



# 16<sup>TH</sup> ANNUAL EUROMEETING PRAGUE 2004

EXPANDING HORIZONS - HOPES AND CHALLENGES

MARCH 10-12, 2004 - CONGRESS CENTRE, PRAGUE, CZECH REPUBLIC



**CD-ROMs with Synch'd PowerPoint Presentations and Audio  
or Audio CD**

**CDPP = CD-ROMs containing all available PowerPoints synched to audio**

**CD = Audio CDs**

**\* = 2 CDs/CDPPs (single item price)**

## Track 1 Drug Discovery and New Technologies

- CD  CDPP 010...Genetics and Personalised Medicine, Managing Drug Development in the Post-Genomic Era
- CD  CDPP 020...Pharmacogenomic Guided-Drug Development: Regulatory and Research Policy Perspectives
- CD  CDPP 030\*...Ensuring Diagnostic Standards for Genetically Informed Drug Development
- CD  CDPP 040...Comparability of Biotechnological/Biological Products
- CD  CDPP 050...Immunogenicity of Biotechnology-derived Therapeutic Products
- CD  CDPP 060...Biosimilar Medicinal Products
- CD  CDPP 070...Gene Therapy (*does not contain presentation by Lincoln Tsang*)

## Track 2 Clinical Trials and Therapeutic Areas

- CD  CDPP 090...  090 CNS and Neuropathic Pain Guidelines
- CD  CDPP 100...Should New Data Change the Osteoporosis Guideline? (HRT – duration of CTS)
- CD  CDPP 110...European Directive on Clinical Trials: Current Implementation Status in the 15 Member States and in the Industry – Part I - Ethical Issues
- CD  CDPP 120\*...European Directive on Clinical Trials: Current Implementation Status in the 15 Member States and in the Industry – Part II
- CD  CDPP 130...Compliance with GCP
- CD  CDPP 140...Development of Oncology Products (Part I)
- CD  CDPP 150...Development of Oncology Products (Part II)
- CD  CDPP 160\*...Telematics

## Track 3 Project Management and Outsourcing

- CD  CDPP 170...Competency Mapping and Developing High-performance Teams
- CD  CDPP 180...The Present and Future Shape of Project Management in Pharma R&D
- CD  CDPP 190\*...Knowledge Management for Clinical Teams: Identifying Training Needs
- CD  CDPP 200...Project Planner: A New Role on the Project Team
- CD  CDPP 210...Project Management Outside Product Development
- CD  CDPP 220...Project Management in the "NEW EU" – Central and Eastern Europe
- CD  CDPP 230...Outsourcing Strategies of Selecting a CRO

## Track 4 EU Regulatory Environment

- CD  CDPP 240...Centralised Procedure - the Role of Therapeutic Advisory Groups (TAG)
- CD  CDPP 250\*...Key Elements in the Regulation of the New European Medicines Legislation
- CD  CDPP 260...CPMP Scientific Advice and Protocol Assistance
- CD  CDPP 270\*...Key Elements in the Directive 2001/83/EC – Non Centrally Approved Products
- CD  CDPP 280\*...Referrals – Which Way Now?
- CD  CDPP 290...Regulatory Data Protection
- CD  CDPP 300...Variations (*does not contain presentation by Shirley Norton*)
- CD  CDPP 310...Transparency in European Procedures

## Track 5 EU Enlargement

- CD  CDPP 320\*...Regulatory Implications: From 15 to 25 Member States

- CD  CDPP 330...Centrally Approved Products: The Impact of EU Enlargement
- CD  CDPP 340...MRP: Smooth Phasing in of 10 New EU Member States
- CD  CDPP 350...Good Regulatory Practice Challenge
- CD  CDPP 360...Market Structure and Impact on Existing Products
- CD  CDPP 370\*...The Treaty of Accession, Specific Mechanism and Derogation Provisions
- CD  CDPP 380...Consequences of Implementation of EU Regulation on Promotion of Medicinal Products
- CD  CDPP 390...Implications of EU Enlargement in Conducting Clinical Trials in Europe

## Track 6 International Regulatory Issues

- CD  CDPP 400...Implementation of CTD
- CD  CDPP 410...e-CTD Implementation
- CD  CDPP 420...Partnership in Harmonisation with Non-ICH Countries/Regions
- CD  CDPP 430...Regional Cooperation in the EU Moving East

## Track 7 Statistics and Data Management

- CD  CDPP 440...Endpoints in Clinical CPMP Guidelines: Statistical Implications
- CD  CDPP 450...Current Strategies for Dealing with Missing Data in Clinical Trials
- CD  CDPP 460...Reporting Guidelines for Clinical Trials
- CD  CDPP 470...Electronic Trials and Document Management
- CD  CDPP 480\*...Statistical Consideration in the Evaluation of PK/PD Data
- CD  CDPP 500...Statistical Tools to Manage the Product Development Process
- CD  CDPP 510...Statistical and Data Management Issues in Paediatric Drug Development

## Track 8 Clinical Safety & Pharmacovigilance

- CD  CDPP 520...Clinical Safety in Clinical Trials: The New EU Directive and Guidance Documents
- CD  CDPP 530\*...New ICH Guidelines: Addendum to E2C; E2D; QT Prolongation
- CD  CDPP 540...The Pharmacovigilance at the EMEA: EudraVigilance and other Initiatives
- CD  CDPP 550...International Harmonisation of the Electronic Transmission of Individual Case Safety Reports: ICH E2BM Implementation Working Group
- CD  CDPP 560...Pharmacovigilance in the Accession Member States
- CD  CDPP 570\*...Risk Management: Various Approaches (*does not contain presentation by June Raine*)
- CD  CDPP 580...Compliance in Pharmacovigilance and Inspections
- CD  CDPP 590...Good Pharmacovigilance Practices

## Track 9 Emerging Nonclinical Issues

- CD  CDPP 600...Safety Pharmacology: ICH Update and New Approaches
- CD  CDPP 610...Immunotoxicology: ICH Update and Tricky Issues
- CD  CDPP 620\*...Animal Juvenile Toxicity Testing of Drugs Intended for the Treatment of Children
- CD  CDPP 630...First-time-in-man Studies Using Biomarker Approaches - What Does the Clinician Expect from the Toxicologist?

CD  CDPP 640\*...Quality Aspects of Toxicology Studies: The Minimisation of Drug in Control Samples

**Track 10 Quality Issues and Manufacturing**

CD  CDPP 650\*...Quality Guideline Update  
 CD  CDPP 660...Mutual Recognition Agreement  
 CD  CDPP 670...GMP Inspections  
 CD  CDPP 680...EU Certification

**Track 11 Medical Devices**

CD  CDPP 690...Classification of Devices in the EU  
 CD  CDPP 700...The Regulation of Device/Drug Combination Products – An International Comparison  
 CD  CDPP 710...Regulatory, Clinical and Statistical Considerations in Evaluating Medical Devices  
 CD  CDPP 720...Adverse Incident - Vigilance and User Reporting

**Track 12 Public Policy and Patient Access to Medicines in Europe**

CD  CDPP 730\*...Collaboration between "Health Technology Assessment" and Industry: A Way Forward  
 CD  CDPP 740...The Changing Economical Environment for Pharmaceutical Innovation and New Trends in Reimbursement Policies  
 CD  CDPP 750...Medicines Evaluation in the Real-Life Setting  
 CD  CDPP 760...EU Enlargement and Product Diversion: How to Meet the Needs of Public Health (does not contain presentation by Dermot Glynn)

**Track 13 Public Health, Patient Needs, and Orphan Drugs**

CD  CDPP 770...Patients, Science and Industry: A European Way of Promoting Research and Raising Awareness Together  
 CD  CDPP 780...From Concept to Therapy: The Influence of Patient Groups in the Research Agenda

CD  CDPP 790\*...The Challenge of Golden Standards: Clinical Trials for Rare Diseases, a Public Health Perspective

CD  CDPP 800...Policy Continuity in Orphan Drugs: From Concept to Patients  
 CD  CDPP 810...Should Patients Have a Voice in the European Health Agenda?  
 CD  CDPP 820...Access to Medicines in Developing Countries  
 CD  CDPP 830...Ignored or Informed: What Should Patients Know  
 CD  CDPP 840...Serving the Public's Health: Health Literacy and MedGuides

**Track 14 OTC/SM and Herbal Products; Generic Medicinal Products**

CD  CDPP 850...Future Legislative Framework for Non-Prescription Medicines  
 CD  CDPP 860...Future Legislative Framework for Herbal Medicinal Products  
 CD  CDPP 870...Scientific Assessment of Medicinal Plants  
 CD  CDPP 880...Food Supplements and Borderline between Medicines and Food  
 CD  CDPP 890...Generics and the Future Medicines Legislation  
 CD  CDPP 900...Implementation of Harmonised SmPCs: Policies and Strategies  
 CD  CDPP 910\*...Generics and EU Enlargement  
 CD  CDPP 920...Generics: Impact on Public Health Systems and Innovation

**Track 15 Special Populations**

CD  CDPP 930\*...Drug Development in Pregnancy  
 CD  CDPP 940...Better Medicines for Children: Not an Easy Road  
 CD  CDPP 950...Drug Development in the Aging Population  
 CD  CDPP 960...Ethical Issues in Studies with Vulnerable Populations

**When ordering, please identify program by #240310**

**BY PHONE:**

With your credit card, please call: (800) 747-8069 (U.S. only) or (818) 957-0874 8:30-4:00 PST, Mon – Fri.



**BY FAX:**

FAX your order form w/credit card information to: (818) 957-0876 (if non N. America add country and city code if applicable) 24 hours/day; 7 days/week

**ON-LINE:**

Visit our secure order site at: <http://www.softconference.com/240310>



**BY EMAIL:**

Submit your order with credit card information to: [craigm@cmcg.com](mailto:craigm@cmcg.com)

**BY MAIL:** Complete this form, with payment to: Content Management Corp., 3043 Foothill Blvd., Suite #2 La Crescenta, CA 91214, USA

**MAIL ORDER FORM**

• Audio CD.....USD \$15.00

• CD-ROM with synchronized powerpoint presentation and audio.....USD \$22.00

All CDs are covered by a lifetime guarantee, Defective audios will be replaced free-of-charge  
FREE STORAGE ALBUM WITH EACH 12 CD PURCHASE  
ALL SALES FINAL AFTER 30 DAYS, All returned audios within 30 days subject to 25% restocking fee

**We accept VISA, MC, and AMEX**

\_\_\_\_\_ Total Audio CD-ROM w/PPT selections @ \$22 ea . \$ \_\_\_\_\_

\_\_\_\_\_ Total Audio CD selections @ \$15 ea ..... \$ \_\_\_\_\_

U.S./Canada Mail & Handling: \$1/CD to \$10 max..... \$ \_\_\_\_\_

**All other Mail/Hand. - ADD \$2/CD to \$75 max..... \$ \_\_\_\_\_**

**TOTAL AMOUNT ..... \$ \_\_\_\_\_**

**ALL PRICINGS ARE USD**

VISA  MC  AMEX

Credit Card Number: \_\_\_\_\_

Exp. Date: \_\_\_\_\_

Signature: \_\_\_\_\_

**Ship to:**

Name: \_\_\_\_\_

Company: \_\_\_\_\_

Address: \_\_\_\_\_

City/State/Zip \_\_\_\_\_

Phone Number: \_\_\_\_\_

Fax Number: \_\_\_\_\_

Email address: \_\_\_\_\_