BULGARIAN ASSOCIATION OF DRUG INFORMATION (BADI)

With the kind support from the Medical University - Sofia,
organizes its regular autumn course on Pharmaceutical Regulations on the following topics:

09. 10. 2015 - Update of Product information requirements - Regulatory update in Clinical trials according to the new Regulation 536/2014 – in force from May 2016, Personalised Medicine - medicinal products

23. 10. 2015 - Pharmacovigilance update - Part I

13. 11. 2015 - Pharmacovigilance update - Part II

27. 11. 2015 - Medical Devices - Change in the regulatory requirements; Medical Pricing and Reimbursement and HTA in Bulgaria and in the MSs

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Pharmaceutical regulations are applied by the pharmaceutical companies, regulatory authorities, contractual research organisations, and consulting companies in order to test and authorise production of medicinal products and monitoring of their safety, the risks associated with the medicines and the prevention of adverse drug reactions.

The programme of the course for 2015 on pharmaceutical regulations consists of 4 Modules lasting one day on the indicated Fridays in October and November 2015 and is designated besides for those working in the pharmaceutical industry but also for students in pharmacy, medicine, biology or biochemistry and pharmacy assistants who would wish to work in the regulatory departments in the pharmaceutical industry of in regulatory authorities.

The course is also suitable for experts, regulatory specialists and regulatory managers who already work in pharmaceutical companies, regulatory authorities or contractual research organisations and are willing to update and supplement their knowledge in all or any of Modules 1 – 4, to keep n synchrony with the new directions of the authorisation regimes and procedures that apply to the medicinal product after being placed on the market.

The pharmacovigilance system in the European Union (EU) operates with the management and involvement of regulatory authorities in Member States, the European Commission and the European Medicines Agency. In some Member States, regional centres are in place under the coordination of the national competent authority. Fundamental update of the pharmacovigilance and clinical trial requirements will be done. The pharmacovigilance update is focussed on Legal requirements for MAH to electronically submit information on medicinal products authorised in the EU., Submission of information on products to the EMA using the electronic format referred to as Article 57 format / eXtended EudraVigilance Product Report Message (XEVPRM) format and Data maintenance. Regulation 1027/ 2012 which will be part of the two days education.

The new EU Clinical Trials **Regulation No 536/2014** will impact how the conduct of a clinical trial is managed after approval has been granted. New provisions for public access to an EU Clinical Trials Database will enforce disclosure of clinical trials data and information. is expected to become applicable in 2016. The new legislation will have implications on clinical trial sponsors preparing and submitting clinical trial applications. Member States will have to adapt their procedures for the assessment of clinical trial applications by competent authorities and review by ethics committees. forum for information exchange and discussion on conceptual and practical questions through lectures and panel discussions. There will be a particular focus on the critical issues affecting sponsors and Member States as they consider the impact and changes needed to implement the Regulation

The Module for Medical Devices on 27-th of November will give clear and practical updates on how to develop a medical device and how to identify the correct development path under the new Medical Device Regulation. You will get an overview of the EU device legislative changes in various fields, such as the role of notified bodies and requirements in clinical or post-market requirements. EU Medical device regulation: philosophy, content and structure Directive 93/42/EC, as amended by 2007/47/EC CE mark ISO 14155, ISO 13485 and ISO 14791.

Risk-classification of medical devices Drug-device combination products

Medical devices vigilance system Recent and upcoming legal changes in Europe

What is the course that will be carried out in October and November, aiming at:

1. To understand the principles of pharmaceutical regulation and responsibilities of the concerned parties, regulatory authorities and the industry in the regulatory process in the EU;

2. To understand how legislation helps to make incessant assessment of the benefit/risk ratio throughout the whole product life cycle;

3. To analyse the critical points in the pharmaceutical regulation and medicinal products within the context of the EU pharmaceutical legislation framework;

4. How to use good regulatory and good clinical practice practices to improve the environment;

5. To present the main direction and to understand the common principles of the EU legislative framework including Bulgaria in the field of medicinal products;

6. To understand the principles of pharmacovigilance and the legal requirements of 2015 and the forthcoming amendments and requirements in;
7. Principles of pricing and reimbursement in the EU Member States and in Bulgaria in particular;

8. Implementation of pharmacoeconomic approaches, common rules and principles at their assessment, implementation of guide and rules;

9. To do practical drills in order to understand the topics of modules 1 – 4 and to acquire experience in team-working;

10. To accumulate knowledge, experience and contacts, which will be a privilege for employment in representations of the pharmaceutical industry, regulatory authorities and contractual research organisations.

PROGRAMME FOR THE COURSE

Module 1
09 October 2015

Update of Product information requirements; Regulatory update in clinical trials according to the new Regulation 536/2014 - in force from May 2016;
Personalised Medicine - medicinal products
Klaus Menges –BFArM, *Jasmin Koeva - BAPEMED, Raina Kostova,*
Rositsa Vasilevaa -PSI, Pharma,Georgi Georgiev - Astra Zeneca,
Tatyana Benisheva **-** *MU-Sofia.*

9:00 - 9:15
Opening
Prof.Guenka Petrova - Deputy Rector of Medical University – Sofia,
Assoc. Prof. Dobriana Sidjimova - Moderator
Prof. Tatyana Benisheva - MU- Sofia - Modeartor

9:15 - 11:00

Introduction of Drug Regulatory Affairs - SmpC and PIL

- Introduction of Drug Regulatory Affairs - general overview update
  Prof. Tatyana Benisheva – MU, Sofia
- What do you need to know about, current regulatory framework of SmPC and PIL-QRD templates and guidelines - *MPharm, Raina Kostova*
- Product Information within the Application for Marketing Authorisation
  News and Perspectives - *Klaus Menges -BFArM*

11:00 - 11:30 Coffee break
11:30 - 13:30
The new legislation relating to clinical trials (Regulation No 536/2014) and Pharmacovigilance.
Rositsa Vasileva -PSI Pharma and Georgi Georgiev - Astra Zeneca.

- Key aspects of and differences between the present and new requirements on managing clinical trials including;
- Member States preparedness for the Regulation, including plans for co-operation between agencies and ethics committees and coordinated assessment;
- Considerations for the preparation of applications and notifications by sponsors;
- Role of the European Commission and proposals for implementing measures;
- EMA Status report - development of the EU clinical trials portal and database;
- Impact of new requirements for disclosure and transparency of data from clinical trials

13:30 - 14:30 Lunch break
14:30 - 15:30

Scope and impact of the personalised medicine and therapy -
Jasmin Koeva –BAPEMED

Test and Picture of the participants

Module 2
23 October 2015

Pharmacovigilance - Part I

9:00 - 9:15
Opening
Prof. Tatyana Benisheva - Moderator
Assoc. Prof. Dobriana Sidjimova - Moderator
Maria Dimitrova - Moderator

Introduction in the Regulatory Affairs Information-
MPs - Registers and PhV guide lines.
Prof. Tatyana Benisheva

9:15 - 10:30
Fundamentals update in pharmacovigilance requirement acc. Article 57 of the Regulation (EC) № 726/ 2004
Vili Topalova - Lindeq and Maria Doleva - Boehringer-Ingelheim

- Challenges for the implementation of the updated PhV legislation
- New EMA fee requirements
- XEVMPD

10:30 - 11:00 Coffee break
11:00 - 13:00

Collection and management of pharmacovigilance data after receipt of a marketing authorisation
Maria Doleva - Boehringer-Ingelheim, Violeta Ilieva and Rahila Kozarova - Ecopharma

- Expedited reporting in the EU - EMA database - *Maria Doleva*
- Activities of local affiliates - *Maria Doleva and Violeta Ilieva*
- Literature monitoring after granting marketing authorization - requirements for MAHs and latest news from EMA - *Rahila Kozarova*
- PSUR as a part of the management of pharmacovigilance data after receipt of a marketing authorization. PSUR repository - the latest news - *Violeta Ilieva*

13:00 - 14:00 Lunch break
14:00 - 15:30

Pharmacovigilance and communication
Vili Topalova -Lindeq and Maria Doleva - Boehringer-Ingelheim

- Corporate responsibility regarding pharmacovigilance.
- Science, development and pharmacovigilance.
- Regulatory activities and pharmacovigilance.
- Product quality and pharmacovigilance.
- Quality assurance and pharmacovigilance.
- Legal and commercial functions relating to pharmacovigilance.

Pharmacovigilance and contractual interrelations with third parties
Vili Topalova - Lindeq

- Scope of contractual agreements as regards pharmacovigilance.
- Regulatory requirements relating to contractual agreements.
- Contractual agreements between pharmaceutical companies.
- Contractual agreements with service suppliers regarding to pharmacovigilance.
- Drawing up and maintenance of pharmacovigilance agreements.

Test and Picture of the participants

Module 3
13 November 2015

Pharmacovigilance - Part II

9:00 - 9:15
Opening
Prof. Tatyana Benisheva- - *M*oderator
Assoc. Prof. Dobriana Sidjimova - *Moderator*

9:15 - 10:30
Pharmacovigilance system , PRAC scope and activities,
Risk/Benefit Assessment,
Role of the Authorities and EMA- Committees,
Pharmacovigilance Inspections.
Prof.Barbara Sickmuller - Moderator
Kapka Kaneva MD - *Moderator*

Regulatory authorities and requirements
Axel Thiele - Germany

- Pharmacovigilance system
- Pharmacovigilance master file system.
- QPPV
- Role of the Regulatory authorities.

PRAC - role and functions
Maria Popova MD- Bulgarian Drug Agency (BDA)

Pharmacovigilance qualified person - industry point of view

Ecaterina Genova - Ecopharm, Maria Doleva - Boehringer-Ingelheim

- Local Pharmacovigilance contact person responsibilities - *Maria Doleva*
- Basic requirements to QPPV- *Maria Doleva*
- Pharmacovigilance qualified person - industry point of view - *Ekaterina Genova*

10:30 - 11:00 Coffee break

11:00 - 13:00

Maria Popova MD - Moderator
Maria Doleva - Moderator

Assessment of pharmacovigilance information *Axel Thiele - Germany*

- Ongoing safety evaluation
- Regulatory requirements relating to signal detection.
- Assessment of signals and benefit/risk ratio.
- Risk management systems and risk management plans.
- Intensified monitoring.
- Referral procedures.

Practical guidelines on pharmacovigilance: Relevance and applicability of the reported information
Marin Shitzov MD -Takeda

13:00 - 14:00 Lunch break

14:00 - 15:30

Axel Thiele - Moderator
Ekaterina Genova - Moderator

New Pharmacovigilance requirements for marketed products in the EU:

- PASS/PAES
- PSUR/PBRER
- Educational material

Prof.Barbara Sickmuller - Germany

Procedural documentation, quality system and pharmacovigilance
Vili Topalova MD - Lindeq

- Pharmacovigilance System Master File - development and maintenance
- Quality Management System (QMS) and control of procedural documents.

Updated pharmacovigilance topics for discussion
Kapka Kaneva MD - BDA

15:30 - 16:00 Coffee break

16:00 - 17:00

Maria Popova MD- Moderator
Vili Topalova MD - Moderator

Pharmacovigilance inspections
Axel Thiele - Germany

- Purpose and scope of inspections in the EU.
- Preparation for a pharmacovigilance inspection (Inspection readiness)
- Conducting a pharmacivigilance inspection.
- When things are not going well.
- Corrective actions after a regulatory pharmacovigilance inspection, CAPA handling

Test and Picture of the participants
Delivery of certificates

Module 4
27 November 2015

Medical Devices - Change in the regulatory requirements;
Medical Pricing and Reimbursement and HTA in Bulgaria and in the MSs
Dr. Jörg Plessl - Germany, Dr.Romana Tandara Hacek - Zagreb, Croatia,
Prof.Tatyana Benisheva - MU, Sofia, Prof. G. Petrova - MU, Sofia; Vili Topalova - Lindeq,
Daniela Cherneva – Medochemie; Assoc. Prof. Dobriana Sidjimova – MU, Sofia;
Maria Dimitrova and Maria Kamusheva - MU, Sofia; Rumina Atanasova –BADI

9:00 - 9:15
Opening
Prof. Tatyana Benisheva - Modeartor
Assoc. Prof. Dobriana Sidjimova - Moderator

9:15 - 10:30
Medical devices - New European Medical Device Legislation and vigilance
Vili Topalova - Lindeq

"**Where are we heading? An insight into the upcoming new legislation on medical devices in the EU."**
Dr. Jörg Plessl -Germany
Director EU Affiliates, Regulatory Affairs Norgine

10:30 -11:00 Coffee break

11:00 - 13:30
Medical Pricing and Reimbursement and HTA in Bulgaria and in the MSs
Maria Dimitrova - Moderator
Mariya Kamusheva - Moderator

Electronic registers and services. Administrative and information system of NCPRMP
Maria Todprova - Sirma Solution
May Paskaleva - Sirma Soolution

HTA in Croatia: Natioanal and international view
Dr.Romana Tandara Hacek
Department for Development, Research and Health Technology Assessment -Croatia
Agency for Quality and Accreditation in Health Care and Social Welfare

Medica Pricing and Reimbursement and HTA in Bulgaria and in the MSs
Maria Dimitrova -Moderator
Maria Kamusheva - Moderator

- Comparison of the Pricing and reimbursement system in Bulgaria and Romania - *Daniela Cherneva* **-** *Medochemie*
- Challenges at the HTA analysis and evaluation

Prof. Genka Petrova, FPh - MU-Sofia

- Stakeholder Perspectives - *Maria Kamusheva and Maria Dimitrova*

13:30 - 14:30 Lunch break
14:30 - 15:30

- How to validate the prices in the EU-Member States - practices and opportunities for calculation the prices in Bulgaria and last legislative changes - *Daniela Cherneva Medochemie, Prof. Tatyana Benisheva and Rumyana Atanasova*

Test and Picture of the participants and Christmas Games
Delivery of certificates

1. **Who can apply for these modules and who should attend?**

- This workshop is aimed at intermediate and experienced professionals from Regulatory agencies
- The course is also suitable for employees in this field and those who are willing to professionally realise themselves in this direction since knowledge can serve as a foundation with respect to authorisation regimes that lead a medicinal product until its placement on the market.

- Applicants can be ***experts from the pharmaceutical industry***, as well as persons who are willing to enlarge their knowledge in more than one field where they work with a view to acquire competences and transfer to other fields, as well as to deepen their knowledge in the respective field.
  -Regulatory affairs personnel Pharmacovigilance staff
  -The pharmaceutical industry and contract research organisations including:
  - Staff from clinical science and clinical operations monitors, auditors of clinical trials

- The modules are d***esignated primarily for specialists with the degree of "Bachelor" or "Master" in medicine, pharmacy, biology, or biochemistry,*** respectively, who have or do not have experience in these fields or the respective experience in the pharmaceutical/biotechnology industry.

- This course can also be attended by ***students in medicine, pharmacy, as well as pharmacy assistants, biologists and biochemists***, who wish to concentrate in the pharmaceutical industry, its regulatory departments or in regulatory authorities, or in contractual research organisations and have no or have accumulated experience in Modules 1 – 4

Lack of professional qualification is not a barrier for enrolment in the course since its purpose is to go deeper in the matter of the modules. Knowledge in these modules is a requirement for employment in the regulatory departments of pharmaceutical companies, as well as in organisations dealing in clinical trials.

2. **Certificate of the course**

A certificate for pharmaceutical regulations for all modules or the modules chosen. These certificates will confirm your qualifications when you need to verify it.

3. Who lectures on this course?

Lecturers are professors at MU-Sofia or experts in the pharmaceutical industry with long experience in their fields. All lecturers work within their teaching field.
Actual learning activities include training, individual research, interactive discussions on case studies and each course ends with a test that you get a result, how you passed. Applications will be considered in the order of their receipt and seats in the room are limited.

4. Requirements

Aiming at maintaining a professional level in the program, it is required that applicants have at least a relevant bachelor degree or are students who are nearing graduation at the end of their education.
Applicants who do not comply with the requirements for participation in this course will be separately assessed by the Managing Board of BADI and will have a feedback by the Secretariat.
Fees for members and non-members are differentiated.
Fees for students and non-members are differentiated.

Please, complete in block letters or on a computer the attached registration form for the course at BADI's website and sent it there: office@badibg.org