

3rd

International Congress of the Greek Local Chapter of the Controlled Release Society (CRS)

Generics, Complex Drugs,
Biotechnological
Drugs & Biosimilars:
Clinical-Nonclinical
& Regulatory Advances

Under the Auspices of



ATHENA Research & Innovation
Information Technologies

19-20
June
2017

Titania
Hotel
Athens

Final Program

www.afea.gr/crscongress



WELCOME MESSAGE

TOPICS

Dear Colleagues,

It is our privilege and special pleasure to welcome you all to the **3rd International Congress of the Greek Local Chapter of the Controlled Release Society**, in our beautiful city, Athens.

This year the program focuses on the scientific and regulatory aspects of the two main formulation categories, namely, generics and biotechnological drugs/Biosimilars. In addition, special emphasis is given to the emerging field of complex drugs.

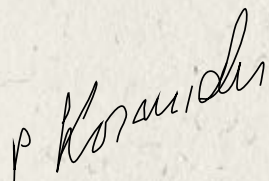
The list of topics quoted below gives a more detailed picture of the topics covered. We encourage the submission of oral or poster presentations from young scientists.

In order to guarantee the quality of future research and new practical applications, a dialogue between experienced colleagues, young scientists and professional is also encouraged.

We invite you all to actively participate!



*Emeritus Professor
Panos Macheras*
Faculty of Pharmacy
University of Athens



Paraskevas Kosmidis
Medical Oncologist
Head Department
of Medical Oncology
Hygeia Hospital Athens

GENERICs:

A. Scientific aspects of drug development and research such as dissolution and permeability studies, formulation work for conventional and modified release formulations (various routes of administration), analytical work, pharmacokinetic/pharmacodynamic and bioequivalence studies; pharmacology and clinical pharmacology work. B. Regulatory issues such as biopharmaceutic classification of drugs, biowaiver concepts, pediatric formulations, EMA and FDA guidelines, good manufacturing practice, good laboratory practice and good clinical practice.

COMPLEX DRUGs:

Scientific and regulatory aspects for polymeric micelles, glatiramoids, iron carbohydrate complexes, low molecular heparines (molecules very close to complex drugs) will be discussed.

BIOTECHNOLOGICAL DRUGS (BIOSIMILARS):

Physicochemical, immunological and regulatory aspects; clinical and non clinical work; applications in clinical practice.



COMMITTEES



Co-Chairs

Emeritus Professor Macheras Panos, University of Athens, President of the CRS Greek Local Chapter
Paraskevas Kosmidis, Medical Oncologist, Head Department of Medical Oncology, Hygeia Hospital Athens

Organizing Committee

Georgia Valsami, Past President of the CRS Chapter
Lida Kalantzi, Vice President of the CRS Chapter
Rena Christodoulou, Treasurer of the CRS Chapter
Konstantina Soulele, General Secretary of the CRS Chapter
Stavros Politis, Board member of the CRS Chapter

ORGANIZATION

ORGANIZING INSTITUTION



CRS
Greek Local Chapter

PROFESSIONAL CONGRESS ORGANIZER



Professional Congress Organizer
Likavittou 39-41, 10672 Athens, Greece
Tel: (+30) 210 3668853 Fax: (+30) 210 3643511
e-mail: crscongress@afea.gr

CONGRESS FINAL PROGRAM

Monday 19 June 2017 / Apollon Hall

Regulatory Science

Moderators: *C. Wilson - I. Klebovitch*

- 09.00-09.30** Regulatory framework and European guidelines concerning approval of medicinal products: Recent developments
Constantinos Markopoulos, *Pharmacist, MSc, PhD National Organisation For Medicines Human Medicines Assessment Section Product Assessment Division, Greece*
- 09.30-10.00** Challenges in the assessment of similarly or equivalence of non biological complex drugs
Vinod P. Shah, *Professor, Pharmaceutical Consultant; Member, NBCD Working Group, USA*
- 10.00-10.30** Reflections on quantitative criteria to assess similarity and interchangeability of complex drugs
Laszlo Endrényi, *Canada*
- 10.30-11.00** Recent developments and challenges in anti-cancer drug licensure
Konstantinos Ghirtis, *Pharmacist, PhD, MSc, MPH Expert Scientist National Organization for Medicines Product Evaluation Division Human Medicines Assessment Section, Greece*
- 11.00-11.30** **COFFEE BREAK**
- Moderators:** *L. Endrenyi - G. Digenis*
- 11.30-12.00** Health based exposure limits (including Permitted Daily Exposure) determination for use in risk identification in the manufacture of different medicinal products in shared facilities: Line - specific approach
Sofia Poulou, *Clinical Pharmacist, MSc, Greece*
- 12.00-12.30** Projection of quality by design activities to scale up and process verification
Stavros Politis, *MSc, PhD, Director Formulation Development Genepharm SA, Greece*
- 12.30-13.00** Model dependent and model independent approaches for the biopharmaceutic classification of drugs
Panos Macheras, *Emeritus Professor, University of Athens, Greece*

13.00-14.00 BREAK

Drug Delivery

Moderators: *A. Hincal - H. Blume*

- 14.00-14.30** The place of imaging in drug delivery research
Clive Wilson, *Research Professor, UK*
- 14.30-15.00** Drug delivery applications for neuroprotection: Nanoparticles, nanofibers, microparticles
Hakan Eroglu, *Assoc. Professor, Faculty Staff, Hacettepe University Faculty of Pharmacy Department of Pharmaceutical Technology Turkey*

Monday 19 June 2017 / Apollon Hall

- 15.00-15.30** Self-assembled chimeric liposomal structures. Thermodynamic and biophysical considerations
Costas Demetzos, Professor Faculty of Pharmacy, & University of Athens, Greece
- 15.30-16.00** Perivascular sustained release formulations: design and testing on two in vivo models
Ioanna Mylonaki, PhD Post-doctoral researcher Pharmaceutical Technology Dpt. University of Geneva, Switzerland
- 16.00-16.30** **COFFEE BREAK**
- Moderators:** V. Shah - P. Macheras
-
- 16.30-17.00** Multifunctional nano systems for targeted anticancer therapy
Maria Gazouli, Associate Professor of Molecular Biology Medical School National and Kapodistrian University of Athens, Greece
- 17.00-17.30** Positively charged cyclodextrins as functional drug carriers
Yannakopoulou Panagiota, Researcher A Institute of Nanoscience & Nanotechnology, NCSR "Demokritos" Aghia Paraskevi Attikis, Greece
- 17.30-18.00** Mixed and multi-compartmentalized nanosystems: Biomimetic approach of cellular structure and applications in drug delivery
Natassa Pippa, Postdoctoral Researcher, National and Kapodistrian University of Athens, Greece
- 18.00-19.30** **Opening Cerenomy - Welcome Reception**
(Foyer of Apollon Hall)

20 June 2017 / Apollon Hall

Biologics

Moderators: H. Blume - S. Kyroudi

- 09.00-09.30** Developing Biosimilar mAb: what are the critical components for clinical confidence,
Nikos Karamanos, Professor of Biochemistry and Organic Biochemical Analysis Department of Chemistry University of Patras, Greece
Sponsored by **AMGEN**
- 09.30-10.00** Challenges in pharmacokinetics assessment of biosimilarity
Henning H. Blume, Professor, University of Frankfurt, Germany
- 10.00-10.30** Humanized mouse models for preclinical testing
Ksanthi Kranidioti, M.Sc. Preclinical Senior Study director, Greece
- 10.30-11.00** **COFFEE BREAK**

20 June 2017 / Apollon Hall

Moderators: P. Macheras - M. Denis

- 11.00-11.45** Attributes that complicate drug development with orally administered monoclonal antibodies
George Digenis, Ph.D., Chief Scientific Officer, US WorldMeds Emeritus Professor, Medicinal Chemistry and Pharmaceuticals College of Pharmacy, University of Kentucky, USA
- 11.45-12.15** Cheminformatics-aided discovery of small molecules to explore new treatments for Rheumatoid Arthritis and other Chronic Inflammatory Diseases
Georgia Melagraki, MBA, PhD NovaMechanics Ltd, Greece
- 12.15-13.30** **Η αξία των καινοτόμων φαρμάκων-θεραπειών στην εποχή της οικονομικής κρίσης:**
από την πλευρά του ιατρού, **Βασίλης Μπαρμπούνης**
από την πλευρά του οικονομολόγου, **Κώστας Αθανασάκης**
από την πλευρά των ασθενών, **Λεωνίδας Φωτιάδης**
από την πλευρά του ερευνητή, **Δέσποινα Σανούδου**
από την πλευρά του νοσοκομειακού φαρμακοποιού, **Δέσποινα Μακριδάκη**
- 13.30-14.30** **BREAK**
- Moderators:** G. Valsami - V. Karalis
-
- 14.30-15.00** Nanotechnological approaches for delivery and targeting of biological drugs
Sophia Antimisiaris, Professor, Dept. of Pharmacy, University of Patras & FORTH/IEC-HT, Greece
- 15.00-15.30** The discovery of Autotaxin inhibitors as therapeutic agents for the treatment of Idiopathic pulmonary fibrosis: from bench to bedside
Vasilis Aidinis, PhD Molecular Biologist, Researcher A' Biomedical Sciences Research Center Alexander Fleming, Greece
- 15.30-16.00** Pharmacoproteomic Applications in Biomedical Research,
Martina Samiotaki, Greece

16.00-16.30 **COFFEE BREAK**

Cancer Immunotherapy in clinical oncology

Moderator: Paris Kosmidis

- 16.30-17.00** Immunotherapy and combinations in metastatic melanoma
Apostolos Laskarakis, Medical Oncologist, 1st Oncology Department, Metropolitan Hospital, Greece
- 17.00-17.30** Therapeutic applications of immunotherapy in lung cancer
Giannis Mountzios, MD, MSc, PhD Medical Oncologist 251 Airforce General Hospital Athens, Greece
- 17.30-18.00** Immunotherapy in head and neck cancer
Panagiota Oikonomopoulou, MD, PhD Medical Oncologist Scientific associate 2nd Department of Internal Medicine, Attikon University Hospital, Greece
- 18.00-18.30** Immunotherapy in urothelial and kidney cancer
Georgios Lainakis, Medical Oncologist, Medical Center, Athens, Greece

POSTER PRESENTATIONS

PP001

FORMULATION OF ATORVASTATIN CALCIUM LOADED CHITOSAN NANOPARTICLES BY NANO-SPRAY DRYING METHOD FOR SUSTAINED DRUG DELIVERY

M.K. Haidar¹, G. M. Demirbolat², E. Nemitlu³, K. Ulubayram^{4,5}, L. Öner¹, H. Eroglu¹

¹Hacettepe University, Faculty of Pharmacy, Department of Pharmaceutical Technology, 06100, Ankara, Turkey

²Gazi University, Faculty of Pharmacy, Department of Pharmaceutical Technology, 06330, Ankara, Turkey

³Hacettepe University, Faculty of Pharmacy, Department of Analytical Chemistry, 06100, Ankara, Turkey

⁴Hacettepe University Faculty of Pharmacy Department of Basic Pharmaceutical Sciences, 06100 Sıhhiye, Ankara, Turkey

⁵Hacettepe University, Institute for Graduate Studies in Science and Engineering, Bioengineering Division, 06100, Beytepe, Ankara, Turkey

PP002

DEVELOPMENT AND PHARMACOKINETIC ASSESSMENTS OF OLMESARTAN MEDOXOMIL-LOADED SELF-NANOEMULSIFYING DRUG DELIVERY SYSTEMS

Mohamed El-Gendy, Mona El-Assal, Mina Ayad, Omaira El-Gazayerly

PP003

REGULATORY ASPECTS OF BIOSIMILARS IN TURKEY – DIFFERENCES TO EMA AND FDA

Baspınar Yücel

Ege University

PP004

IMPROVEMENT OF PARTICLE SIZE AND ENTRAPMENT EFFICIENCY OF NANOCARRIERS BASED IN FLEXIBLE LIPOSOMES LOADED WITH INSULIN WITH ADDITION OF PEG-2000

Sara Melisa ARCINIEGAS RUIZ^a, Maria Josefa BERNAD BERNAD^b, Sara del Carmen CABALLERO CHACON^a, Roberto DIAZ TORRES^c, Raquel LOPEZ ARELLANO^c, and Dinorah VARGAS ESTRADA^{a,*}

^aPhysiology and Pharmacology. Veterinary Medicine Faculty. Universidad Nacional Autonoma de México (UNAM). México

^bPharmaceutical Technology. UNAM. México

^cFacultad de Estudios Superiores (FES) - Cuautitlan. UNAM. México

PP005

POPULATION PHARMACOKINETIC ANALYSIS OF INHALED FORMOTEROL IN ASTHMA PATIENTS

Konstantina Soulele¹, Panos Macheras^{1,2}, Vangelis Karalis¹

¹Department of Pharmacy, School of Health Sciences, National and Kapodistrian University of Athens, Greece

²Pharma-Informatics Unit of Research & Innovation Center ATHENA

PP006

THERMO-RESPONSIVE CHIMERIC LIPOSOMES AS INNOVATIVE DRUG NANOCARRIERS

A.Tzani¹, N.Naziris¹, N.Pippa^{1,2}, A.Meristoudi², S.Pispas², C.Demetzos^{1,*}

¹Department of Pharmacy, School of Health Sciences, National and Kapodistrian University of Athens

²Theoretical and Physical Chemistry Institute, National Hellenic Research Foundation

PP007

SPRAY DRYING OF FLAX SEEDS MUCILAGE (LINUM USITATISSIMUM)

Yana Gergjeva¹, Bissera Pilicheva^{1,2}, Plamen Katsarov^{1,2}, Margarita Kassarova^{1,2}

¹Department of Pharmaceutical sciences, Faculty of Pharmacy, Medical University-Plovdiv, Plovdiv, Bulgaria

²High-technological Center of Emergency Medicine, Plovdiv, Bulgaria

PP008

INTERACTIONS OF POLY(ETHYLENE GLYCOL-B-PHENYL OXAZOLINE) DIBLOCK COPOLYMERS WITH PROTEINS

Eleni Vlasi*, Aristeidis Papagiannopoulos and Stergios Pispas

PP009

LIPOSOMAL AND NIOSOMAL NANOCARRIERS: DIFFERENCES IN PHYSICO-CHEMICAL CHARACTERISTICS

Christina Massala#, Konstantina Zouliati#, Natassa Pippa, Costas Demetzos

Department of Pharmacy, School of Health Sciences, National and Kapodistrian University of Athens, 15784, Athens, Greece.

PP010

ROLE AND TRANSLATIONAL POTENTIAL OF HYDROGEN SULFIDE IN OBESITY

Antonia Katsouda^{1,2}, Sevasti Karaliota², Noriyuki Nagahara³, Andreas Papapetropoulos^{1,2}

¹Laboratory of Pharmacology, Faculty of Pharmacy, National and Kapodistrian University of Athens, Greece

²Center of Clinical, Experimental Surgery & Translational Research, Biomedical Research Foundation of the Academy of Athens, Greece

³Isotope Research Center, Nippon Medical School, Tokyo

PP011

POPULATION PHARMACOKINETICS OF TOTAL EZETIMIBE IN HEALTHY SUBJECTS

Eleni Rerra, Konstantina Soulele, Vangelis Karalis

Department of Pharmacy, School of Health Sciences, National and Kapodistrian University of Athens, Greece

PP012

A POPULATION PHARMACOKINETIC ANALYSIS OF LOSARTAN

Paraskevi Poulou¹, Vangelis Karalis¹

¹Department of Pharmacy, School of Health Sciences, National and Kapodistrian University of Athens, Greece

PP013

POPULATION PHARMACOKINETICS OF ORALLY ADMINISTERED HYDROCHLORTHIAZIDE

Paschalina Kasviki¹, Vangelis Karalis¹

¹Department of Pharmacy, School of Health Sciences, National and Kapodistrian University of Athens, Greece

PP014

INFLUENCE OF POLYMER CROSS-LINKING ON THE PROPERTIES OF SPRAY-DRIED CHITOSAN MICROPARTICLES LOADED WITH DOXYLAMINE AND PYRIDOXINE

Plamen Katsarov^{1,2}, Bissera Pilicheva^{1,2}, Yana Gergjeva¹, Margarita Kassarova^{1,2}

¹Department of Pharmaceutical sciences, Faculty of Pharmacy, Medical University-Plovdiv, Plovdiv, Bulgaria

²High-technological Center of Emergency Medicine, Plovdiv, Bulgaria

PP015

ANTIOXIDANT PROPERTIES OF SPRAY-DRIED LEAF EXTRACT OF BETULA PENDULA ROTH

Dimitar Penkov^{1,2}, Velichka Andonova^{1,2}, Margarita Kassarova^{1,2}

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²High-technological Center of Emergency Medicine, Plovdiv, Bulgaria

PP016

A TRIPHENYLPHOSPHONIUM-FUNCTIONALIZED MITOTROPIC NANOCARRIER FOR EFFICIENT CO-DELIVERY OF DOXORUBICIN AND CHLOROQUINE

Katerina N. Panagiotaki¹, Zili Sideratou¹, Spiros Vlahopoulos², Maria Paravatou-Petsotas³, Dimitris Tsiourvas¹

¹Institute of Nanoscience and Nanotechnology, NCSR "Demokritos", Greece

²First Department of Pediatrics, National and Kapodistrian University of Athens, Horemeio Research Laboratory, Greece

³Institute of Nuclear and Radiological Sciences and Technology Energy and Safety, NCSR "Demokritos", Greece

PP017

POPULATION PHARMACOKINETICS OF INHALED BUDESONIDE IN ASTHMA PATIENTS

Konstantina Soulele¹, Panos Macheras^{1,2}, Vangelis Karalis¹

¹Department of Pharmacy, School of Health Sciences, National and Kapodistrian University of Athens, Greece

²Pharma-Informatics Unit of Research & Innovation Center ATHENA

PP018

THE CONTRIBUTION OF AMPHIPHILIC AND PH-SENSITIVE DIBLOCK COPOLYMERS IN THE DEVELOPMENT OF FUNCTIONALIZED DRUG DELIVERY NANOSYSTEMS

N. Naziris¹, N. Pippa^{1,2}, V. Chrysostomou², S. Pispas², C. Demetzos^{1,*}, M. Libera³, B. Trzebicka³

¹Department of Pharmacy, School of Health Sciences, National and Kapodistrian University of Athens, 15784, Athens, Greece.

²Theoretical and Physical Chemistry Institute, National Hellenic Research Foundation, 48 Vasileos Constantinou Avenue 11635, Athens, Greece

³Centre of Polymer and Carbon Materials, Polish Academy of Sciences, ul. M. Curie-Sklodowskiej 34 41-819, Zabrze, Poland

PP019

PREPARATION OF PH-INDEPENDENT EXTENDED RELEASE MATRIX TABLET OF PROPRANOLOL HYDROCHLORIDE

Israa H. Al-Ani

Faculty of Pharmacy and medical Science, Al-Ahliyya Amman University, Amman – Jordan

PP020

DESIGN, PREPARATION AND EVALUATION OF CHIMERIC PH-SENSITIVE LIPOSOMES INCORPORATINGDIMETHOXYCURCUMIN

Maria Chountoulesi¹, Nikolaos Naziris¹, Natassa Pippa^{1,2}, Anastasia Meristoudi², Stergios Pispas², Costas Demetzos¹, (*)

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PP021

THERMAL ANALYSIS AND EVALUATION OF LIPOSOMAL SYSTEMS AND CLASSIC SOLID-STATE PHARMACEUTICAL EXCIPIENTS WITH FUROSEMIDE

Aimilia Kyrili¹, Angeliki Siamidi¹, Natassa Pippa^{1,2}, Stergios Pispas², Costas Demetzos¹, Vangelis Karalis¹, Marilena Vlachou¹

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PP023

OH-IRMOF-16 as potential drug carrier for gemcitabine delivery. A DFT study.

Marianna Koizabasaki¹, Emmanuel Klontzas¹ and George E. Froudakis^{1,*}

¹Department of Chemistry, University of Crete, Vasilika Vouton, Iraklion 71003, Crete, Greece

PP024

CHEMOINFORMATICS APPROACHES FOR THE DISCOVERY OF PAN-VIRAL INHIBITORS

A. Afantitis, A. Tsoumanis, G. Melagraki

NovaMechanics Ltd, Nicosia Cyprus



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Η ΑΝΤΙΜΕΤΩΠΙΣΗ
ΤΩΝ ΜΕΓΑΛΥΤΕΡΩΝ
ΠΡΟΚΛΗΣΕΩΝ ΣΤΟΝ ΤΟΜΕΑ
ΤΗΣ ΥΓΕΙΑΣ ΜΑΣ ΑΦΟΡΑ
ΟΛΟΥΣ

Για το λόγο αυτό, συνδυάζοντας το πνεύμα της βιοτεχνολογίας με τη δύναμη μιας επιτυχημένης φαρμακευτικής εταιρείας, εφαρμόζουμε νέες, καινοτόμες και στοχευμένες προσεγγίσεις που μπορούν να κάνουν ουσιαστική διαφορά.

Για όλους εμάς στη βιοφαρμακευτική εταιρεία AbbVie, το να συνεισφέρουμε θετικά στις ζωές των ανθρώπων και στη βιωσιμότητα του συστήματος υγείας είναι κάτι περισσότερο από υπόσχεση. Είναι ο σκοπός μας.

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- 10+ Προγράμματα σε Φάση III σχετικά με την Ιολογία, τη Νευρολογία, την Ανοσολογία, τη Γυναικολογία και τις Μεταβολικές παθήσεις, την Ογκολογία και την Αιματολογία

ΑΝΑΜΕΣΑ ΣΤΙΣ ΠΙΟ ΑΞΙΟΛΟΓΕΣ
ΕΤΑΙΡΕΙΕΣ ΣΤΟΝ ΚΟΣΜΟ

1η θέση στο διαγωνισμό **Best Workplaces 2015 & 2017**,
2η θέση το 2016 στην κατηγορία των εταιρειών με
50-250 εργαζομένους

Great Place To Work Institute

2η θέση στη λίστα των φαρμακευτικών εταιρειών με
την καλύτερη εταιρική φήμη παγκοσμίως, σύμφωνα
με τις απόψεις των ασθενών

PatientView

8η θέση στις πιο αξιόλογες εταιρείες στον κλάδο των
φαρμακευτικών προϊόντων

Fortune Magazine

Ανάμεσα στα 5 κορυφαία brands παγκοσμίως

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- ΝΕΥΡΟΛΟΓΙΑ



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GENERAL INFORMATION

CONGRESS SECRETARIAT

The Congress Secretariat is located at the foyer of Apollon Hall during the following days and hours.

Hours of Operation

Monday, June 19, 2017	08:00 - 19:30
Tuesday, June 20, 2017	08:30 - 18:00

CONGRESS VENUE

Titania Hotel

Panepistimiou 52, Athens 106 78 - Greece

Tel: +30.210-33.26.000 - Fax: +30.210-33.00.700

web: www.titania.gr / e-mail: titania@titania.gr

LECTURE HALL

Apollon Hall (Level +1)

CONGRESS MATERIAL

Badges & Congress material can be provided by the Congress Secretariat. The badges are absolutely necessary for the admission and access to the Congress Hall.

INTERNET ACCESS

Wireless Internet access is provided free of charge. Participants may use their own laptops.

LOST & FOUND

For lost & found items, please contact the Congress Secretariat.

CERTIFICATE OF ATTENDANCE

A Certificate of Attendance will be available for all registered participants at the Congress Secretariat, on Tuesday, June 20th.

OFFICIAL LANGUAGE

The Congress' official language is English. No interpretation will be provided.

COFFEE BREAKS

Coffee is offered to all registered participants according to the time schedule announced in the Program.

Important Dates:

Opening Ceremony - Welcome Reception: **19 June, 2017**



REGISTRATIONS

Registration Fee

Registration Categories	On-site
Participants	90 €
Industry	120 €
Students	30 €
Postgraduate Students	50 €

Registration Fee includes:

- Attendance of the Scientific Program
- Participation to the Opening Ceremony, Welcome Reception
- Congress material
- Certificate of Attendance
- Coffee Breaks

DESTINATION INFORMATION

THE CITY OF ATHENS

Athens - The city of mythology and modernity, the city of history and vision. Each year, more and more travelers are choosing Athens for their leisure and business travel all year round. There are several reasons; Athens offers a variety of things to see and do, and most of the times, under favorable weather conditions. Athens is considered one of Europe's safest capitals; its transportation network is userfriendly; there are numerous museums and archeological sites and hundreds of restaurants to satisfy every taste. Surrounded by a lining of stunning seas and mountains, Athens is filled with gems just waiting to be discovered. Located at the crossroads of three continents, the capital of Greece with an overall population of close to four million has often been the hub of many cultures. Characterized by a culture and people that are welcoming and hospitable, every visitor just feels at home. Athens takes the fuss out of sightseeing. Athens is an ideal congress destination, combining state-of-the-art infrastructure, excellent conference facilities and easy access from all over the world with world-class cultural attractions, modern amenities, diverse entertainment and natural beauty. In addition, most hotels in Athens underwent extensive renovation in preparation of the 2004 Olympic Games, a great benefit for contemporary visitors that can enjoy comfortable and stylish accommodation.

From the Airport: The airport is easily accessible from MAICC and the city centre via motorway, express bus or metro. An average journey by taxi from the airport to the city centre should take approximately 40-50 minutes, depending on traffic, costing around € 25-30. The express bus line X95 (direction "Syntagma") serves Athens city centre & MAICC. The metro line 3 runs every 10 minutes from the airport and the trip to "Megaro Mousikis" station takes approximately 30 minutes.

TRAVELLING IN & AROUND ATHENS

The Athens public transportation network offers a wide variety of routes, combining many different means, namely the metro, railway, buses, trolley buses and trams. With a 1,40 € ticket anyone can move around using one or more means of transport within 1 hour and 30 minutes. Tickets are available at all metro and train stations as well as at the kiosks on the streets. Day or weekly tickets are also available offering public transport at a discounted rate. When travelling on the bus, metro, railway and tram, passengers are

required to validate their tickets after purchasing them and before boarding (metro, tram) or on board (busses etc). The fine for a nonvalidated ticket in Athens is 40 times its value. The validation machines in the buses and trolley buses are orange boxes. On the metro, the boxes are in the station lobby and on the tram, there are beige boxes located on the platform and inside the car Integrated Ticket: 1,40 € (valid for multiple trips on all public transport options, in urban zone - buses, trolleys, tram, metro, suburban railway-, in any direction for up to 90 minutes).

- One Way Ticket: **1.40 €**
- Airport Express Bus Lines Ticket: **5 €** (valid only for one trip from or to the airport)
- Airport Metro And Suburban Railway Ticket: **10 €** (valid only for one trip from or to the airport)
- Day ticket: **4 €** (valid for all means of public transport for 24 hours)
- Weekly ticket: **14 €** (valid for all means of public transport for 7 days)

CURRENCY & BANKING

Greece is a full member of the European Union since 1981 and its currency is the Euro (€). All major credit cards are widely accepted in Greece. ATMs and Exchange Offices are widely available. Foreign currency may be exchanged to Euros at most Greek and foreign banks and at exchange bureaus located in the city centre. Travelers are kindly requested to bring their passport when exchanging money as they will need it for the transaction. Traveler's checks and credit cards issued by major companies are also widely recognized and an accepted means of purchasing items in Athens. Banks are open to the public, Monday through Thursday 08:00 to 14:30 and Friday 08:00 to 14:00, except for public holidays. ATM's can be found almost everywhere.

SIGHTSEEING

Athens takes the fuss of sightseeing. It is a user-friendly town thanks to the pleasant demeanor of the English speaking Athenians and the easy to use and manageable transportation system. The visitor can see a lot in one day. Archaeological Sites & Classical Greek, Byzantine & Ottoman Monuments, Museums, Art Galleries, street performances, festivals and many other attractions. Needless to say, the Acropolis remains a "must see" ... There is a special ticket package at the price of € 12 with which the visitor can visit almost all archaeological sites within the Athens City

Center, namely:

- The Acropolis of Athens (The Museum is not included)
- The Ancient Agora
- Kerameikos
- The North slope of Acropolis
- Olympeion
- The Roman Agora
- The South Slope of Acropolis

This special ticket package can be bought at the entrance of each one of the above mentioned archaeological sites.

SHOPPING

Shopping in Athens can be fascinating and satisfying experience for all. There are many well-known international name brand outlets and traditional Greek art and folklore shops. The visitor must make sure to stop in at least one of the many wonderful year-round outdoor cafes and restaurants in order to make his experience of shopping in the Athenian way, complete!

Shopping Hours:

Major outlets:

Monday - Friday
Saturday

09:00 to 21:00
09:00 to 18:00

Other Shops:

Monday, Wednesday & Saturday
Tuesday, Thursday & Friday

09:00 to 15:30
09:00 to 20:30



INSURANCE & LIABILITY

The Organizers accept no liability for any personal injury, loss or damage of property or additional expenses incurred to Conference participants either during the Conference or as result of delays, strikes or any other circumstances. Participants are requested to make their own arrangements with respect to health and travel insurance.

ELECTRICITY

The electricity current in Greece is **220v, 50Hz** and the socket type is European Standard.

HEALTH

Public hospitals work on a rotation basis with regards to dealing with emergency incidents. To find out which hospitals are open for emergency incidents at a specific time, dial 14944. Treatment in public hospitals is free of charge.

RESTAURANTS

Restaurants and taverns are normally open for lunch from **12.30hrs** to **16.00hrs**, for dinner from 19.00hrs to midnight. Fast food and Souvlaki shops usually serve food all day long, and some of them stay open till late at night. Cafes and Bars are open all day long until late at night.

TIPPING

Tipping is not compulsory, but it is quite usual in Greece.

MOBILE PHONES

Please note that mobile phones must be switched off during all sessions.

SMOKING POLICY

Starting from July 1st 2009 smoking is prohibited by the law at all indoor public areas in Greece.

WEATHER

The average daytime temperature in June can vary between 22°C and 29°C.

EMERGENCY PHONE NUMBERS

Ambulance	166	Fire Brigade	199
Hospitals	14944	Athens International Airport	210 3530000
Pharmacies on duty	14944	Poisoning Treatment Centre	210 7793777
Police	100	SOS Doctors	1016
Telephone Directory Service	11888	Tourist Police	71
European Emergency Number	112		

TELECOMMUNICATIONS

The international access code for Greece is +30 and for Athens 210. The outgoing code is 00 followed by the relevant country code.

TIME

Greece is two hours ahead of Greenwich Mean Time GMT+2
Greece 12:00 - London 10:00 - New York 05:00 - Sydney 20:00



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Founded in 1998, İDE is a fully integrated "Contract Research & Service Organization" (CSO) which offers a comprehensive range of Regulatory and Scientific Consultancy and Bioavailability (BA)/Bioequivalence (BE), PDE/ADE services in compliance with applicable guidelines and regulations on a truly international basis with complete secrecy policy.

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SERVICES

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- General regulatory affairs services (CTD and variation dossier preparations, SPC&PIL update) for pharmaceutical, biotechnology, biosimilar, veterinary, medical device and orphan products
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- Prioritize Application for new drug and orphan drug submissions to TITCK
- Preparation of expert reports, renewals, variations, SmPC, PIL and Labeling
- Scientific consultancy and training
- Formulation development consultancy
- Reference product procurement
- Dissolution investigations
- Bioequivalence investigations
- Therapeutic equivalence for pharmaceutical and biosimilar products
- Biowaiver dossier preparation
- Cosmetic and medical device applications
- Ministerial follow-up services

OUR NEW SERVICES

- Extractables and Leachables Consultancy
- Permitted Daily Exposure (PDE) Calculation Evaluation Report
- Acceptable Daily Exposure (ADE) Calculation Evaluation Report
- Environmental Risk Assessment (ERA) Report
- Occupational Exposure Limits (OEL) Report
- Health Vigilance Protocols
- Elemental Impurities
- Phase 1 Trials

REFERENCES

Abdi İbrahim, Acdima Biocenter, Alexion, Amgen, Astrazeneca, Avis, AZBiopharm, Azierta, Bayer, Bial, Biofarma, Boehringer Ingelheim, Celgene, Cinnagen, Deva, Eisai, Centurion, Generica, İlsar, İ.E. Ulagay, İlko, Julphar, Koçak Farma, Krebs, Leo Pharma, Meditera, Meditop, Neutec, Onko Koçsel, PharmActive, PharmaVision, Recordati, Sanovel, Santa Farma, Takeda, Vem İlaç, Vetal Serum, World Medicine, Zentiva.

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