Developing Effective Assays for High Throughput ADME/Toxicology Studies

Friday 9th July 1999 • The Café Royal, London

Rapid changes in technology and demands of the pharmaceutical industry, drug discovery and development has undergone a revolutionary change. With an increased focus on cost-benefit in drug development, and given that a good medicine is a balance of potency, safety and PK, important concepts of PK and metabolic support are being incorporated earlier into primary and secondary assays. This 1-day conference will focus on the increased understanding of ADME and toxicology studies being undertaken and designed into screening for a better understanding and prediction of drug response.

09.00 Coffee & Registration

09.30 The Use of ADME/PK Assays as Part of a Combinatorial Approach to Lead Optimisation
Dr Peter J Eddershaw, Bioanalysis & Drug Metabolism
Glaxo Wellcome Research & Development, UK
The presentation will review the role of ADME/PK screening in early drug discovery. The basic components of ADME/PK screens will be outlined and examples presented to show how these screens can be used as part of a lead optimisation strategy. The ability to fully exploit ADME/PK data through the use of *in silico* models will also be considered.

10.15 Cytochrome P450 Screening Assays: What is the question?
Dr Els de Groene, Product Manager Molecular Pharmacology & Diagnostics
TNO Pharma, The Netherlands
Strategic choices of applying cytochrome P450 screening assays depend largely on the question to be answered. Are you seeking information about metabolic stability or the complete metabolic pattern of your potential new drugs? Are polymorphic CYP450s involved in metabolism of our drug in development? What assay should we use: microsomes, isolated enzymes, hepatocytes or CYP450 expressing cell lines?

11.00 Refreshment Break & Opportunity to Visit Exhibition

11.30 Selection & Development of Assays to Assist in the Understanding of Chemical Characteristics & Solubility
A representative from
OSI Pharmaceuticals, Inc., USA
Cell-based and *in vitro* formatted assays measuring specific disease targets have proven utility in the initial identification of bioactive compounds from large library collections. Distinct assay types measuring physicochemical, metabolic and potential toxicological parameters may be utilised in lead selection and SAR studies. A working assay will be described to illustrate general principles.

12.15 **HT PK & CYP450 Induction Protocols in Drug Discovery**
Dr David C Evans, Director, DMPK
Merck Sharp & Dohme, UK
Central registration of assay conditions, the posting of data to Oracle and the ability to view large data sets, the so called Data Life Cycle, drives Medicinal Chemistry innovation and appropriate exploration of chemical space. This has fueled the requirement for DMPK high throughput assays, which are validated, quality assured, and consistent across our research sites. HTP pharmacokinetic and CYP450 induction protocols will be presented to exemplify this point.

13.00 Lunch & Opportunity to Visit Exhibition

14.00 **Selecting Model Cell Lines**
Speaker To be confirmed

14.45 Is High Throughput Toxicology an Oxymoron?
Dr Donald Robertson, Director of Biochemical Toxicology
Parke-Davis Pharmaceutical, A Division of Warner-Lambert, USA
High throughput toxicology (HTT) assays can be broadly divided into discovery toxicology, in which toxicology end-points are used to select or reject compounds very early in the discovery process, and development toxicology where endpoints are used to characterise the compound. Advances are being made in discovery HTT while development HTT is lagging behind. This presentation will focus on the needs and requirements for HTT assays particularly from a development perspective.

15.30 Supporting Absorption Assays with Simulation Software
Dr John Rose, Senior Scientist & Programmer
Simulations Plus, Inc., USA
This presentation will cover absorption screening in discovery and supporting simulation software:

- Molecular Permeability
  - SMILES
  - GA-PLS model
  - Quantitative Molecular Permeability Relationships (QMPR Plus)
- Intestinal Absorption and PK
  - Physiochemical parameters
  - Drug formulation
  - Physiological parameters
  - GastroPLUS

16.15 End of Conference

Supporting Publications

DRUG&MARKETDEVELOPMENT

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Effective Assay Development - IT1131

Wednesday 7th – Thursday 8th July 1999 - The Café Royal, 68 Regent Street, London W1R 6EL

Assays for ADME/Tox Studies - IT1132

Friday 9th June 1999 - The Café Royal, 68 Regent Street, London W1R 6EL

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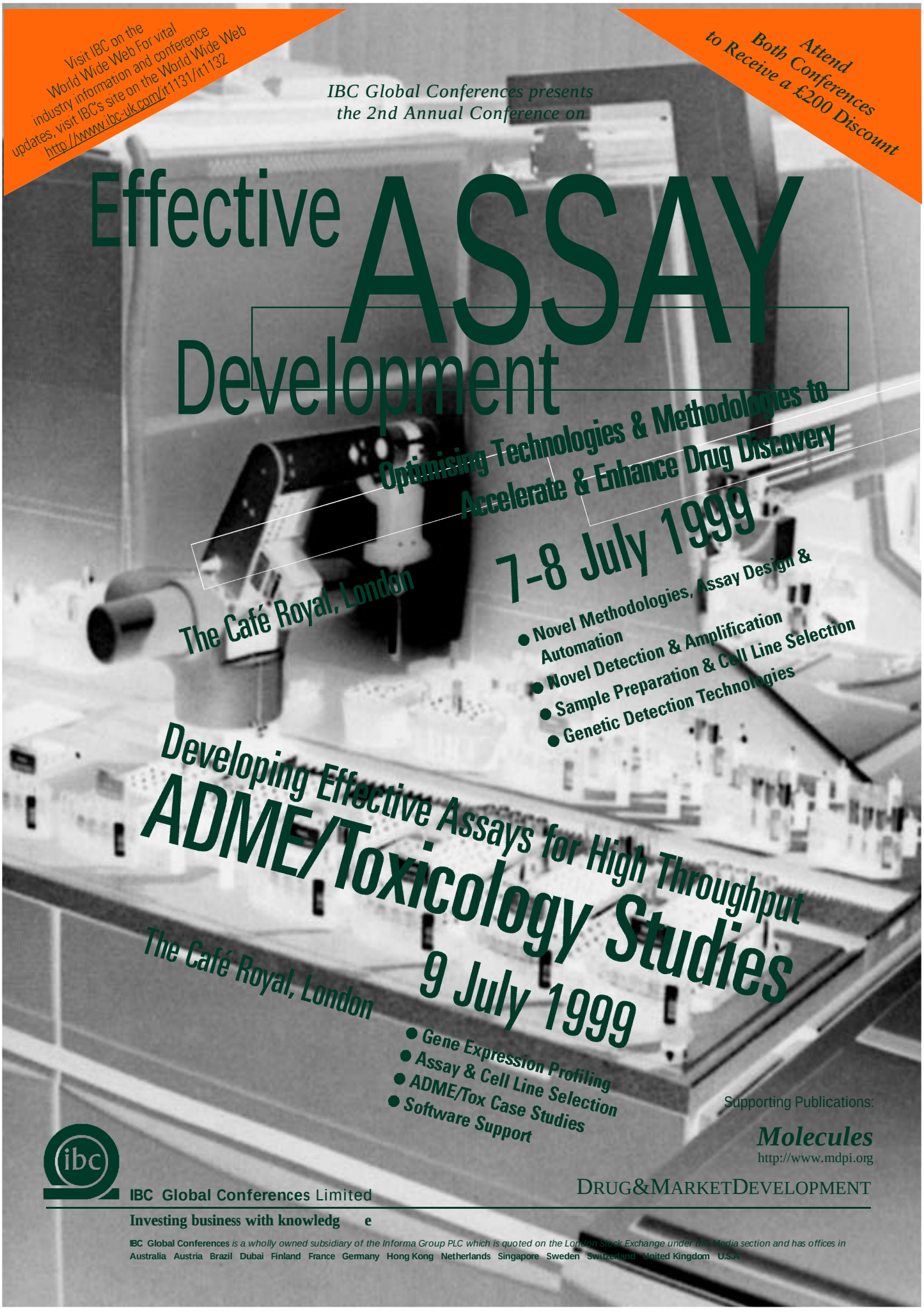
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Effective Assay Development

Optimising Technologies & Methodologies to Accelerate
& Enhance Drug Discovery

Wednesday 7th - Thursday 8th July 1999 • The Café Royal, London

The Evolution of Assay Development and Technologies

Effective and robust assay technologies have evolved quite dramatically, responding to the demand to effectively screen libraries of compounds, which are currently being generated and to screen increasing numbers of targets. The options to accelerate your assay and screening capacity means the necessity to capitalise on *novel assay technologies*, adopting *new methodologies* for current assays, increasing your investment in *miniaturisation* and *automation.*

IBC has produced the 2nd Annual conference on **"Effective Assay Development"** with the direct input of the pharmaceutical industry. We have also developed a unique Post-conference Seminar on **"Developing Effective Assays for High Throughput ADME/Toxicity Studies"** because of considerable demand from the industry. You will not only learn how to *increase throughput, decrease costs, reduce time* but also *better predict drug response* by optimising technology and methodologies in your assay and screening programmes.

Who Should Attend this European Forum

Directors, Managers, Heads, Research Scientists, CEO, CSO, Vice President, President, Business Development Managers from Departments of: Screening, High Throughput screening, Biomolecular Screening, Lead Finding, Drug Discovery, Technology & Applications, Assay Development, Cell Biology, Biochemistry, Pathology, Biosensors, Detection & Amplification, Drug Metabolism, Drug Safety, PK/PD, Molecular Toxicology, Toxicology, Pre-clinical, Information Technology & Software Development

- **SELECT** the most appropriate type of assay for the desired task
- **DETERMINE** the most favourable assay elements, based on practical design principles
- **IMPLEMENT** standardised sample preparation and treatment strategies
- **INTEGRATE** assay development in DNA arrays
- **INCORPORATE and INTEGRATE** robotics and automated components in assay and screening functions
- **UPDATE** yourself on sensitive detection and amplification developments
- **EMPLOY** miniaturised and microtechnologies to reduce reagent costs and increase throughput
- **STANDARDISE and VALIDATE** assay procedures
- **UTILISE** molecular pharmacology and toxicology in assay technology
- **SELECT** the best cell types for ADME and toxicology assays
- **DEVELOP** practical tools for the analysis and interpretation of assay data
- **APPLY** technologies in medical device, clinical diagnostic and drug discovery

Wednesday 7th July

09.00 Coffee & Registration

NOVEL METHODOLOGIES, ASSAY DESIGN & AUTOMATION

09.30 Effectively Managing Lead Discovery
Dr Bob Gordon, Director, Biotechnology & HTS
Janssen Research Foundation, Belgium
This presentation will cover:
- Lead discovery at Janssen
- Target identification and subsequent assay and HTS development
- Compound acquisition and supply to HTS
- Lead discovery using HTS and follow up by pharmacology

10.15 Novel Assay Technologies Based on Mass Spectrometry for Simultaneous Screening & Chemical Characterisation of Active Compounds
Dr Hubertus Irth, Managing Director
ScreenTec BV, The Netherlands
Modern screening technologies require the use of various analytical technologies for the assessment of structure, purity and biological activity of newly synthesized compounds. Key techniques in this area are, on the one hand, biological assays for the measurement of biological activity and, on the other hand, mass spectrometry and NMR - frequently in combination with HPLC - for structure elucidation and purification. In most screening operations, these activities are performed sequentially, often in different laboratories. This presentation will demonstrate the use of integrated biochemical detection systems where the biological assay is an integral part of an HPLC-based screening method.

11.00 Refreshment Break & Opportunity to Visit Exhibition

11.30 Development of Miniaturised LeadSeeker Assays
Speaker To be confirmed
The demand to screen increasing numbers of targets while reducing reagent costs and screening times has stimulated the pharmaceutical industry to consider assay miniaturisation. Leadseeker is a homogeneous imaging system which combines imaging instrumentation and software with new scintillant-containing particles that can be used in radioactive proximity assays. Using this system, the miniaturisation of several formats, including kinase and GPCR assays, has been accomplished. Case Studies from the industry will be presented.

12.15 Luminescent Signalling Systems for Homogeneous Assays & Immunoassays
Professor P G Sammes, Department of Chemistry
University of Surrey, UK
This presentation will cover a range of new molecular switches involving fluorescence, time-resolved luminescence and chemiluminescence that are currently being prepared. The limitations of different signalling systems present challenges and results of highly sensitive and robust signalling systems, that allow for the development of a wide range of homogenous and immunoassays will be covered.

13.00 Lunch & Opportunity to Visit Exhibition

NOVEL DETECTION & AMPLIFICATION TECHNOLOGIES

14.00 Combining Cell-based Assay & Homogeneous Time Released Fluorescence (HTRF) to Develop Relevant & Miniaturised Functional Tests for HTS
Dr Claudine Grepin, HTS/Assay Development Laboratory
Rhône Poulenc Rorer, France
The increasing demand for new leads has made high throughput screening (HTS) a key platform in drug discovery. The throughput objectives are now achieved thanks mainly to the reconfiguration of the assays in format allowing automation and miniaturisation. The Homogeneous Time Released Fluorescence (HTRF) is such a detection system which transform any type of test (kinase, ligand binding, or protein/protein interaction assays) into robust, homogeneous, sensitive, non-radioactive and cost effective tests amenable to miniaturisation. This technology, amongst others, brought quantitative changes into the screening output by increasing the number of leads generated. The central issue now, is to introduce qualitative improvements into the process in order to reduce the failure rate of a drug. Notably, this relies at the HTS level, on the accurate choice of a physiologically relevant format of test. For this purpose, we are developing several functional generic cellular tests. This new generation of format combine the robustness and the throughput of the HTRF technology with the physiological relevance and the power of the cell based-assay.

14.45 High Performance Screening Using Confocal Fluorescence Spectroscopy
Dr Sylvia Sterrer, Project Manager
Evotec BioSystems AG, Germany
We have built an automated, integrated miniaturised high throughput screening system, EVOscreen. At the heart of this system is a proprietary detection technology based on fluorescence correlation spectroscopy (FCS+plus). This novel detection technology uses confocal optics to enable the measurement of single molecules in sub-microlitre sample volumes, making it ideally suited for miniaturised, homogeneous assay formats. The system is now in routine operation using the FCS+plus detection technology for screening. This presentation will describe how conventional assays are adapted to homogeneous, miniaturised format. We will discuss the advantages of using confocal fluorescence spectroscopy for sub-microlitre assay volumes. Data from current assay development programmes will be presented to illustrate the power of FCS+plus for a variety of assays. Additionally, our efforts in the development of novel ADME/Tox assay technology will be outlined.

15.30 Refreshment Break & Opportunity to Visit Exhibition

16.00 Surface Plasmon Resonance (SPR) as a Tool in Assay Development
Dr Gunnar Brink, CEO
BioTul Bio Instruments GmbH, Germany
SPR and related techniques are widely used to determine analyte concentrations and biomolecular interaction parameters as dissociation constant or kinetic data. SPR can also be used to develop ELISAs and other assays (epitope mapping, optimising antibodies). In addition, our PLASMooN chips are also available with polystyrene and other artificial surfaces, so that SPR real time monitoring can drastically improve assay development time. Other applications of SPR include HTS target development or the use SPR in high throughput itself.

16.45 **Question and Answer Session**

17.00 **Networking Cocktail Reception**
Delegates and speakers are invited to meet in an informal setting at the end of the day in the exhibition area.

18.00 End of Day One

Thursday 8th July

09.00 Coffee

NOVEL DETECTION & AMPLIFICATION TECHNOLOGIES CONTINUED

09.30 High Information Content Screens
Dr Jeff W Paslay, Vice President, Biomolecular Assay Technologies
Cellomics, Inc., USA
The coupling of uHTS and High Content Screening (HCS) introduces a powerful new paradigm in drug discovery. It is now possible to achieve subcellular resolution of fluorescence signals from many cells in a field from a single well in 96 to 1536 microtiter plates. Multi-channel, multi-parameter analysis coupled with cross-correlation of temporal and spatial dynamics of these signals provides information rich data about compound effects on target activity. We are developing a CellChip™ System that will further miniaturise and decrease the cost of integrated uHTS and HCS.

10.15 Reagentless Assays
Professor Douglas B Kell, Director of Research, Institute of Biological Sciences
University of Wales, UK
There are a number of spectroscopic and other approaches to analysis – whether high throughput or conventional – which do not necessarily require labels. Those based on acoustic, optical, electrical and thermal exchanges with the detector system of interest fall into this category. We concentrate in particular on the direct analysis of complex biosystems using infrared and mass spectrometries.

11.00 Refreshment Break & Opportunity to Visit Exhibition

SAMPLE PREPARATION & CELL LINES

11.30 Criteria for Cell Line Selection
Dr Renate Schnitzer, Head of Screening
Boehringer Ingelheim, Austria
Cell-based assays can offer significant advantages over cell-free test systems if designed appropriately. The selection and design of cell lines for high throughput screening requires consideration of different critical parameters which will be described in more detail. Results obtained with a panel of cell-lines tested in parallel will also be presented.

12.15 Concepts of Automated Sample Preparation for Genetic Analysis
Dr Dietrich Hauffe, Senior Product Manager
Qiagen GmbH, Germany
Automating molecular biology processes is a challenge being faced by routine molecular biology facilities. Sample handling, isolation of nucleic acids, preparation of amplification and detection assays are every-day tasks, which require careful and labour-intensive manipulation of large numbers of samples.

Based on a modular system layout with integrated application procedures, we have developed the BioRobot™ systems as Molecular Biology Workstations for Genetic Analysis. The BioRobot 96O4™ is designed for the preparation of nucleic acids from cell cultures, blood, plasma, and other body fluids. Equipped with positive identification for the samples and hardware used, the system automatically isolates nucleic acids and sets up routine PCR for compatible downstream detection assays. Ready-to-run protocols have been developed and validated, and are now used in several reknowned labs across the world. Another system, the BioRobot 96OO™, complements the BioRobot 96O4™ with respect to the set-up of small-volume reaction assays, such as PCR and restriction digests. Purification of PCR products for microarray analysis are also performed by the system. All BioRobot™ systems allow complete process documentation and sample data exchange with other laboratory instruments (e.g., PaqMan, Cobas Amplicor, or automated sequencers). In this paper, we present our concept of Molecular Biology Workstations with integrated hardware, software, and chemistries.

13.00 Lunch & Opportunity to Visit Exhibition

14.00 FACS Based Whole Cell HTS Assays
Dr Alain Bernard
Serono Research Institute, Switzerland
Analysis of cell populations by flow cytometry with Fluorescence Activated Cell Sorters (FACS) is routinely performed to measure cell surface markers and/or certain types of response (changes in intracellular pH, cytosolic free Ca^{++} concentration, etc). This technology was automated to make it compatible with robotic operations based on 96-well microtitre plates. An interface was designed for the injection of the content of each individual well into the FACS instrument. The performance of the system was evaluated by measuring different population of cells and validating the results by comparison with manual analyses. This technological advance permits a new approach to drug discovery and opens the way to high throughput screening of cell attributes and responses by single cell analysis.

GENETIC DETECTION TECHNOLOGIES

14.45 A Genome Analysis Production Line
Dr Patrik Scholler
LION bioscience AG, Germany
In order to speed up the drug discovery process we have set up a genome analysis production line. We have automated crucial process steps of our proprietary strategy Directed Minimal Sequencing. The development of new software tools, including a Laboratory Information Management System and the integration of our bioinformatics platform, allows for highly efficient data production and functional genome annotation.

15.30 Validation of Genomics-Derived Drug Targets Using Yeast
Dr Christine Klein, Group Leader, Functional Genomics
Cadus Pharmaceuticals Corporation, USA
The yeast-based system for functional assay of human G protein-coupled receptors has been extended to orphan receptors. Agonists discovered for orphan GPCRs , together with expression data, have enabled the validation of receptors as viable drug targets. These agonists further provide an antagonist screen for these newly validated targets.

16.15 Refreshment Break & Opportunity to Visit Exhibition

16.45 End of Day Two