Physics & Instrumentation from the Cork Institute of Technology. He is a DCS Programmer with over 14 years experience working on automation projects primarily in the pharmaceutical industry.

Speaker: Ms. Laura Burke *(Indaver Ireland)*
Graduated in Chemical Engineering from University College Dublin in 1992. In 1995 Laura joined MinChem Environmental Services Ltd as Technical Manager. MinChem export hazardous waste to Britain and the Continent for recovery or disposal. In November 1999, Indaver (a Belgian Waste Management Company) acquired a 60% shareholding in MinChem. Laura was appointed as Operations Manager of Indaver Ireland, a new company set up to implement integrated waste management in Ireland.

Speaker: Dr. Trevor Deeks *(Manager of Validation, Fluor Limited, UK)*
Dr. Deeks has 22 years experience in pharmaceutical manufacturing, development, quality assurance and validation. He is a registered pharmacist and he has experience of a wide range of validation projects which includes conducting pre-inspections and audits. Trevor joined Fluor Ltd. in November 2000 and previously held senior positions with the Washington Group, Boehringer Ingelheim and Marion Merrell Dow.

He has acted for both 'WHO' and 'UNICEF' as an auditor for suppliers of vaccines and essential drugs. He has published over 30 papers in peer reviewed journals and books including the Pharmaceutical Codex.
He has sat on a number of BSI, CEN, ISO and European Pharmacopoeia Commission expert working groups. He is a Past Chairman of the Parenteral Society and was Editor-in-Chief of the European Journal of Parenteral Sciences from 1996-2000.

Speaker: Mr. John Feehan *(EPA)*
Mr. John Feehan is based at the EPA Regional Inspectorate, at Inniscarra, Co. Cork. John joined the EPA in 1995 where he initially worked in the strategic management and policy areas before moving to the Licensing and Control Division. Graduated in Environmental Science & Technology from Sligo Institute of Technology and in Environmental Chemistry from University College Cork. He previously worked in the Pharmaceutical Manufacturing Industry for five years. John Feehan is an Inspector with the Environmental Protection Agency.

Paper Brief

Approaches to the Validation of a Biotechnology Facility - Dr. Trevor Deeks

Trevor's presentation will outline the different approaches open to you in the validation of your biotechnology facility. He will discuss the different approaches that are used and outline the factors that will influence the approach you should take. Mr. Deeks will address the regulatory considerations and his experiences gained over the years in this area.

He will use an illustrative example to outline a successful validation approach for a multi-million pound Biotechnology project.

FLUOR DANIEL EEL

International Conference

ISA Ireland Section

in association with

Fluor Daniel EEL

Meeting the Challenges within the Pharma/Bio industry, 2001.

Wednesday 3rd October, 2001.
Great Southern Hotel, Cork Airport, Ireland.

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

Costs: **ISA Member £150.00**
Non-Member £195.00 (INCLUDES ONE YEARS SUBSCRIPTION TO ISA)

Please reserve _____ place(s). I enclose a payment/cheque of £_____ made payable to ISA Ireland.

Mail completed form to:
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ISA Ireland Section,
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Cork, Ireland.
Tel: -353-21-4804612
Fax: -353-21-4346030
E-mail: info@isa.ie

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.