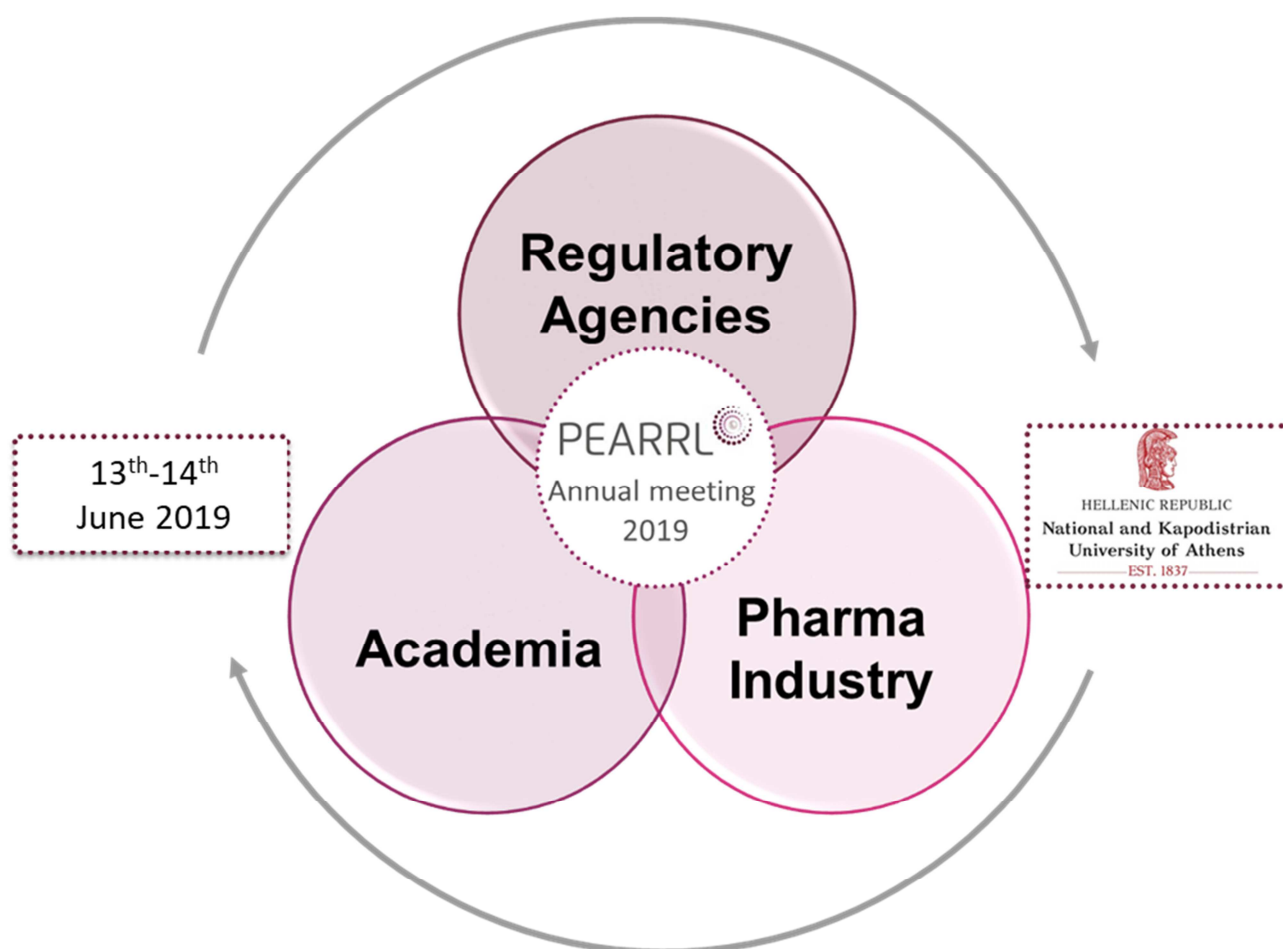


3rd PEARRL Annual Open Scientific Symposium

Model Informed Drug Development



13th – 14th June 2019

National and Kapodistrian University of Athens,
Department of Pharmacy, Greece

<http://www.pearrl.eu/rss2019.html>

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Programme

H2020 ITN	PEARRL project (no.674909) https://www.pearrl.eu/am2019.html
Date	13 th – 14 th June 2019
Theme of Annual meeting	Model Informed Drug Development
Schedule	<p>Day 1</p> <p>Session I – Drug discovery / development interface</p> <p>Session II: Model informed pre-clinical development</p> <p>Day 2</p> <p>Session III: Model informed Clinical Pharmaceutical Development</p> <p>Session IV: Emerging trends in pharmaceutical product lifecycle management</p>
Networking events	<p>Day 1 Pls and speakers dinner</p> <p>Day 2 Pls, Speakers and ESRs dinner</p>
Location	Athens, Greece
Address	National and Kapodistrian University of Athens, Main Building, Panepistimiou 30, 10679 Athens
Wi-Fi access	EDUROAM access available / Additional Username & Password will be provided on site

Welcome Note

Dear participant,

Welcome to the 3rd PEARRL Annual Open Scientific Symposium!

Following to the previous two very successful meetings in Cork (2017) and Frankfurt (2018) we hope you will also enjoy our 2019 meeting in Athens.



Frankfurt 2018 PEARRL Open Scientific Symposium

With the help of our coordinator (Brendan Griffin), WP1 leader (Martin Kuentz) and WP3 leader (Jennifer Dressman), we have tried to put together an exciting program both from the scientific and networking points of view. In particular, the external invited speakers for our open two-day symposium are among the top scientists in the field of oral drug product development at least in Europe. We would like to thank them all for their kind contribution. We would also like to thank the National and Kapodistrian University of Athens and Pharmathen S.A. for their support.

We hope you will all enjoy your stay in Athens!

Christos Reppas and Maria Vertzoni

About Athens



Sightseeing

Athens takes the fuss out 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 Monuments, Byzantine Monuments & Ottoman Monuments, Museums, Art Galleries, street performances, festivals. Needless to say, The Acropolis remains a "must see"...

You may explore Athens [here](#)



Getting around

A state-of-the-art metro system, wide avenues, an efficient public transportation system and a compact city center, all make moving around Athens easy and convenient. The Athens transportation network now includes new buses, pollution-free trolleys, tram and a revamped electric railway system that connects to two metro lines. Piraeus's port, in short distance from the Athens city center, serves national and international sea lines. The modern highways make driving to and from the city, a pleasant experience.

Gastronomy

Gourmet and traditional Greek cuisine, in the past decade, has become one of the most popular in the world as it has been proven to provide a flavourful healthy and balanced diet. Culinary aficionados are encouraged to delight in the myriad of sophisticated restaurants that boast tastes and interiors inspired from all parts of the world. The local and traditional outdoor seaside taverns and cafes are plentiful and a cultural mainstay.

Shopping

Shopping in Athens - a showcase for its traditional and modern culture and lifestyle - can be a fascinating and satisfying experience for all. Amidst the many well-known international name brand outposts and traditional Greek art and folklore shops, are hundreds of chic boutiques and specialty stores blossoming with great fashion finds for every taste and budget. Make sure to stop in at one of the many wonderful year-round outdoor cafés and restaurants to make your experience of shopping in the Athenian way, complete!

Sea & Sun

Athens is the only European city surrounded by pristine beaches, where you can swim for many months during the year. Visit a beach in Athens and you are likely to feel like you're on a Greek island, as you are greeted with stretches of crystal sands, fine pebbles and breathtaking, blue clean waters. Some beaches boast barren rocks and cliffs that carve caves and coves you can explore. Other beaches have floating bars, music and seaside spas, while others are secluded for romance. Most offer beach amenities, such as lounge chairs, umbrellas, lifeguards, fun playgrounds, restaurants and water sports for all ages.

In Athens, enjoying a sunset stroll or a seaside meal is a part of daily life. Walk on the many Athenian esplanades lined by tropical palm trees. Beach hopping is made possible by the new tramway. Hop-in from the center of Athens and watch the sunset over the Saronic Gulf.

Athens City Facts

Weather: Athens is an ideal year-round destination with comfortable and favourable climate conditions for travel and sightseeing. Rainfall is minimal and the summers (June through August) are dry and hot with temperatures ranging, on average, from 78° to 94°F or 20° to 34°C. The Mediterranean climate makes for mild winters and even milder autumns in low-lying areas, with the coldest temperatures reported in January at a very temperate 41° to 55° F or 5° to 13°C.

Language: Most Athenians speak English and those in the hospitality industry are likely to speak French and German too. Signage, menus and transportation signs are written in Greek and English.

Currency: Euro €

Shopping Hours: Major outlets Monday-Friday. 9:00-21:00; small shops Monday, Wednesday 9:00 to 15:30; Friday, 9:00 to 20:30; Saturday 9:00 to 15:30.

The airport: The new award winning Athens International Airport, Eleftherios Venizelos, serves 83 international destinations. Its close proximity to the city centre, 30 minutes by car and 40 minutes by train, makes Athens easily accessible.

For more information, you may visit the official site of the [Athens International Airport](http://www.athens-airport.gr/)

Transportation: Network includes new buses, pollution-free trolleys, tram and a revamped electric railway system that connects to the metro lines. Taxis are inexpensive by European standards.

More information can found here http://www.stasy.gr/index.php?id=1&no_cache=1&L=1

Hotels recommended by the Organizers

Titania Hotel

52, Panepistimiou Ave., Athens, 10678, Greece

<http://www.titania.gr/>

Room prices: 130-160 €/night

350 m from the National and Kapodistrian University of Athens (main building), 4 min walking distance. The hotel is 300 m from Panepistimio metro station and 12 minutes walk from Syntagma metro station.

Ilisia Hotel

25, Mihalakopoulou St., Athens, 11528, Greece

<http://www.ilisiahotel.gr/>

Room prices: 100-110€/night

We would be happy to make the reservation for you at a special rate for PEARRLers (80€, breakfast and all taxes are included). Please send us your full name, preferred room (single or double), check in and check out dates and we will book the room for you (vertzoni@pharm.uoa.gr).

2.5 km from the National and Kapodistrian University of Athens (main building), 10 min metro ride from Megaro Mousikis metro station.



Location of Venue

Monday 10th June through Thursday 13th June

National and Kapodistrian University of Athens (main building),
Argyriadis Lecture Room

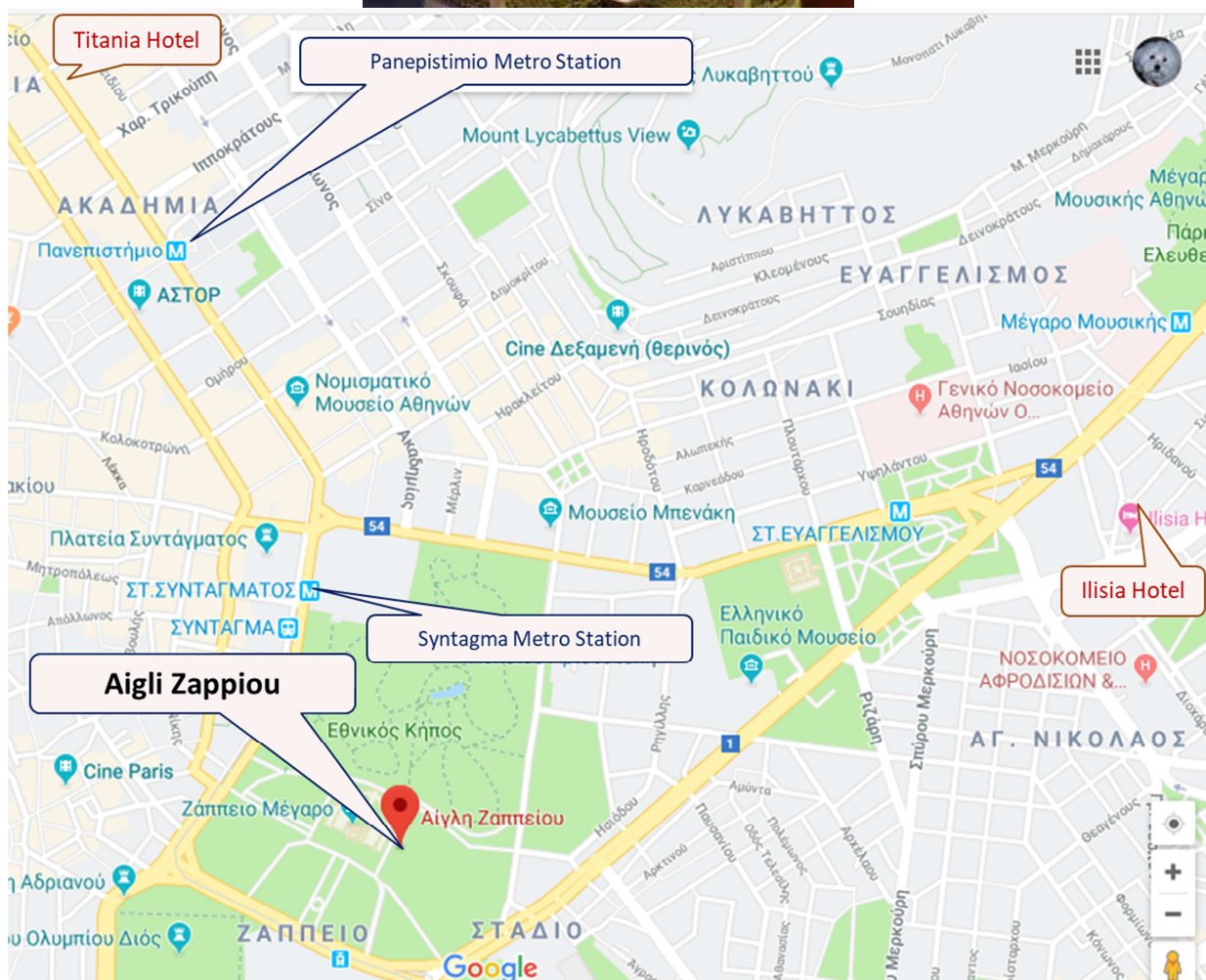
Address: Panepistimiou 30, 10679 Athens



PEARRL Dinner | Speakers and Pls

Tuesday, 11th June 2019 || 20:00

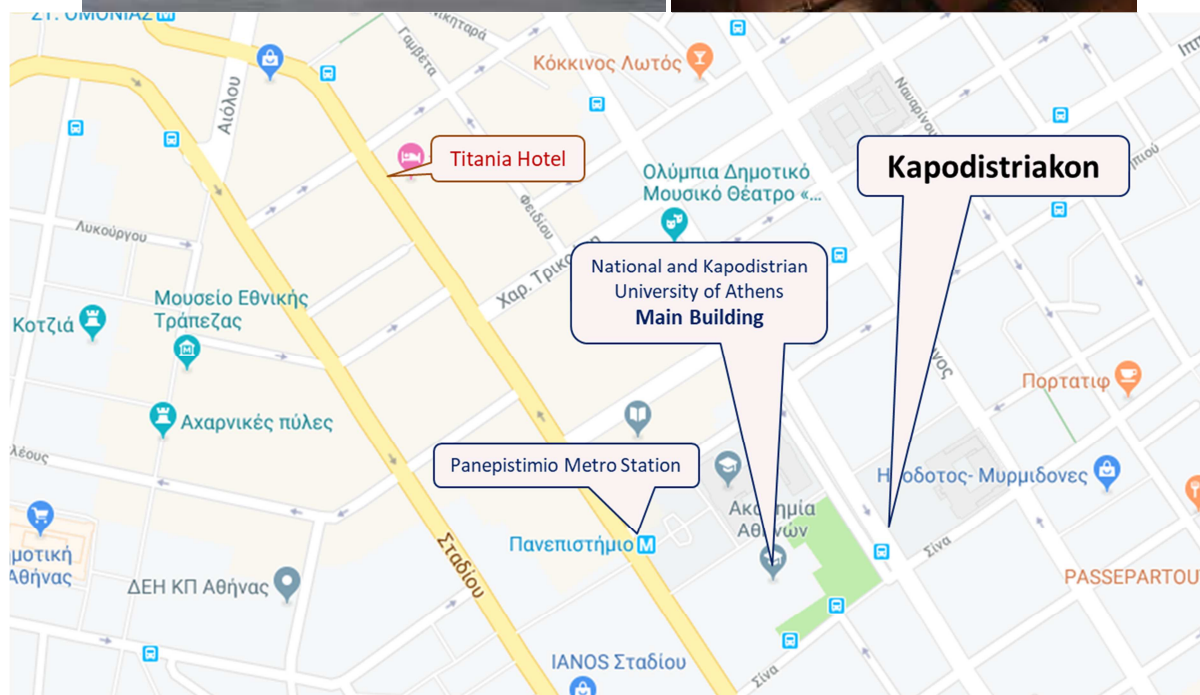
Aigli Zappiou, Zappion, Athens 105 57, Tel 2103369364, www.aeglizappiou.gr



PEARRL Symposium Dinner | Speakers, Pls and ESRs

Wednesday, 12th June 2019 || 20:00

Kapodistriakon Restaurant, Kostis Palamas Building, Akadimias 48, Athens 106 79, Tel 21 0368 8711,
<https://www.facebook.com/EstiatorioToKapodistriakoKterioKostesPalamas>



PEARRL Consortium Participants list

#	Short name	Organisation	Name(s)	Attendance checklist				
				Day 1 10 th	Day 2 11 th	Day 3 12 th	Day 4 13 th	Day 5 14 th
B1	UCC	University College Cork	Brendan Griffin					
			Caitriona O'Driscoll					
			Niklas Köhl (ESR1)					
B2	JWGU	Johann Wolfgang Goethe University	Jennifer Dressman					
			Edmund Kostewicz					
			Chara Litou (ESR6)					
			Rafael Paraiso (ESR8)					
			Ioannis Loisios-Konstantinidis (ESR13)					
B3	UoA	National and Kapodistrian University of Athens	Christos Reppas					
			Mira Symillides					
			Maria Vertzoni					
			Christina Pentafragka (ESR7)					
			Marina Statelova (ESR11)					
B4	UBAH	University of Bath	Nikoletta Fotaki					
			Mariana Guimarães (ESR12)					
			Angela Effinger (ESR15)					
B5	FHNW	University of Applied Sciences and Arts Northwestern Switzerland	Martin Kuentz					
			Georgios Imanidis					
			Felix Ditzinger (ESR2)					
			Sandra Jankovic (ESR5)					
B7	Merck	Merck KGaA	Anita Nair					
			Christoph Saal					
			Daniel Price (ESR3)					
B9	Pharmaten	PHARMATHEN SA	Lida Kalantzi					
			Georgia Tsakiridou (ESR4)					
B10	Sirius	Sirius Analytical	Karl Box					
			Patrick O'Dwyer (ESR10)					
B11	Janssen	Janssen	Rene Holm					
			Roxana Ilie (ESR14)					

#	Short name	Organisation	Name(s)	Attendance checklist				
				Day 1 10 th	Day 2 11 th	Day 3 12 th	Day 4 13 th	Day 5 14 th
P1	BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte	Jobst Limberg					
P5	ACCEL	accelopment AG	Jeanette Müller					
P6	BioREL	Biorelevant.com Ltd. (BioRel)	Daryl Leigh					
P7	UCB	UCB Biopharma SPRL (UCB)	Pascal Somville					
P10	Pfizer	Pfizer Ltd.	Mark McAllister					
S1		University of Pavia	Carla Caramella					

Invited Speakers



Dr. Bertil Abrahamsson
AstraZeneca R&D
Mölndal, Sweden



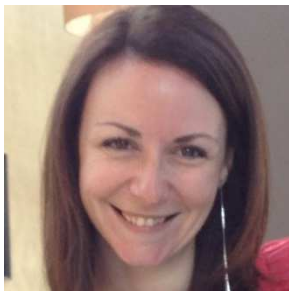
Apostolis Aivaliotis
Pharmathen S.A.
Marousi Attica, Greece



Dr. Jochem Alsenz
F. Hoffmann- La Roche
Ltd. Basel, Switzerland



Dr. James Butler
GlaxoSmithKline
Ware, UK



Sandy Van Hemelryck
Janssen Pharmaceutica
Belgium



Dr. Masoud Jamei
Certara
United Kingdom



**Dr. Essam Ahmed
Ghazaly Kerwash** The
Medicines and
Healthcare Products
Regulatory Agency
(MHRA), United Kingdom



Ian Flawn Orpana
Verto Pharma AB, SE



Neil John Parrott
F. Hoffmann- La Roche
Ltd., Basel, CH



Dr. Christian Wagner
Merck Group
Darmstadt, Germany

Day 1 – 12th June 2019

Open scientific symposium on Model Informed Drug Development

Theme: Lead optimisation through to pre-clinical development

Time	Topic	Speaker	Presentation Title
08:30	Registration		
08:45	Welcome address	C. Reppas B. Griffin	PEARRL
Session I – Drug discovery/development interface Chair: B. Griffin, UCC			
09:00	Pharmaceutical Profiling	Jennifer Dressman (UGoethe, Germany)	Pharmaceutical Profiling in the pharmaceutical industry
09:45	Drug candidate lead optimisation	Martin Kuentz (FHNW, Switzerland)	Digital approaches from drug candidate selection to computational pharmaceuticals
10:30	PEARRL approaches to predicting formulation design	Dan Price (Merck, Germany)	COSMOquick as a predictor of drug/excipient interactions in enhanced dosage forms
10:45	Coffee		
11:15	High throughput biopharmaceutical screening	Jochem Alsenz (Roche, Switzerland)	High throughput biopharmaceutical screening
12:00	PEARRL approaches to Biorelevant in vitro screening	Patrick O'Dwyer (Pion, UK)	A guide to small scale screening for drug-specific questions
12:15	PEARRL approaches to predicting formulation design	Felix Ditzinger (UNWS, Switzerland) Georgia Tsakiridou (Pharmathen, Greece)	Solid dispersions based on a modelling rationale
12:45	PEARRL approaches to predicting formulation design	Niklas Koehl (UCC, Ireland) Roxana Ilie (J&J, Belgium)	A guide to bioenabling formulation selection in development: focus on lipid based approaches
13:15	Lunch		
Session II – Model informed pre-clinical development Chair: J. Dressman (UGoethe)			
14:15	Role of rDCS in guiding preclinical pharm development	James Butler (GSK, UK)	Role of rDCS in guiding preclinical pharm development
15:00	Role of PBPK in guiding preclinical pharm development	Christian Wagner (Merck, Germany)	Role of PBPK in guiding preclinical pharm development
15:45	Coffee		
16:15	Role of animal modelling in preclinical pharm development	Sandy Van Hemelryck (J&J, Belgium)	Preclinical Bioavailability Strategy for Decisions on Clinical Drug Formulation Development
17:00	PEARRL approaches to biorelevant in vitro screening	Chara Litou (UGoethe, Germany)	The role of biorelevant testing in formulation development
17:15	PEARRL approaches to biorelevant in vitro screening	Christina Pentafragka (UoA, Greece)	Using luminal data for modelling absorption in the fed state
17:30	End of Day 1		

Day 2 – 13th June 2019

Open scientific symposium on Model Informed Drug Development

Theme: Clinical development through to pharmaceutical product lifecycle management

Time	Session/Topic	Speaker	Presentation Title
Session III – Model informed clinical development C. Reppas (UoA)			
09:00	Formulation for first in man studies	James Butler (GSK, UK)	Formulation for first in man studies
09:45	Transitioning to the final formulation. What are the challenges?	Bertil Abrahamsson (AZ, Sweden)	Transitioning to the final formulation. What are the challenges?
10:30	Coffee		
11:00	PBPK modelling of food effects	Neil Parrott (Roche, Switzerland)	PBPK modelling of food effects
11:45	PBPK modeling of DDIs	Masoud Jamei (Certara, UK)	Applications of PBPK modelling in predicting complex DDIs
12:30	PEARRL approaches to predicting in vivo outcomes using in silico tools	Angela Effinger (Bath, UK)	Targeting GI diseases
12:45	PEARRL approaches to biorelevant <i>in vitro</i> screening	Mariana Guimaraes (UBath, UK))	<i>In vitro</i> evaluation of drugs/drug products for paediatrics
13:00	PEARRL approaches to predicting in vivo outcomes using <i>in silico</i> tools	Marina Statelova (UoA, Greece	<i>In silico</i> evaluation of drugs/drug products for paediatrics
13:15	Lunch		
Session IV – Emerging trends in pharmaceutical product lifecycle management Chair: M. Kuentz (FHNW)			
14:00	Developing generic products	Lida Kalantzi (Pharmathen, Greece)	Modelling and simulation in the development of generics
14:45	A regulatory perspective on PBPK modelling	Essam Ahmed Ghazaly Kerwash (MHRA, UK)	Regulatory perspective on the use and qualification of PBPK modelling
15:30	Coffee		
16:00	Manufacturing and Quality Control	Ian Flawn Orpana (Verto Pharma AB, Sweden)	Statistical Process Control (SPC) in Manufacturing and Quality Control of Drug Products
16:45	PEARRL approaches to predicting formulation design	(Sandra Jankovic (UNWS, Switzerland)	Emerging process analysers in pharmaceuticals
17:00	PEARRL approaches to predicting in vivo outcomes using in silico tools	Ioannis Loisios (UGoethe, Germany)	Establishing virtual bioequivalence trials simulation using population-based PBPK modelling
17:15	PEARRL approaches to predicting in vivo outcomes using in silico tools	Raphael Paraiso (UGoethe, Germany)	The role of <i>in vitro</i> and <i>in silico</i> tools to support bioequivalence studies
17:30	End of Day 2		