

The second QP conference: QP challenges in modern pharmaceutical trading



1st and 2nd of October, 2015

Venue

Best Western Hotel M,
56a Bulevar Oslobođenja Street, Belgrade



For registration, hotel arrangements,
organisation etc. please visit

www.smarttravelpc4.rs

Conference language: The official
conference languages will be both
English and Serbian.

Information also at:
www.pharmacy.bg.ac.rs



join us

***Centre for continuing education
Centre for Industrial Pharmacy***

**Faculty of Pharmacy – University of
Belgrade**



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Organizing Committee:

Biljana Stupar
Katarina Popović
Ljiljana Solomun
Nataša Knežević
Slavica Kojić
Snjezana Tvrdorjeka
Sonja Georgieva Jovanović
Svetlana Ibrić
Valentina Marinković
Zorica Vujić



Objective

The Conference is designed for all Qualified Persons and aspiring Qualified Persons. It also addresses upper management functions and authority representatives who want to be informed about the latest development regarding the duties and responsibilities of Qualified Persons.

Fees

Pharmaceutical Industry representatives:

Early registration (till 1st September 2015): 250 €
Registration after 1st September 2015: 300 €

Government/Academia representatives:

Early registration (till 1st September 2015): 200 €
Registration after 1st September 2015: 250 €

Students:

Early registration (till 1st September 2015): 100 €
Registration after 1st September 2015: 150 €

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Conference programme



Thursday, October 1st 2015

Themes

Update on the EU GMP Regulations
OOS results; regulatory expectations and remediation approaches
The role of QP in assuring the GMP compliant APIs
Strategic development plan for Drug Agency of Republic of Macedonia
Modern Data and Documentation Management and recording.
State of the art Data and Document Structuring:
Data Integrity -Electronic Signatures vs. digital Signatures.
Electronic Signature Law and requirements on signing electronically

PAT and Real Time Release

Speakers

Dr Bernd Renger, Renger Consultancy
Dr Christopher Burgess, EQPA
Andrej Ferlan, Solutiones d.o.o., Consulting,
Education and Training, Ljubljana, Slovenia
Marija Darkovska, Macedonian Drug
Agency
Stephan Dresen, Actavis, Weiterstadt,
Germany
Doc dr Jelena Đuriš, Faculty of Pharmacy
University of Belgrade

Friday, October 2nd 2015

Continual production and release into the market

The revised Annex 16 of the EU GMP Guide
and its Implications for QPs

What QPs need to know about statistics

THREE PARALLEL WORKSHOPS:

Workshop 1

Risk management during drugs transportation

Workshop 2

OOS in stability studies

Mate Poropat, Jadran-Galenski
Laboratorij d.d., Croatia

Dr Bernd Renger, Renger Consultancy

Dr Christopher Burgess, EQPA

Workshop 3

QP role in managing conflict situations

