Wednesday 9 February 2005			
	Auditorium **Stream 1** **R&D**	**Presentation Room II** **Stream 2** **Marketing & Branding**	**Presentation Room III** **Stream 3** **Manufacturing, Packaging & Logistics**
07:30-08:15	Event Registration – **marcus evans** Registration Desk		
08:15-08:30	**marcus evans** Opening Address **Christian Sorensen**, Congress Director, Europe **marcus evans**		
	Welcome Address **Dr Lumir H. Krocek,** Executive Director, **CAFF (Czech Republic) Generic Association**		
08:30-09:15	Opening Keynote Presentation **INTERNATIONAL REGULATIONS AND NATIONAL RULES: HOW DO THEY WORK TOGETHER?** • Revisions of the European legislative: Impact on the package leaflet in the international and national context • Levels of changes for publicly available information on authorised products? • Changing the business process of all Competent Authorities • Addressing the activities needed to cover the requirements on a European and national level: Germany as a case study **Dr Klaus Menges,** Director, Clinical Pharmacology II, **FEDERAL INSTITUTE FOR DRUGS & MEDICAL DEVICES (BfArM)**		
09:15-10:00	Keynote Presentation Stream 1 **THE EU DIRECTIVE: IMPLICATIONS FOR CLINICAL RESEARCH, MARKET EFFICIENCY & THE QUEST FOR INNOVATION?** • The implementation of The EU Directive • Ethics, economics and global trends • The new clinical research environment • Implications for research innovation **Dr Keith Bragman,** Consulting Physician, Former Director & Head of Global Development, **UCB SA**	Keynote Presentation Stream 2 **MARKETING COMMUNICATIONS FOR PHARMA PRODUCTS:** • Optimising the effects of synergy • Integrating different marketing strategies • Communicative strategies for pharma • Sales force effectiveness **Professor Christo Kaftandjiev,** Professor, **SOFIA UNIVERSITY,** Bulgaria	Keynote Presentation Stream 3 **OUTSHINING THE REST AT BOEHRINGER-INGELHEIM, UK** • Our business • Transformation at Bracknell • Blow fill seal specialist technology • Positioning ourselves **Mark Foss,** Head of Engineering, **BOEHRINGER-INGELHEIM,**UK
10:00-10:30	**Coffee Break** **Exhibitor Meetings & Appointments**		
10:30-11:15	Case Study Presentation **ADMET FIRST IN THE SELECTION OF CANDIDATES TO DEVELOPMENT** • New approaches for candidate selection • "Classical" vs non-classical pharma • REACH and its impact on safety assessment • In Vitro Testing Industrial Platform **Dr Joan-Albert Vericat,** Pre-clinical Development Director, **NEUROPHARMA SA**	Case Study Presentation **BRINGING ORPHAN PRODUCTS TO MARKET** • Definitions of orphan & ultra orphan diseases • Why most orphan diseases lack treatment • The orphan product business model • Reviewing the challenges • Critical success factors for the launch **Leanna M. Caron,** Head, European Marketing & Business Unit, **GENZYME**	Case Study Presentation **TPM IN A PHARMA PRODUCTION PLANT** • Implementing TPM • Overcoming organisational obstacles • Change management • Dealing with cultural change **Dr Wim Mens,** Vice President Production, **NV ORGANON**

11:15-12:00	Case Study Presentation **THE NEW ROLE OF PHARMOCOVIGILANCE IN THE PHARMA INDUSTRY** • Safety representative's roles and responsibilities • The impact of Eudravigilance • Organising a pharmocovigilance department in your country **Dr Dimos Florakis,** Medical Manager, **ABBOTT LABORATORIES HELLAS SA**	Case Study Presentation **UNDERSTANDING THE CEE MARKET: GLOBAL VERSUS LOCAL MARKETING STRATEGIES** • Addressing regional differences: • What do CEE markets really look like? • Identifying trends for future development • Implementing step measures **Dr Jasmina Koeva,** Head of Marketing, **ACTAVIS**	Case Study Presentation **MANAGING COMPLIANCE IN PHARMACEUTICAL PRODUCTION** • Measuring operational compliance • Developing compliance assessment • Internal benchmarks in production • Defining site specific compliance paths **Dr Wolfgang Steven,** Head of Department Integrated Quality Management, **SCHERING AG**
12:00-13:00	**Lunch** **Exhibitor Meetings & Appointments**		
13:00-13:45	Case Study Presentation **IMPROVING CLINICAL TRIAL PERFORMANCE AT COUNTRY LEVEL** • The Success of a clinical trial? • The origin of failures or unsuccessful trials? • Decisions on clinical trials in your country? • What are the lessons for the future? **Dr John Shillingford,** Managing Director, **IMFORM GmbH**	Case Study Presentation **DTC IN THE HEALTH CARE SECTOR: A THREAT OR A HELPFUL TOOL?** • Direct To Consumer advertising • Fostering awareness of illness, or harmful in aggressive promotion of misleading claims? • Serving the patient community **Marta Wielondek,** Senior Project Manager, Sales & Marketing Effectiveness, **NOVO NORDISK REGION EUROPE A/S**	Case Study Presentation **FINDING A SOLUTION THAT BALANCES BUSINESS NEEDS, REGULATORY CRITERIA AND THE SOPHISTICATED REQUIREMENTS OF GRAPHIC ARTS** • Harmonising artwork management processes • Introducing a new artwork management system across global business • The rationale for change • Issues in introducing the new global labelling system "Gazelle" **Steven Burgess,** International Project Leader, **ASTRAZENECA**
13:45-14:30	Roundtable Panel Discussion **JOIN KEITH, JOAN-ALBERT, DIMOS AND JOHN, OUR DAY 1 SPEAKERS, TO DISCUSS THE MAIN THEMES OF TODAY'S PRESENTATIONS AND THE FUTURE OF R&D.**	Case Study **OVERCOMING REGULATORY CHALLENGES IN THE POST-ACCESSION PHARMACEUTICAL MARKET** Patent protection law & Future Medicines Legislation Increasing product launches Managing opportunities and threats in the new EU The expected contribution of CEE pharma to the EU **Radunka Cvejc,** Governmental Affairs Director, **ASTRAZENECA Poland**	Case Study Presentation **RE-ENGINEERING STRATEGIES IN THE SUPPLY CHAIN TO COPE WITH FUTURE TRENDS & CHALLENGES** • Re-visiting supply chain strategies • Streamlining our organisation • Considerations in the transition phase • Strategic responses & future action **Peter Holm Tygesen,** Vice President, Pharmaceutical Production SOE, **H. LUNDBECK A/S**
14:30-15:00	**Coffee Break** **Exhibitor Meetings & Appointments**		
15:00-15:45	Keynote Presentation **PARALLEL TRADE – DISPELLING THE MYTHS** • Separating fact from fiction • Common myths about the parallel trade industry • Price harmonisation and the value of parallel trade in the EU • Now and Beyond: The scale of parallel trade in Europe **Tomasz Dzitko,** President & CEO, **DELFARMA,** Poland & CEE Member, **EUROPEAN ASSOCIATION OF EURO-PHARMACEUTICAL COMPANIES (EAEPC)**		

15:45-16:30	Keynote Presentation **PROTECTING THE INTEGRITY OF MEDICINES TO COUNTER THE GROWING THREAT OF COUNTERFEIT MEDICINES IN THE LEGITIMATE SUPPLY CHAIN** • New and enhanced regulations & oversight by regulatory authorities • Enhanced business practices by all participants in the supply chain • The use of new technologies • Heightened diligence & increased accountability by ALL in the distribution channel **Julian Mount,** European Director of Trade, **PFIZER INC.**
16:30-18:00	Cocktail Reception – Gallery B - Upstairs

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08:30-09:15	Keynote Presentation **IP RIGHTS – POST EU ACCESSION** • Definition of IP rights • Harmonisation of IP rights with EU regulations & Directives • Extension of patent monopoly in the pharmaceutical industry **Dr Attila Mandi,** Head Industrial Property Rights Department, **EGIS Pharmaceuticals Ltd.**		
09:15-10:00	Keynote Presentation Stream 1 **BIOTECHNOLOGY IN THE CEE REGION: SPOTLIGHT ON HUNGARY** • Hungarian biotech companies • Scientific & business environment • Traditions in pharmaceutical sector • Subsidies on patenting **Erno Duda,** President, **HUNGARIAN BIOTECHNOLOGY ASSOCIATION** & President & CEO, **SOLVO BIOTECHNOLOGY**	Keynote Presentation Stream 2 **SALES FORCE EFFECTIVENESS TO SELL YOUR PRODUCT** • Re-branding of Novartis generics to Sandoz • Positioning of the corporate brand Sandoz • Key elements of the Sandoz brand • Future outlooks **Dr Arnim Jost,** Head Global Marketing & Sales Services, **SANDOZ GMBH,** Austria	Keynote Presentation Stream 3 **PHARMACEUTICAL PACKAGING - LESSONS AND FUTURE TRENDS** • Learning from history • The future environment • Implications for packaging **Dr Laura Cohen,** International Packaging Project Manager UK Operations, **ASTRAZENECA** & Chairman, **UK INSTITUTE OF PACKAGING PHARMACEUTICAL FORUM**
10:00-10:30	**Coffee Break** **Exhibitor Meetings & Appointments**		
10:30-11:15	Case Study Presentation **EXPERIENCES OF SMALL BIOTECH COMPANIES WITH BIG PHARMA IN BUSINESS DEVELOPMENT** • Identifying target companies • Development of customised strategies • Marketing strategies in drug development • Agreements & timelines for partnering **Dr Gerhard Wolff,** Director Preclinical and Clinical Development, **REVOTAR BIOPHARMACEUTICALS**	Case Study Presentation **SALES FORCE EFFECTIVENESS AT GRUNENTHAL** **Gerard Akkerhuis,** Head of Area Management Europe, **GRUNENTHAL**	Case Study Presentation **PERFORM & IMPROVE IN ORDER TO COMPLY & SAVE** • Meeting industry requests in transport • Distribution in the business chain • Balancing multiple parameters • Release your creativity **Zeljka Bilos Kovacic,** Distribution Manager, **PLIVA CROATIA LTD**

11:15-12:00	Case Study Presentation **CORPORATE LICENSING STRATEGY - PAST AND FUTURE** • Product in-licensing & launches • Reconstruction of new product franchises • Quality & training of medical representatives • Territory alliances **Takefumi Miyamoto,** Head of London Office Corporate Licensing, **TANABE SEIYAKU CO. LTD.**	Case Study Presentation **LOCALISATION VERSUS GLOBALISATION: CREATING A BRAND PERSONALITY** • Research and strong strategic planning • A clear vision of the personality of the brand • Local habits, psychology and motivation • Tradeoffs **Dr Elena Magura,** Product Manager for Ukraine & Moldova, **POLPHARMA S.A.**	Case Study Presentation **MAJOR QUALITY ISSUES 2005; FROM MANUFACTURER TO SUPPLIER** • Quality Assurance for Pharma Suppliers • A New Quality: ISO 15378 • Integrating and complimenting GMP requirements into ISO 9001 & ISO 9001:2000 **Dr Philippe Sempé**, retired Senior Manager of Supplier Assurance/Worldwide QA, **AVENTIS**
12:00-13:00	**Lunch** **Exhibitor Meetings & Appointments**		
13:00-13:45	Keynote Presentation **THERAPEUTIC INFORMATION DIRECT TO THE CITIZEN: A NEW WAY OF LOOKING AT THE PROBLEM?** • Advertising Vs. Information • Drugs Sales Online • Comparative Advertising • Therapeutic Information & Responsibility **Nuria Amarilla**, CEO, **EUROPEAN PHARMACEUTICAL LAW GROUP**		
13:45-14:30	Closing Keynote Presentation **THE CHANGING ROLE OF QUALITY MANAGEMENT** • Common misunderstandings in QM: Doing things right vs doing the right things • Learning from common audit findings to improve processes and systems in future clinical trials • Aligning QM to the drug development stage: how much of what and when? • Identifying the added value of QM and developing QM into a strategic position **Rita Hattemer-Apostel,** CEO, **VERDANDI AG,** Editor-in-Chief, **THE QUALITY ASSURANCE JOURNAL,** President, **SPAQA (Swiss Professional Association of Quality Assurance)**		
14:30-14:45	Closing Address **Dr Lumir H. Krocek,** Executive Director, **CAFF (Czech Republic) Generic Association**		