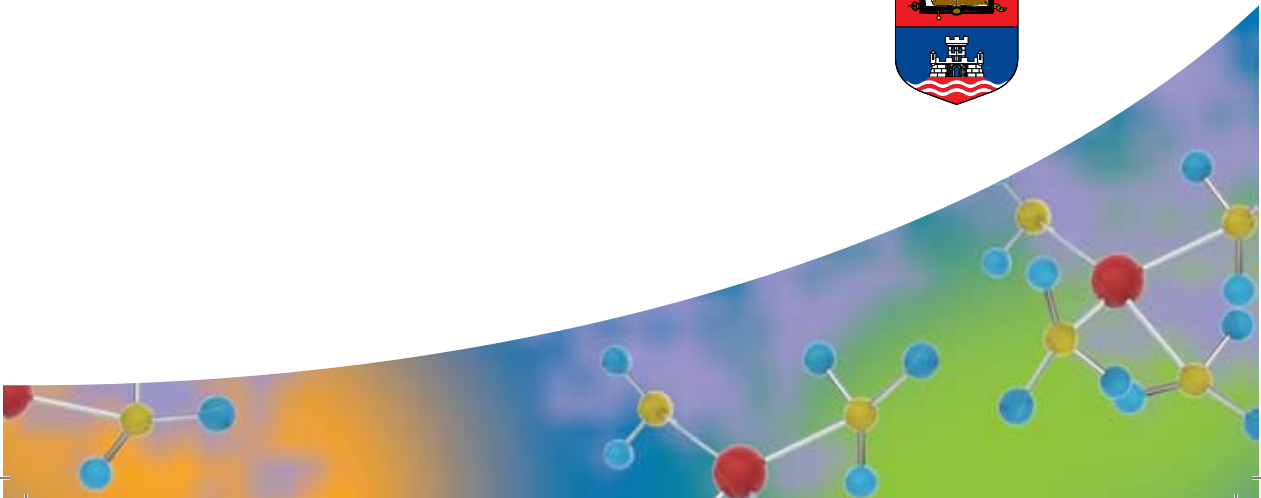




70 GODINA STUDIJA FARMACIJE
NA UNIVERZITETU U BEOGRADU
1939-2009



УНИВЕРЗИТЕТ
У БЕОГРАДУ
1808 • 2008



Počasni članovi Programskog Saveta proslave



Ministar prosvete Republike Srbije – Prof. dr Žarko Obradović
Ministar zdravlja Republike Srbije – Prof. dr Tomica Milosavljević
Rektor Univerziteta u Beogradu – Prof. dr Branko Kovačević

Programski Savet proslave

Prof. dr Nada Kovačević
Prof. dr Danica Agbaba
Prof. dr Sote Vladimirov
Dr Vesna Kuntić, vanr. prof.
Dr Mira Zečević, vanr. prof.
Dr Vladimir Savić, vanr. prof.
Aleksandar Popović
Mr sc. Ružica Nikolić
Prof. Dr Ivanka Miletić
Prof. Dr Nada Majkić-Singh
Dipl. farm. Aleksandra Dimitrijević-Salom
Mr sc. Zlata Žuvela
Prim. Dr spec. Velibor Canić
Prim. Dipl. farm. spec. Tomislav Solarović
Prof. dr Dragomir Marisavljević
Dipl. farm. Rade Lazarević
Dr Olivera Aleksić

Pokroviteljstvo

Ministarstvo prosvete Republike Srbije
Ministarstvo zdravlja Republike Srbije



Jubilej 70 godina studija farmacije na Univerzitetu u Beogradu (1939 – 2009)

Naučni i stručni skupovi posvećeni jubileju

1. XXV Biohemijski dani; XI Susreti biohemičara Srbije

21-24. jun 2009. Sokobanja
Organizatori: Komora biohemičara Srbije, Društvo medicinskih biohemičara Srbije i Institut za medicinsku biohemiju Kliničkog centra Srbije;
Suorganizator: Farmaceutski fakultet Univerziteta u Beogradu

2. Promocija zdravlja i prevencija bolesti žena Srbije – iskustva farmaceutske prakse
Završni izveštaj po projektu „Promocija zdravlja i prevencija bolesti žena Srbije u farmaceutskoj praksi“
Septembar 2009., Beograd
Organizator: Farmaceutski fakultet Univerziteta u Beograd,
Kordinator: prof. dr Ljiljana Tasić,

3. Novine u laboratorijskoj dijagnostici; 33. Medipharm – Beogradski sajam
1-3. oktobar 2009., Beograd

Organizatori: Društvo medicinskih biohemičara Srbije i Institut za medicinsku biohemiju Kliničkog centra Srbije;
Suorganizator: Farmaceutski fakultet Univerziteta u Beogradu

4. 5th EFCC Symposium for Balkan Region - Proteins: From Electrophoresis to Proteomic
8-10. oktobar 2009., Beograd
Organizatori: Društvo medicinskih biohemičara Srbije, Institut za medicinsku biohemiju Kliničkog centra Srbije;
Suorganizator: Farmaceutski fakultet Univerziteta u Beogradu

5. Obezbeđenje kvaliteta leka – preduslov efikasne terapije
20. oktobar. 2009., Beograd

Organizatori: Grupacija „Inovija“; Grupacija domaćih proizvođača lekova Privredne komore Srbije, Grupacija veletrgovlja Privredne komore Srbije, Farmaceutski fakultet Univerziteta u Beogradu

6. Vizija razvoja savremene farmaceutske usluge u apotekarskoj praksi Srbije
21. oktobar 2009., Beograd

Organizatori: Farmaceutska komora Srbije, Farmaceutsko društvo Srbije, Savez privatnih apotekara Srbije – SPAS
Suorganizator: Farmaceutski fakultet Univerziteta u Beogradu

7. Biofarm - Uticaj faktora formulacije i proizvodnog procesa na biofarmaceutska svojstva leka
22. oktobar. 2009. Beograd
Organizatori: Farmaceutski fakultet Univerziteta u Beogradu; Farmaceutsko društvo Srbije

8. Novi trendovi u razvoju i primeni leka
23. oktobar. 2009. Beograd

Organizator: Farmaceutski fakultet Univerziteta u Beogradu

9. Dvanaesta naučna konferencija „Profesor Ivan Berkeš“
4. decembar 2009., Beograd

Organizatori: Društvo medicinskih biohemičara Srbije, Institut za medicinsku biohemiju Kliničkog centra Srbije;
Suorganizator: Farmaceutski fakultet Univerziteta u Beogradu.

Aktivnosti studenata posvećene jubileju

1. Savetovanje pacijenta

Maj 2009

Organizator: NAPSer; Marketing Hemofar Logica, Farmaceutski fakultet u Beogradu

Koordinatori: Doc. dr Katarina Ilić i Doc. Dr Jelena Stanković - Antić

2. Pripreme za Kongres o lekovitom bilju

22-23 maj 2009., Beograd

Organizator: Evropska asocijacija studenata Farmacije (EPSA);

Koordinator: Prof. dr Nada Kovačević

3. Farmakoterapijski pristup

Novembar 2009

Organizator: NAPSer i udruženje studenata Medicinskog fakulteta Univerziteta u Beogradu;

Koordinator: Prof. dr Branislava Miljković

Socijalni događaji

19. oktobar 2009. Svečana sednica Nastavno-naučnog veća Farmaceutskog fakulteta Univerziteta u Beogradu

24. oktobra 2009. Svečana akademija, Centar Sava, Beograd

Sekretarijat

G-đa Slobodanka Čobanov, G-đa Dobrila Vujadinović

Farmaceutski fakultet Univerziteta u Beogradu,

Vojvode Stepe 450, Beograd

Tel. +381 11 3951399;

Fax. +381 11 397 2 840

e-mail: dekan@pharmacy.bg.ac.rs; dobrila.vujadinovic@pharmacy.bg.ac.rs

Izvršni organizator

Turistička agencija „Smart“, Svetog Save 43/I, 11 000 Beograd

Tel. +381 11 244 12 53; 308 74 86; 308 74 87;

Fax. +381 11 30866 95

e-mail: smart4@eunet.rs



*D*rage kolege i prijatelji,

Nastavnici i saradnici Farmaceutskog fakulteta u saradnji sa članovima Programskog saveta i kolegama iz prakse, organizovali su nekoliko simpozijuma i stručnih sastanaka koji su posvećeni obeležavanju jubileja 70 godina studija farmacije na Univerzitetu u Beogradu.

Želja nam je i namera da ukažemo na aktuelna dešavanja u okviru farmaceutske delatnosti u Srbiji, kako sa aspekta farmaceutske nauke, tako i sa stanovišta farmaceutske prakse. Iskreno se nadamo se da će organizacija ovih skupova postati sastavni deo aktivnosti našeg Fakulteta i deo naše zajedničke tradicije.

U nastavku su date detaljnije informacije o programu naučnih i stručnih skupova koji će biti organizovani u danima od 20. do 23. oktobra 2009.

Radi bolje organizacije predviđenih naučnih i stručnih skupova, molimo da svoje prisustvo prijavite telefonom (011 3951399); faksom (011 3972840) ili na e-mail adrese: dobrila.vujadinovic@pharmacy.bg.ac.rs; slobodanka.cobanov@pharmacy.bg.ac.rs.

Radujemo se predstojećim susretima sa Vama.

Predsednik Programskog saveta
Dekan Farmaceutskog fakulteta

Prof. dr sc. Nada Kovačević





**Mini simpozijum
Zdravlje žena Srbije - nauka i praksa
u službi zdravlja**

**utorak 06. oktobar 2009
sala „Velefarm“
VELEFARM AD Holding kompanija**

Koordinator: Prof. dr Ljiljana Tasić



Mini simpozijum Zdravlje žena Srbije - nauka i praksa u službi zdravlja

utorak 06. oktobar 2009

sala „Velefarm“
VELEFARM AD Holding kompanija

Program

12.00-12.20	<p>Pozdravna reč Prof. dr Ljiljana Tasić, <i>Farmaceutski fakultet Univerziteta u Beogradu</i> Prof. dr Nada Kovačević, <i>Dekan, Farmaceutski fakultet Univerziteta u Beogradu</i> Mr ph Rade Lazarević, <i>pomoćnik Generalnog direktora za komercijalne poslove kompanije „Velefarm AD“</i> Dr Dragana Nalić, <i>direktor Doma zdravlja „Voždovac“</i> Mr ph Svetlana Stojkov Rudinski, <i>direktor Apoteke „Subotica“</i></p>
12.20-12.35	<p>Predstavljanje Projekta „Promocija zdravlja i prevencija bolesti žena Srbije kroz farmaceutsku praksu“ Prof. dr Ljiljana Tasić, <i>Farmaceutski fakultet Univerziteta u Beogradu</i></p>
12.35-12.50	<p>Predstavljanje naučne monografije „Zdravlje žena u Srbiji - Promocija zdravlja, prevencija bolesti i terapija“ Doc. dr Katarina Ilić, <i>Farmaceutski fakultet Univerziteta u Beogradu</i></p>
12.50-13.10	<p>Pauza za kafu</p>
13.10-13.25	<p>Primarna zdravstvena zaštita i faktori rizika za zdravlje žena Prof. dr Snežana Simić, <i>Medicinski fakultet Univerziteta u Beogradu</i></p>
13.25-13.40	<p>Reproduktivno zdravlje žene - kako ga sačuvati Prof. dr Nebojša Radunović, <i>Institut za ginekologiju i akušerstvo, Klinički centar Srbije</i></p>
13.40-13.55	<p>Klinički značajne farmakokinetičke varijabilnosti lekova kod žena Prof. dr Branislava Miljković <i>Farmaceutski fakultet Univerziteta u Beogradu</i></p>
13.55-14.10	<p>Osteoproza-faktori rizika, prevencija i terapija Doc. dr Nada Vujasinović- Stupar, <i>Medicinski fakultet Univerziteta u Beogradu</i></p>
14.10-14.55	<p>Koktel</p>



Obezbeđenje kvaliteta leka – preduslov uspešne terapije

Assurance of the drug quality – the base for the efficacy in therapy

**Utorak, 20. oktobar 2009/
Tuesday, October 20, 2009.**

**Farmaceutski fakultet u Beogradu
Faculty of Pharmacy Beograd**

Koordinator: Prof. dr Nada Kovačević



Obezbeđenje kvaliteta leka – preduslov uspešne terapije
Assurance of the drug quality – the base for the efficacy in therapy

Utorak, 20. oktobar 2009
Tuesday, October 20, 2009.

Farmaceutski fakultet u Beogradu
Faculty of Pharmacy Beograd

Program/Programme

Prof. Dr Nenad Ugrešić

Uvodne napomene

10,00 – 10,30

Rossen Koytchev

Clinical trials programme for the registration of a biosimilar human recombinant epoetin: Epoetin Zeta

10,30 – 11,00

Marija Vujasin

Diabetes Mellitus: savremeni koncept lečenja insulinskim analogima
Diabetes Mellitus: modern concept of treatment with insuline analogs

11,00 – 11,30

Ilija Rosić

Vakcine - uloga u preventivnoj medicini, inovativne vakcine, stanje i perspektive
 Vaccines - role in preventive medicine, innovative vaccines, situation and perspective

Pauza/Pause

12,00 – 12,30

Suzana Miljković

Upravljanje portfoliom farбрика generičkih lekova
 Management of a generic pharmaceutical company portfolio

12,30 – 13,00

Biljana Stupar

Razvoj generičkih proizvoda
 Generic Drug Product Development

13,00 – 13,30

Valentina Marinković

Sistem kvaliteta u multinacionalnim farmaceutskim kompanijama
 Quality system in the multinational pharmaceutical companies

13,30 – 14,00

Snežana Hadži-Arsić Novaković

Kvalitetna distribucija – bezbedan lek
 Quality in distribution - Safety of medical products

Koktel / Coctail

Clinical trials programme for the registration of a biosimilar human recombinant epoetin: Epoetin Zeta

Rossen Koytchev

CCDRD AG, Neuenhagen, Germany

The clinical trials programme completed for the registration of Epoetin Zeta as biosimilar to Epoetin Alfa consisted of following trials: (1) Two comparative Phase I trials in healthy volunteers, (2) One prospective, randomized, double-blind comparative Phase III trial with intravenous administration for the maintenance treatment in patients with renal anaemia having haemoglobin levels stabilized within the target range, (3) One prospective, randomized, double-blind comparative Phase III trial with intravenous administration for the correction treatment in patients with renal anaemia having haemoglobin levels lower than 9 g/dl, (4) One open follow-up Phase III trial for long-term intravenous treatment with epoetin zeta in patients with renal anaemia after the end of the double-blind period of trials 2 and 3 (5) One open Phase III trial for subcutaneous treatment in patients with cancer and chemotherapy-induced anaemia.

The results of the trials listed above confirmed the clinical biosimilarity of epoetin zeta to epoetin alfa defined as equivalent effect on haemoglobin levels at an equivalent dose. Based on these trials epoetin zeta received marketing authorization from the EMEA for following indications:

- Treatment of anaemia associated with chronic renal failure in adult and paediatric patients on haemodialysis and adult patients on peritoneal dialysis (intravenous administration).
- Treatment of severe anaemia of renal origin accompanied by clinical symptoms in adult patients with renal insufficiency not yet undergoing dialysis (intravenous administration).
- Treatment of anaemia and reduction of transfusion requirements in adult patients receiving chemotherapy for solid tumours, malignant lymphoma or multiple myeloma, and at risk of transfusion as assessed by the patient's general status (subcutaneous administration).
- To increase the yield of autologous blood from patients in a predonation programme (intravenous administration).

Ongoing trials are as follows: (1) Post-approval safety cohort observation planned in 1500 patients with renal anaemia and intravenous administration (2) Prospective, randomized, double-blind comparative Phase III trial with subcutaneous administration for the maintenance treatment in patients with renal anaemia having haemoglobin levels stabilized within the target range. After the end of the second ongoing trial (a positive result in this trial regarding efficacy endpoints is already available) the subcutaneous route of administration will also be available for epoetin zeta in patients with indications other than chemotherapy-induced anaemia.

Dr. med. Rossen Koytchev

Dr Koytchev je rođen 1960. Godine u Sofiji, Bugarska. Medicinski fakultet u Sofiji završio je 1987. godine, a specijalizaciju iz kliničke farmakologije 1991. godine na Insitutu za kliničku farmakologiju Hymboldt Univerziteta u Berlinu. Autor je brojnih naučnih radova u međunarodnim časopisima, kao i poster prezentacija i usmenih prezentacija na međunarodnim skupovima.

Curriculum vitae

Name:	Rossen Koytchev
Date of birth:	09.06.1960
Site of birth:	Sofia, Bulgaria
State of family:	married, 3 children
Education and Graduation	
1967-1980	High school and Grammar school in Sofia
1982-1987	Study of medicine at the Higher Medical School Sofia 1987 Full licence as physician and M.D.
1988-1991	Postgraduate specialisation for clinical pharmacology at the Institute for Clinical Pharmacology, Humboldt University, Charité, Berlin, and CCDRD, Berlin, Employment
1987-1988	Work at the Dept. for Infectious Diseases and Epidemiology in the regional hospital Michailovgrad, Bulgaria 1988-1991 Ph.D. at the Institute for Clinical Pharmacology, Humboldt-University, Charité, Berlin
1991-	CCDRD GmbH, member of managing board Department head of Human Pharmacology, Department of Clinical Research (phase II-IV)
2001-	CEO of CCDRD AG
Clinical trials	Summary planning and management, evaluation of more than 200 trials in phase I-IV
Specific postgraduate training	Specialist for Clinical Pharmacology
Scientific papers	incl. scientific papers in different journals, poster demonstrations, abstracts, oral presentations: 165

Diabetes Mellitus: savremeni koncept lečenja insulinskim analogima

dr Marija Vujasin

Novo Nordisk pharma d.o.o., Beograd

Pronalazak insulina početkom dvadesetih godina prošlog veka predstavlja jedno od najvećih medicinskih otkrića. Prvi insulinski preparati koji su se našli na tržištu, bili su goveđeg i svinjskog porekla i sadržali su mnoge nečistoće, dok im je efikasnost mnogo varirala od jedne do druge serije. Razvojem tehnoloških procesa za pripremu i prečišćavanje insulina, uključujući semisintezu i rekombinantnu biotehnologiju, nastajali su protamin cink insulin, izofan insulin, poznat kao NPH insulin, cink insulin suspenzije, semisintetski humani insulini. Dugotrajne kliničke studije DCCT i UKPDS objavljene 93., odnosno 98., potvrdile su neophodnost stroge glikemijske kontrole u cilju prevencije i odlaganja komplikacija šećerne bolesti. Ograničavajući terapijski dometi humanih insulina nametnuli su potrebu razvoja insulinskih analoga modifikacijom strukture humanih insulina, sa poboljšanim farmakokinetičkim i farmakodinamskim karakteristikama i boljim terapijskim uspehom. Prvi insulinski analozi kratkog dejstva (insulini lispro i aspart) pojavili su se na tržištu 1996. i 1999. godine, a do danas su u promet pušteni i analozi dugog dejstva - insulini detemir i glargin, insulin glulizin kratkog dejstva i bifazni insulinski analozi srednje dugog dejstva (rastvorljivi insulin aspart i kristalni insulin aspart protamin; insulin lispro protamin suspenzija i insulin lispro). Insulinski analozi neuporedivo bolje oponašaju fiziološki profil lučenja insulina, uz istu ili bolju glikemijsku kontrolu u odnosu na humane insuline, uzrokuju mnogo manje hipoglikemija, pogotovo noćnih, dok je primenom nekih manji dobitak telesne mase. Njihovom primenom obezbeđuje se terapijski režim koji je daleko prilagodljiviji svakodnevnom životu obolelih od dijabetesa, smanjuje se rizik od razvoja hroničnih komplikacija, poboljšava se tok, ishod i umanjuju troškovi lečenja šećerne bolesti.

Dr med. Marija Vujasin



Dr Marija Vujasin je Medicinski fakultet Univerziteta u Beogradu završila 1997. godine sa prosečnom ocenom 8,6. Obavezni jednogodišnji lekarski staž pohađala je u okviru Zemuske bolnice. Od 1998. do 2002. godine radi kao monitor za klinička ispitivanja lekova u Vujaklija CRO, Beograd. Od 2002. godine radi u Novo Nordisk A/S, Predstavništvu Beograd, odnosno od 2006. godine u Novo Nordisk Pharma d.o.o. Beograd i to na poslovima monitora za klinička ispitivanja lekova od 2002.-2005. godine i od 2005. kao rukovodilac Medicinskog odeljenja.

Pored velikog iskustva u kliničkim ispitivanjima lekova na pozicijama CRA i LTM, na svim rukovodećim poslovima u Medicinskom odeljenju, dr Vujasin ima višegodišnje iskustvo i u radu sa medicinskim informacijama, u regulatornim poslovima, održavanju sistema kvaliteta i sistemu farmakovigilance.

Diabetes Mellitus: Contemporary treatment concept with insulin analogues

Marija Vujasin, MD

Insulin discovery during beginning of twenties' of the last century was one of the greatest medicinal discoveries. First insulin preparations at the market were of bovine and porcine origin and contained many impurities, while their efficacy varied a lot between batches produced. Thanks to development of technological processes for preparation and purification of insulins including semisynthesis and recombinant biotechnology, protamine zinc insulin, isophane insulin known as NPH insulin, zinc insulin suspensions, semisynthetic human insulins were produced and developed. Long clinical trials DCCT and UKPDS that were published in 1993, i.e. in 1998, confirmed necessity for strict glycaemia control in order to prevent and delay complications of Diabetes Mellitus. Limiting therapeutic achievements with human insulins inflicted demand for development of insulin analogues, through modification of human insulin's structure, with improved pharmacokinetic and pharmacodynamic characteristics and better therapeutic success. First short-acting insulin analogues (insulin lispro and aspart) appeared at market in 1996. and 1999., and later on, long acting insulin analogues – insulin detemir and glargine, short-acting insulin glulisine, and biphasic insulin analogues (soluble insulin aspart and crystallized insulin aspart protamine; insulin lispro protamine suspension and insulin lispro) were launched. Insulin analogues imitate physiologic insulin secretion profile much better than human insulins, with similar or better glycaemic control, induce less hypoglycaemic events, especially during night, some of them causing less weight gain. Therapeutic regimen with insulin analogues enables far more adjustable way of treatment to everyday life style of diabetic patients, minimises risk of chronic complications development, improves disease course and outcome and reduces costs of treatment of Diabetes Mellitus.



Vakcine - uloga u preventivnoj medicini, inovativne vakcine, stanje i perspektive

Ilija Rosić

Sanofi Pasteur GmbH predstavništvo u Beogradu

Vakcina je biološki proizvod i nalazi se u sistemu hladnog lanca (2-8 C) u toku proizvodnje i distribucije i spada u preventivnu medicinu. Kalendari imunizacije se menjaju tokom godina u svim zemljama sveta – u njih se uvode nove vakcine koje su medicinski opravdane, a svojim kvalitetom i oblikom doprinose maksimalnoj zaštiti. Tako je u Srbiji uvedena hepatitis B vakcina u kalendar imunizacije: odmah po rođenju, posle mesec dana i posle šest meseci. Drugo, nakon nemilih događaja u Nišu pre par godina, kada je jedna beba umrla od Hib meningitisa, uvedena je i Hib vakcina. Uskoro očekujemo i uvođenje inaktivisane polio vakcine (IPV) u domaći kalendar imunizacije, umesto oralne (OPV) kao prva doza. Sanofi Pasteur je posebno razvio i petovalentnu vakcinu (DtacP-IPV-Hib, Pentaxim). Sa 2 meseca, po srpskom kalendaru imunizacije, dete dobija DTP, odvojeno OPV i Hib. Sa petovalentnom vakcinom (DtacP-IPV-Hib) je sve to pokriveno, s tim što je umesto oralne, inaktivirana poliomijelitis vakcina (IPV). Prva doza se daje sa dva meseca, druga sa četiri, treća sa šest, i sa 18 meseci booster. Sa ovom vakcinom smo u Srbiji startovali 2003. godine i do sada je aplikovano preko 150.000 doza. U pitanju je vrlo sigurna i komforna vakcina, na kojoj se dugo radilo, kako bi se dobila određena kombinacija i dobio željeni imuni odgovor. Sanofi Pasteur mnogo radi i na prilagođavanju svoje ponude potrebama pacijenata. Tako je nedavno razvio FluID vakcinu za grip, čija se primena očekuje sledeće sezone. U pitanju je vakcina pakovana u špricu, kao i do sada, ali sa takvom iglom koja omogućava da se ljudi sami vakcinišu. Igla je promera 1,5 mm, kako ne bi ušla u masno tkivo, već ostala u slojevima kože, gde su najbolji receptori za antigene gripa. Novosti je heksavalentna vakcina, koja uključuje i hepatitis B. Ostale zemlje je nisu još uvek prihvatile, jer rastvarač koji se koristi za hepatitis B vakcinu umanjuje imuni odgovor na Hib komponentu, koji se nalazi u kompletu, tako da ne postoji imuni odgovor veći od 70%. U budućnosti ce se davati preko 50 vakcina sto profilaktickih sto terapijskih, stoga je definitivno budućnost u primeni multivalentnih vakcina. U 21 veku davace se detetu od 0-2 meseca obavezna hepatitis B vakcina i vakcina protiv respiratornog sincicijalnog virusa. Od 2-6 meseci davace se DTaP (difterija+tetanus+acelularni pertusis), hepatitis B, hepatitis A, konjugovane Hib, pneumokokna i meningokokna vakcina, vakcina protiv otitisa (Haemophilus netipiziran i Banhanela catarlis), Rota virus. Od 1-2 godine davace se MMRV (Morbilli+Mumps+Rubella+Varicella), influenza (intranazalna živa). Od 4-6 godina : MMRV (buster), antikarijes vakcina (streptococcus mutans), lajmska bolest (za endemična područja), krpeljski meningoencephalitis (za endemična područja). Od 11-13 godine humani papiloma virus, herpes simplex virus 2, naiseria gonorrhoeae, HIV virus, citomegalo virus, parvo virus, epštajn Bar virus. Imunizacija je najefikasnija i najekonomičnija mera prevencije bolesti i smrti.

Dr med. Ilija Rosić

Dr Ilija Rosić rođen je 1973. godine u Beogradu. Medicinski fakultet Univerziteta u Beogradu završio je 2000. godine. Magistarski rad na Medicinskom fakultetu odbranio je 2003. godine. U periodu od 2005 do 2009 godine završio je nekoliko Sanofi Pasteur seminara. Od 2003. godine zaposlen je prvo u Aventis Pasteur GmbH predstavništvu u Beogradu, kao mlađi stručni saradnik, od 2004. godine kao viši stručni saradnik u Sanofi Pasteur GmbH predstavništvu u Beogradu, zatim od 2009. godine kao Product Manager regiona u Sanofi Aventis d.o.o. u Beogradu. Autor je nekoliko naučnih radova u međunarodnim časopisima, kao i stručnih radova u nacionalnim časopisima.



Vaccines - role in preventive medicine, innovative vaccines, situation and perspective

Ilija Rosić

Sanofi Pasteur GmbH Belgrade office

Vaccine is biological product and has to be in cold – chain system (2-8 °) during the process of production and distribution. It is included in preventive medicine.

Immunization calendars are changing during the years in all the countries of the world – and they are including new vaccines that are medically proved, and which can improve medical protection with their quality and design. This is the example how the vaccine for hepatitis B was included in immunization calendar in Serbia – at the birth, after one month and after six months. Also, after unfortunate events in Nis few years ago, when one baby died of Hib meningitis infection, Hib vaccine was included. We expect soon inactivated polio vaccine to be included in domestic calendar of immunization instead of oral (OPV) as a first dose. Sanofi Pasteur has developed pentavalent vaccine (DtacP – IPV – Hib, Pentaxim). When it is two months old, according to domestic immunization calendar, child receive DTP, separately OPV and Hib. With pentavalent vaccine (DtacP – IPV – HiB) it is all covered, with difference that instead of oral OPV is inactivated IPV vaccine. First dose child should receive when it is 2 months old, second one when it is 4 months old, third with six months, and booster dose when it is 18 months old. We started with this vaccine in Serbia in 2003, and so far over 150,000 doses was applicated. It is very safe and comfortable vaccine, which was developed during long time in order to gain necessary immune response.

Sanofi Pasteur is also orientated to need of patients. That is why it has developed new vaccine FluID, which application should start next season. It is vaccine packed in syringe, but with needle that is designed on specific way so that patients can vaccinate themselves. The needle has 1.5 nm width, so it does not penetrate into fat tissues, and it stays in skin layers where are best receptors for flu antigens.

Hexavalent vaccine that includes hepatitis B is something new. Other countries still haven't accepted it, because solvent which is used for hepatitis B vaccine, can decrease immune response on HiB component, which is also in package, so there is no immune response higher than 70%.

In future over 50 vaccines, prophylactic and therapeutic, will be given, that is why future in the field of vaccines is in use of multivalent vaccines.

Immunization is most effective and most economic measure in prevention of diseases and death!

Upravljanje portfoliom fabrike generičkih lekova

Suzana Miljković

Sektor marketinga, Galenika a.d.

Upravljanje portfoliom farmaceutske kompanije vrši se u skladu sa strateškim odlukama i razmatranjem niza parametara koji definišu zahteve i potencijale tržišta, aktuelna naučna dostignuća i mogućnosti lečenja. Razvoj i uvođenje novog leka predstavlja značajnu odluku kojoj prethodi niz opsežnih istraživanja i procena, a zatim i ogromna ulaganja koja, u proseku, tek posle oko 12 godina, rezultuju novim lekom na tržištu. Novi, brend-lek poseduje patentnu zaštitu, koja originatoru-proizvođaču, garantuje mogućnost eksploatacije u narednih 10, pa čak i do 12 godina. Generički lekovi su lekovi koji imaju isti kvalitativni i kvantitativni sastav aktivne supstance, isti oblik i bioraspoloživost kao lek originatora, a pojavljuju se na tržištu tek pošto istekne patentna zaštita brend-leka. Njihove prednosti su značajno niže cene, minimalni troškovi promocije, kao i neznatni ili dobro poznati rizik kod primene leka. Zdravstveni sistemi mnogih zemalja podržavaju uvođenje generičkih zamena u terapiju. Međutim, originatori sprečavaju razvoj generičkih paralela jer žele da produže period ekskluziviteta i izvuku maksimalni profit iz postojećih proizvoda. Definicija generičkog leka, prvi put se pojavila u zakonskoj regulativi SAD 1984. godine, a kroz Direktivu 2004/27/EC i u EU. Ovi propisi favorizuju generičke lekove, definišu period ekskluziviteta brend-leka i ograničavaju mogućnosti brend-proizvođača da spreče pojavljivanje generičkih paralela na tržištu. Očekuje se da će zastupljenost generičkih lekova u EU i SAD značajno rasti u narednom periodu. Galenika a.d. je kompanija sa dugom tradicijom i renomeom, koja poseduje velike potencijale za razvoj i reformulacije leka. Svoju stratešku orijentaciju na proizvodnju generičkih lekova, Galenika a.d. će ostvarivati kroz licencnu saradnju sa originatorima, kupovinu gotovih fajlova, ali i razvojem sopstvenih tehnologija i dokumentacije za generičke lekove.



Suzana Miljković je obavljala poslove: farmaceuta i upravnika u apoteci, zastupnika nekoliko firmi iz Nemačke i Velike Britanije, autora većeg broja originalnih tehnologija za kozmetičke proizvode u kozmetičkoj kući Dahlia. Od 1994. godine zaposlena je u Galenici a.d., na poslovima razvoja i uvođenja novih proizvoda u Institutu, u marketingu parafarmaceutskih proizvoda, a zatim i u marketingu lekova.

Završila je specijalizaciju (1991) i magisterijum iz kozmetologije (1997) i specijalizaciju iz Farmaceutskog marketinga i menadžmenta (2006), na Farmaceutskom fakultetu u Beogradu. Nosilac je zvanja "Istraživač saradnik" (2001) i zvanja "Primarijus" (2003. godine).

Autor je jedne i ko-autor u dve knjige. Do sada je organizovala 4 simpozijuma o zaštiti od sunca. Stalno objavljuje stručno-popularne tekstove, autor je i/ili učesnik emisija o zdravlju na mnogim radio i TV stanicama. Učestvuje na stručnim i naučnim skupovima i ima veliki broj

publikovanih radova. Član je uređivačkog saveta časopisa Apotekarska praksa od avgusta 2004. godine i ima zvanje »tutora« Farmaceutske komore Srbije.

Management of a generic pharmaceutical company portfolio

Suzana Miljković,

Marketing Department, Galenika a.d.

A pharmaceutical company portfolio is managed based on the strategic decisions and considering the parameters that specify market requirements and potentials, current scientific achievements and therapeutic options. New drug development and introduction relies on the decision preceded by comprehensive research and assessments, and huge investment resulting in a new drug on the market after about 12 years. The new brand-medicinal product is the subject of patent protection guaranteeing the originator-manufacturer its exclusive exploitation for the next 10, even 12 years. Generic medicines are those having identical qualitative and quantitative active ingredient content, pharmaceutical form and bioavailability profile as the original medicine; however, that generic medicine is launched on the market only after the patent protection of the brand medicine has been expired. Its advantages are significantly lower price, minimum promotion costs, and a negligible but well known administration risk. The health systems of numerous countries support the introduction of generic parallels in the therapy. However, originators tend to interfere with the development of generic parallels in order to draw maximum profit from the existing product. The definition of generic drugs was first presented in the US legislation in 1984, and EU in the Directive 2004/27/EC. Such regulations favour generic medicines, specify the period of exclusivity of brand medicines and limit the capacity of brand manufacturers to interfere with launching generic parallels on the market. Generic market share in the EU and USA is expected to grow significantly in the next period. Galenika a.d. is a company with the long tradition and reputation in drug manufacturing possessing strong potentials for drug development and reformulation. Galenika a.d. intends to direct its strategic orientation towards generic manufacturing through licencing relationship with originators, purchasing already prepared files but will also rely on internally-developed technologies and documents pertaining to generic medicines.



Razvoj generičkih proizvoda

Biljana Stupar

kompanija Hemofarm-Stada

Generičke alternative brendiranim lekovima pojavljaju se kao dominantna snaga na globalnom tržištu sa povećanjem broja lekova koji gube patentnu zaštitu. Dostupnost generičkih lekova obezbeđuje prednosti za korisnike zbog ušteda u odnosu na brendirani, ekvivalentni lek što rezultira boljom dostupnošću i usaglašenošću velikog broja lekova.

Razvoj generičkih lekova koristi različit pristup i strategiju u odnosu na razvoj proizvoda koji sadrži novi hemijski entitet. Proizvođači generičkih lekova moraju formulirati lekoviti proizvod tako da bude terapijski i biološki ekvivalentan u odnosu na brendirani, referentni proizvod ali jeftiniji i u saglasnosti sa patentnim ograničenjima. Kako postići ovaj cilj? Ne postoji jedinstven odgovor na ovo pitanje ali je izvesno da znanje i kreativnost predstavljaju glavne alate u realizaciji ovog zadatka. U skladu sa činjenicom da se razvoj generičkog proizvoda uobičajeno dešava godinama nakon razvoja originalnog proizvoda, generički proizvođači imaju mogućnost da u razvoju formulacije koriste nove polazne materijale i njihove kombinacije a u razvoju procesa novu, savremenu opremu/procese. Na taj način je moguće napraviti optimizacije koje doprinose pravovremenom izlasku na tržište kvalitetnog, efikasnog ali i jeftinog leka.

Biljana Stupar, dipl. ph. spec, MBA,

Biljana Stupar, menadžer istraživanja i razvoja u Hemofarmu A.D. Zvanje diplomiranog farmaceuta stekla na Univerzitetu u Sarajevu 1989. Specijalizaciju iz farmaceutske tehnologije završila na Farmaceutskom fakultetu u Beogradu 2001. MBA diplomu Sheffieldskog Univerziteta dobila 2007.



Na početku profesionalne karijere Biljana je bila uključena u proizvodnju i kontrolu farmaceutskih proizvoda i to iskustvo je bilo izvrsna polazna tačka za kasniji rad u odeljenju razvoja. U poslednjih petnaest godina direktno je uključena u kreiranje Hemofarmovog proizvodnog portfolia i u tom periodu je na tržište lansirano više od 200 proizvoda u gotovo svim farmaceutskim oblicima (tablete, kapsule, parenteralni proizvodi malog i velikog volumena, masti, gelovi).

Danas je Biljana odgovorna za upravljanje multidisciplinarnim R&D timovima kao i za definisanje istraživačke i razvojne strategije i programa uključujući i uspostavljanje visokoeфикаsne R&D organizacione strukture.

Generic Drug Product Development

Biljana Stupar

Company Hemofarm-Stada

Generic alternatives to brand-names prescription medication are emerging as a dominant force in the global drug markets as an increasing number of prescription drugs lose patent protection. The availability of generic drugs provides advantages to consumers because of the cost savings over brand-name equivalent, resulting in increased accessibility to prescription drugs and increased compliance with drug regimen.

Generic drug product development uses a different approach and strategy compared to that used to develop drug product containing a new chemical entity. Generic drug product manufacturers must formulate a drug product that will be therapeutically equivalent and bioequivalent to the brand name (reference) drug product but cheaper than it and in accordance with patent restrictions. How to achieve this target? There is no universal answer on this question but it is certain that the knowledge and creativity represent the main tools for realization of this task. In accordance with the fact that development of the generic drug product usually happen years after the originator, generic drug producers have a chance to use a new raw materials and combination of materials during the formulation development as well as a new, up-to-date manufacturing equipment/ processes during the process development. Such a way it is possible to make some optimizations which contribute to launch of quality, efficacy as well as a cheap drug product on time.



Sistem kvaliteta u multinacionalnim farmaceutskim kompanijama

Valentina Marinković
FHI ZDRAVLJE-ActavisSrbija

Trend savremene farmaceutske industrije, bilo da je reč o inovativnim ili generičkim kompanijama, je implementacija najnovijih standarda iz oblasti kvaliteta, zaštite životne sredine, bezbednosti na radu, društvene odgovornosti, u cilju poboljšanja zdravlja ljudi, ali u isto vreme i povećanja profita. Ovakav način razmišljanja i strateškog razvoja podrazumeva racionalizaciju resursa. Usvojen je generalni pristup pravljenja "sites of excellence" unutar jedne korporacije. Posledica takvog koncepta je grupisanje proizvođača aktivnih supstanci ili istraživačko-razvojnih laboratorija u jednom delu sveta, proizvođača (sterilnih/nesterilnih proizvoda) u drugom, a pakovanja na trećoj lokaciji. Vrlo često, laboratorije za ispitivanje i kontrolu lekova, kao i kvalifikovane osobe za oslobađanje proizvoda, obavljaju svoje aktivnosti nevezano od mesta proizvodnje. U ovom radu su razmatrani rizici u poslovanju u kompleksnim farmaceutskim sistemima, kao što su multinacionalne kompanije, ugovorna proizvodnja/analiza, ugovorne istraživačke laboratorije, regulatorno okruženje nosioca dozvole za promet. Takođe, prikazan je koncept integrisanog modela upravljanja- mogućnost racionalizacije standarda: GxP, ISO 9001, ISO 14001, OHSAS 18001, BS 25999, HACCP, ISO 27000...

Dati su elementi integracije i alati koji se koriste u cilju uspostavljanja složenog, ali efikasnog Farmaceutskog sistema kvaliteta.

Dobro dizajnirani sistem upravljanja kvalitetom, osiguraće farmaceutskoj kompaniji pre svega, kvalitetan, bezbedan i efikasan lek, ali i efikasniji, brži način pojavljivanja leka na tržištu, uz smanjenje mogućih grešaka. Pozitivni rezultati takvog fleksibilnog i robusnog sistema upravljanja biće prepoznati od svih zainteresovanih strana (društvena zajednica, akcionari, regulatorni organi).

Doc. dr Valentina MARINKOVIĆ

Rođena u Leskovcu, 24.10.1963. godine. Farmaceutski fakultet završila u Beogradu, aprila 1987. godine, sa prosečnom ocenom 9,04. Specijalizaciju iz ispitivanja i kontrole lekova završila na Farmaceutskom fakultetu u Beogradu 1993.

Doktorsku disertaciju pod nazivom "Stabilnost i kinetika degradacionih reakcija nitrendipina i nizoldipina" odbranila na Farmaceutskom fakultetu 2003. godine. Zvanje docenta za naučnu oblast "tehnološko inženjerstvo" stekla je na Univerzitetu u Nišu 2005. godine. Završila je desetina internacionalnih edukacija iz oblasti farmaceutske regulative i GxPa. Objavila više od 30 naučnih i stručnih radova u međunarodnim i domaćim časopisima. Član i predsednik više programskih i organizacionih odbora domaćih simpozijuma, konferencija i kongresa iz oblasti farmacije i upravljanja kvalitetom. Član je evropske QP asocijacije. Član je komisije za izradu nacionalne farmakopeje. Član je izvršnog odbora Sekcije za ispitivanje i kontrolu lekova, FDS. Član je izdavačkog odbora nacionalnog časopisa za kvalitet "TQM and excellence". Predsednik komiteta za farmaciju, u Jedinstvenom udruženju za kvalitet Srbije je od 2006. godine. Radi na poslovima direktora kvaliteta u FHI ZDRAVLJE- Actavis Srbija.



Quality system in the multinational pharmaceutical companies

Valentina Marinković
ZDRAVLJE-ActavisSerbia

Abstract:

The trend of a present day pharmaceutical industry, regardless whether they be innovative or genetic companies, is the implementation of the newest standards, from the fields of Quality, Environmental protection, Work safety, Social responsibilities, all in the aim of improving the health of people, but also at the same time, to increase profit. This way of thinking and the strategic development means the rationalization of resources. The overall approach of forming "Sites of Excellence" within a Corporation was adopted. The consequence of such a concept is the grouping of active pharmaceutical ingredient manufacturers or research and development premises in one part of the world, the manufacturers of sterile/non sterile products in another part, while packaging would be found at a third location. Very often, quality control laboratories, as well as product release qualified persons, carry out their activities independently from the production site.

This paper covers the business risks in large pharmaceutical systems, such as multinational companies, contracted manufacture/analysis, contracted research and control laboratories, regulatory obligations of those holding trading permits.

Also, the concept of the integrated managing model – the possibility of standard rationalization: GxP, ISO 9001, ISO 14001, OHSAS 18001, BS 25999, HACCP, ISO 27001 was shown.

The integration elements and tools used in the aim of establishing a complex, but effective pharmaceutical Quality System were given.

A well designed quality management system will ensure a pharmaceutical company, above all, quality, safety and an efficient medicine, but it will also enable the medicine to be placed on the market much more efficiently and quickly, with a minimum error possibility. The positive effects of such a flexible and robust management system will be recognized by all interested parties (Community, shareholders, regulatory authorities)

Key words: *Integrated management systems, Pharmaceutical Quality System, Risk management, Safety*

Kvalitetna distribucija – bezbedan lek

Snežana Hadži-Arsić Novaković

Velefarm AD Holding kompanija, Beograd

Misija farmaceutske delatnosti je da obezbedi stanovništvu proizvode vrhunskog kvaliteta koji omogućavaju efektivnu terapiju ili služe očuvanju zdravlja. Integritet i kvalitet leka, formiran tokom procesa razvoja i proizvodnje, uz striktno poštovanje rigoroznih zahteva Dobre proizvođačke prakse, ne smeju biti ugroženi u toku lanca distribucije. Odobreni farmaceutski proizvodi se moraju distribuirati do korisnika bez ikakve sumnje u njihova ispravna svojstva, kako bi se u potpunosti ispoštovala Hipokratova zakletva „Primum non nocere“.

Pored čitavog niza preporuka koje definiše Dobra distributivna praksa, poseban akcenat je stavljen na kompetentnost zaposlenih i njihovo kontinualno učenje i usavršavanje.

Ciljevi kvaliteta veledrogerijskog poslovanja, koji se odnose na upravljanje distribucijom farmaceutskih proizvoda, sadržani su u uputstvu Dobra distributivna praksa, a sredstvo za postizanje definisanih ciljeva predstavlja Sistem upravljanja kvalitetom veledrogerije. Ovaj moćan alat obuhvata sve poslovne ciljeve organizacije i daje mogućnosti stalnog unapređenja poslovnih procesa i ispunjavanja očekivanja korisnika usluga i ostalih interesnih grupa.

Učinci procesa (performanse) moraju permanentno da se prate i mere. Merenje se obavlja u specifičnim kontrolnim tačkama, koje nazivamo »ključnim indikatorima performansi«. Samo u kontrolisanim uslovima proces može biti efektivan i zato se oni moraju trajno održavati.

Razvijanje svesti o društvenoj odgovornosti, koja uključuje i prevazilazi zahteve zakona i propisa, daje potvrdu zrelosti organizacije. Ova odgovornost se zasniva na etici i moralu organizacije.



Dipl. ph. Snežana Hadži-Arsić Novaković



Snežana Hadži-Arsić Novaković je diplomirala na Farmaceutskom fakultetu u Beogradu 1980. godine. Po završenom stažu (1980/81) i položenom stručnom ispitu zaposlila se u Velefarmu (danas "Velefarm" AD Holding kompanija). U Kompaniji je, na početku profesionalne karijere, angažovana na poslovima prodaje i planiranja. Od 1984. godine je rukovodila logistikom, što joj je omogućilo da razvije organizacione, pedagoške i analitičke veštine. Profesionalno sazrevajući uz rast i razvoj Velefarma, 1998. godine je prihvatila odgovornost za implementaciju sistema kvaliteta, po zahtevima ISO standarda. Paralelno sa ovom funkcijom, od 2001-2005. god. obavljala je i poslove direktora Velefarm – škole. Uvođenje novih standarda u sistem poslovanja

Kompanije, omogućilo joj je da postavi platformu za Integrirani sistem menadžmenta procesima. Uspešno je završila brojne treninge u organizaciji fakulteta Beogradskog Univerziteta, strukovnih udruženja, domaćih i međunarodnih edukativnih centara i Velefarm – škole. Autor je više radova objavljenih u stručnim časopisima.





Vizija razvoja savremene farmaceutske usluge u apotekarskoj praksi Srbije

**Sreda, 21. oktobar 2009
Farmaceutski fakultet u Beogradu**

Koordinator Mr sc. spec. Zlata Žuvela



Vizija razvoja savremene farmaceutske usluge u apotekarskoj praksi Srbije

Sreda, 21. oktobar 2009.

Farmaceutski fakultet u Beogradu

Program/Programme

- | | |
|---------------|--|
| 12,00 – 12,05 | Mr Zlata Žuvela
Otvaranje i pozdravna reč direktorke Farmaceutске Komore Srbije |
| 12,05 – 12,15 | Prof. Dr Nada Kovačević
Pozdravna reč dekana Farmaceutskog fakulteta u Beogradu |
| 12,15 – 12,35 | Mr Zlata Žuvela, spec - direktorka Farmaceutске Komore Srbije
Uvodno obrazloženje na temu: Vizija razvoja savremene farmaceutske usluge u apotekarskoj praksi Srbije |
| 12,35 – 12,55 | Mr Vanda Marković - pomoćnik ministra zdravlja Republike Srpske
Neka iskustva u vezi sa promenama u oblasti organizacije i usluga apotekarstva u Republici Srpskoj |
| 12,55 – 13,15 | Mr Branka Brzaković
Prikaz farmaceutske delatnosti u Švedskoj - iskustvo jednog Kliničkog farmaceuta |
| 13,15 – 13,25 | Pauza |
| 13,25 – 13,45 | Djordjica Korać, spec.
Neke informacije o statusu apotekarstva u Srbiji i predlozi promena kolega iz prakse - Prikaz rezultata anketa sprovedenih u bolničkim i javnim apotekama |
| 13,45 – 14,05 | Dr Branka Stojanović, spec.
Prikaz pilot projekta: "Unapređenje menadžmenta lekovima u Srbiji" sprovedenog u bolnicama Srbije u saradnji sa Crown Agents, Evropske agencije za rekonstrukciju i Ministarstva zdravlja Republike Srbije |
| 14,05 – 14,30 | Ružica Veličković, spec.
Vizija razvoja savremene farmaceutske usluge u apotekarskoj praksi Srbije |
| 14,30 – 15,00 | Diskusija |

Vizija razvoja savremene farmaceutske usluge u apotekarskoj praksi Srbije

Ružica Veličković, Đurđica Korać Farmaceutska komora Srbije

Poslednjih decenija svi smo svedoci velikih promena u nauci i u društvu. Farmaceuti koji obavljaju apotekarsku praksu u zdravstvenom sistemu Srbije su odavno uključeni u tokove promena ali sa njima nisu zadovoljni. Oni traže od svih koji se nalaze u sistemu, nauci, industriji koja je u vezi sa bolešću i zdravljem kao i socioekonomskim okruženjem, da prepoznaju njihove zahteve i tako omoguće proširenje njihovog stručnog delovanja u zdravstvenom sistemu.

Odgovornost svih učesnika u pružanju zdravstvene zaštite je velika, a farmaceut kao zdravstveni profesionalac svestan je svoje odgovornosti u segmentu farmaceutske zdravstvene delatnosti.

Njegovo aktivno učešće u pružanju zdravstvene usluge potrebno je obezbediti preko: zakonske regulative, tehničkih uslova u baznim i primenjenim istraživanjima, dostupnosti lekova za sve stanovnike, nezavisnih informacija o lekovima iz različitih izvora, kontroli kvaliteta, kreiranju farmaceutske stavova, kreiranju politike lekova i praćenju kao i rešavanju drugih problema u vezi sa lekovima u promociji zdravlja i sprečavanju nastanka bolesti.

Da bi se bolje prepoznali stavovi farmaceuta koji obavljaju apotekarsku praksu Farmaceutsko društvo Srbije (Sekcija za bolničku farmaciju) i Farmaceutska komora Srbije sproveli su istraživanja. Na reprezentativnom uzorku bolničkih farmaceuta (130) i farmaceuta u državnom i privatnom javnom sektoru apoteka (548) preko struktuiranog modela upitnika dobijeni su potrebni podaci o kadrovskim i tehničkim uslovima kao i preporuke koje farmaceuti daju za stvaranje ambijenta u kome će on moći bolje iskazati svoje mogućnosti u pružanju usluga.

Uporedno su korišćene slične inicijative koje su pokrenute poslednjih decenija u svetu (USA, Velika Britanija, Italija, Francuska Švedska) koji su te rezultate implementirali u praksi i imaju već značajna iskustva koja potkrepljuju adekvatnim rezultatima.

Ljudski resurs za zdravstvo Srbije je sigurno najveći resurs. Za Farmaceutsku komoru Srbije je vrlo važna ova analiza rezultata jer ona preko njih želi da upozna opštu i stručnu javnost o kapacitetu farmaceutske ljudskog resursa Srbije.

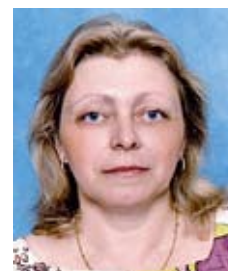


Dipl. ph. Đurđica Korać, specijalista farmakoinformatike



Đurđica Korać rođena je 1953. godine. Zvanje dipl. farmaceuta i specijaliste farmakokinetike stekla je na Farmaceutskom fakultetu Univerziteta u Beogradu 1976., odnosno 1991. godine. Radno iskustvo sticala je u bolničkom I javnom sektoru apoteka, a kraći period u Zavodu za javno zdravlje. Moderator je u Farmaceutskoj komori Srbije I član je Republičke stručne komisije za farmaciju. Trenutno radi kao specijalista farmakoinformatike u Domu zdravlja "Novi Beograd".

Dipl. ph. Ružica Veličković, specijalista kliničke farmacije



Ružica Veličković rođena je u Beogradu 1957. godine. Farmaceutski fakultet Univerziteta u Beogradu, završila 1981. godine. Specijalizaciju Kliničke farmacije, kao prvi kandidat na Farmaceutskom Fakultetu u Beogradu, završila 1998. godine kod prof. Dr Milene Pokrajac. Radila je u Apotekarskoj ustanovi Beograd u Centru za informacije i u apoteci pet godina. Od 1987. godine radila u Institutu za Mentalno zdravlje u Beogradu, kao šef apoteke i laboratorije, baveći se pre svega, poslovima terapijskog praćenja lekova, praćenja neželjenih dejstava i sprovođenja farmakoepidemioloških i farmakoekonomskih studija. Kao član terapijskog tima, učestvovala u dijagnostici i praćenju lečenja bolesti zavisnosti. Kao član tima i prvog etičkog odbora pri nekoj zdravstvenoj ustanovi u našoj zemlji, učestvovala u sprovođenju niza kliničkih ispitivanja II-IV faze. Učestvovala u nizu stručnih i naučnih istraživanja i sprovođenju nekih vidova posle diplomskog nastave u okviru Instituta za mentalno zdravlje i u saradnji sa Farmaceutskim i Medicinskim fakultetom u Beogradu i radionicama Farmaceutske komore. Autor i koautor oko 100 radova prikazanih na stručnim skupovima, objavljenih u časopisima ili kao poglavlja u monografijama i udžbenicima. Aktivan je član Farmaceutskog društva Srbije, ESCP-a (Evropsko udruženje kliničke farmacije), AACC (Američko udruženje kliničke hemije).





Biofarm 2009

Uticaj faktora formulacije i procesa proizvodnje na bioraspoloživost lekova

Četvrtak, 22. oktobar 2009
Zadužbina Ilije Kolarca, Beograd

Koordinatori:
Dr sc. Svetlana Ibrić, van.prof.
Doc. dr Jelena Parojčić



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Program/Programme

9:00 – 9:30	Registracija učesnika
	Otvaranje Simpozijuma Ivanka Miletić, <i>Predsednik Farmaceutskog Društva Srbije</i>
9:30 – 11:00	Uvodna reč Nada Kovačević <i>Dekan Farmaceutskog fakulteta</i>
	The growing importance of industrial pharmacy in research and development Gabriele Betz <i>Industrial Pharmacy Lab, Department of Pharmaceutical Sciences, University of Basel, Switzerland</i>
11:00 – 11:30	Poster sekcija/Pauza za kafu
11:30 – 13:00	Influence of Processing on Drug Physicochemical Properties Owen I. Corrigan, <i>School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin, Ireland</i>
	Machine Learning Technologies in Pharmaceutical Formulation Elizabeth Colbourn, <i>Intelligensys Ltd, UK</i>
13:00 – 14:00	Ručak
14:00 – 15:00	Biofarmaceutski aspekt oralne primene lekova Jelena Parojčić, <i>Farmaceutski fakultet, Univerzitet u Beogradu</i>
	Novi pristupi formulaciji slabo rastvornih lekova Svetlana Ibrić, <i>Farmaceutski fakultet, Univerzitet u Beogradu</i>
15:00 – 15:30	Poster sekcija/Pauza za kafu
15:30 – 17:00	Postregistracione izmene i bioraspoloživost lekova: industrijske vs. regulatorna perspektiva A. Čvrsti dozirani oblici Irena Homšek, <i>Institut za istraživanje i razvoj, Galenika ad, Beograd</i> Marija Ilić, <i>Agencija za lekove i medicinska sredstva Srbije</i>
	Diskusija Proglašenje najboljeg rada u kategoriji poster prezentacija Zatvaranje Simpozijuma

The growing importance of industrial pharmacy in research and development

Gabriele Betz

Industrial Pharmacy Lab, Department of Pharmaceutical Sciences, University of Basel, Switzerland.

The Industrial Pharmacy Research Group is studying pharmaceutical drug formulation including physical pharmacy and process technology focusing on solid dosage forms such as tablets, capsules, pellets, granulates, and multiple unit pellet systems (MUPS).

Formulation science and process technology is a critical issue during the course of the development of a medicament. However, this field is commonly underestimated and “unspecified formulation problems” lead often to delays in approval submissions¹. Thus, there is an urgent need to work in this research field and to suggest rational strategies and mathematical models in order to predict the performance of a formulation for various scales, lab and manufacturing scale.

Powder mixtures and compacts are complex systems and the behaviour of disordered particulates during process and under pressure is not well understood, especially various scales and high-speed compaction cycles used in manufacturing. We are able to simulate multi station rotary tablet presses on the basis of dwell time using a compaction simulator, thus including scale-up problems in the early stage of formulation development. Generally, an extensive experimental program is applied to find the optimal formulation thus, mathematical and computer models can assist pharmaceutical scientists in rational dosage form design. Recent findings dealt with the mechanics of compacts, and we were able to propose realistic models for the elastic modulus, the tensile strength, the crushing strength, and disintegration time of compacts.

In the current presentation focus will be spent on the active substance carbamazepine (CBZ) exhibiting different polymorphic modifications and recently we could show the importance of particle shape and surface of the particulate system during tablet formation and the performance of the compact². The variability of different commercially available CBZ samples is a known problem and therefore intrinsic dissolution measurement is recommended as a monitoring tool to maintain product quality.

Further focus in this presentation is the application of diffuse transmission and reflectance mode in near-infrared non-destructive quantification for quality control.

According to our current investigations considering a 10 mm compact, the central 5 mm carry 77% of the signal and the peripheral 5 mm carry 23% of the signal³. The fact that spectral representation of the tablet fades towards the periphery makes estimation of the sampled mass for both diffuse reflectance and transmission modes overestimated and very much dependent on the tablet physical properties.

Therefore, the influence of compaction variability occurring during the tableting process on the performance of content prediction using NIR spectroscopy is discussed.

¹Nature Reviews, Drug Discovery, Vol.5, Nov. 2006. ²S. Sehic. 2008. Investigation of variability of primary materials on the intrinsic dissolution behavior of carbamazepine. Ph.D Thesis, University of Basel, Switzerland. ³M. Saeed, S. Saner, J. Oelichmann, H. Keller, G. Betz. 2009. Assessment of Diffuse Transmission Mode in Near-Infrared Quantification – Part I: The Press Effect on Low-Dose Pharmaceutical Tablets. J Pharm Sci, early view.

Dr. Gabriele Betz

Gabriele Betz was born in 1971 in Ravensburg/Germany. She received her Abitur at Matthias Erzberger Gymnasium in Biberach/Riss and studied Pharmacy at Albert Ludwig University in Freiburg/Breisgau from 1990-1995. She received her practical training at Novartis, Wehr and Apotheke Stadtmitte, Stuttgart before she moved to Basel, Switzerland to perform her Ph.D-thesis in the field of Transdermal Heparin Application at the Institute of Pharmaceutical Technology, University of Basel. After completing her Ph.D-thesis in 2000, Gabriele started to establish the Industrial Pharmacy Lab in the frame of her Habilitation and holds a teaching position at the Department of Pharmaceutical Sciences since 2003. In 2004 she was selected as High Potential of the Year by the Gebert Rűf Foundation and attended the Babson College in Massachusetts, where she received a Certificate in Entrepreneurship.

Gabriele Betz is working in the area of pharmaceutical drug formulation including physical pharmacy and process technology focusing on solid dosage forms such as tablets, capsules, pellets, granulates, and multiple unit pellet systems (MUPS). Further focus is the relation between NIR transmittance/reflectance and the physical properties of granulates and compacts in the frame of the process analytical technology (PAT) initiative. Gabriele Betz has more than 80 publications, presentations, and conference contributions in her research field.

Since 2006 she is Member of the Executive Board of the Department of Pharmaceutical Sciences, since 2007 she is member of the “Regenz” of the University of Basel, and since 2009 her research group belongs to the Competence Centre of the University.

Awards

NETS Award 2004 for young scientists and NETS Special Award 2004 sponsored by Gebert Rűf Stiftung Basel, Switzerland.

SHARE (Swiss House of Advanced Research) Award, Boston, MA, 2004, Selection as the most promising scientist by the audience in the frame of NETS.

FIP Award 2008 presented by Industrial Pharmacy Section for excellent organisation of the workshop “Modern solid dosage form process design and development using chemometric, PAT, and simulation approaches”.



Influence of Processing on Drug Physicochemical Properties.

Owen I. Corrigan, School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin, Ireland.

The FDA regulatory initiative, 'Quality by Design' (QbD) requires pharmaceutical companies to understand pharmaceutical materials and processes at a level that is scientifically sound, feasible and justifiable. A fundamental knowledge and mechanistic understanding of the solid-state properties of both the Active Pharmaceutical Ingredient (API) and of the excipients employed is necessary to ensure optimal and consistent product performance. These properties can not only impact on bioavailability, through altered solubility and or dissolution rate but can also influence processability. Information on transformations to different energy states and the co-existence of different energy forms are essential to establish the 'developability' of an API. We have a particular interest in disordered solids, high energy forms and amorphous materials.

This presentation will review relevant solid state properties of pharmaceutical materials and the potential impact of processing. Two specific processes, milling and spray drying, will be considered in some detail. Milling is a traditional method for particle size reduction and control, while spray drying is used to produce dry powders, often having improved processing properties, from a solution or slurry. Sulphonamides were selected for investigation because of their known ability to exist in a range of crystal forms. In addition to the processing of single solids, two component (drug plus excipient) systems were also examined.

In addition to the expected size reduction, milling was shown to induce both polymorphic transformations and amorphous state formation. The extent of these solid state changes was influenced by the drug, the duration and temperature of milling and the presence of excipient. Spray drying showed a greater potential to produce amorphous materials. Furthermore the morphology of the particulates produced, could be altered by varying the processing parameters (e.g. solvent, inlet/outlet temperature, etc.) resulting in improved process and biopharmaceutical properties. These effects were evident in spray dried powders prepared for use in dry powder inhalers.

The production of amorphous APIs, raises issues of physical stability, and many materials, subsequent to processing, undergo physical transformation. Approaches to prediction of the likelihood of recrystallization from an amorphous phase will be discussed and approaches to stabilisation considered.

In conclusion an understanding of interrelationships among structure, properties and processing is essential to achieve optimal performance of a pharmaceutical product.



Prof. Dr. Owen I Corrigan

Owen I Corrigan is Professor of Pharmaceutics and currently acts as Director of Research in School of Pharmacy & Pharmaceutical Sciences, Trinity College, University of Dublin, Ireland. He received Ph.D. for research on mechanisms of dissolution from high-energy solid dispersion systems, in 1973. He was a Visiting Scholar at College of Pharmacy, University of Michigan, USA in 1979, with Professor WI Higuchi, investigating transport mechanisms in pharmaceutical systems.

Prof. Corrigan was appointed to the Chair in Pharmaceutics in 1991 and acted as Head of the Pharmaceutics Department from 1991 until 2000. From 1977 until 2002, Prof. Corrigan was Consultant in Biopharmaceutics and Pharmaceutical Technology to Elan Corporation. Prof. Corrigan is a member of the American Association of Pharmaceutical Scientists, the Controlled Release Society, the American Association for the Advancement of Science, European Federation for Pharmaceutical Sciences (EUFEPS), Royal Academy of Medicine in Ireland (RAMI), Pharmaceutical Society of Ireland (PSI) and Irish Pharmaceutical Union (IPU). He is also a member of the International Editorial Advisory Board of The Encyclopaedia of Pharmaceutical Technology and Health Research Board, Ireland.

Prof Corrigan's research interests include Biopharmaceutical aspects of drug delivery systems, drug transport mechanisms across biological membranes with particular reference to the gastrointestinal tract and skin. He has published over 150 scientific research publications and has four patents.



Machine Learning Technologies in Pharmaceutical Formulation

Elizabeth Colbourn, Intelligensys Ltd, UK

Development of commercial pharmaceutical formulations can involve extensive experimentation which generates a large amount of data. Understanding such data and discovering the key relationships within it can be a complex process which adds considerably to the time and expense taken to get a product to market. New computational techniques such as neural and evolutionary computing have the potential to accelerate the mining and modeling of data, and can be made readily accessible to the product formulator. This presentation outlines the basis of these technologies, focusing on neurofuzzy logic, decision trees and gene expression programming, and discusses their use in pharmaceutical formulation.

Dr Elizabeth Colbourn

Elizabeth Colbourn is a founding director of Intelligensys and has 30 years' experience in applying modelling to real industrial problems.

For several years she was based at ICI plc's Wilton Research Centre, where she established and led the materials modelling team which provided modelling solutions for most of ICI's materials-based businesses. In 1990, she was appointed to ICI's prestigious Scientific Ladder, one of the first two women to attain this position.

In 1993, she left ICI to set up Oxford Materials Ltd. focusing on the design and application of a range of simulation tools for materials modelling. In addition, she pioneered the introduction of the CAD/Chem system - a forerunner of INForm - in the UK market. This activity subsequently formed the nucleus for Intelligensys.

A Canadian by birth, she is the author of over 50 refereed publications in the scientific literature as well as a number of popular articles. She has an Honours BSc in Chemistry from Queen's University, Canada, and a D Phil in Theoretical Chemistry from the UK's University of Oxford. She is a Fellow of the Royal Society of Chemistry and a member of the American Chemical Society, and actively participates in UK EPSRC's peer review process.

Primena mašinskog učenja u formulaciji farmaceutskih proizvoda

Elizabeth Colbourn, Intelligensys Ltd, UK

Razvoj farmaceutskih proizvoda često podrazumeva veoma opsežne eksperimente sa velikim brojem podataka. Razumevanje dobijenih podataka i otkrivanje stvarnih odnosa/zakovitosti među njima je kompleksan proces koji zahteva velika materijalna sredstva i vreme koje je potrebno za pojavljivanje proizvoda na tržištu. Nove kompjuterske tehnike, kao što su neuronske mreže i genetski algoritmi omogućavaju brže razumevanje dobijenih podataka i njihovo modelovanje, a dostupne su istraživačima u farmaceutskoj industriji. Ova prezentacija ističe osnovne karakteristike tehnologija mašinskog učenja, sa posebnim osvrtom na neurofazi logiku, stabla odluke i programiranje tipa genetske ekspresije, diskutujući njihovu ulogu u formulaciji lekova.

Dr Elizabeth Colbourn

Elizabeth Colbourn je osnivački direktor *Intelligensys*-a i ima 30-ogodišnje iskustvo u primeni modelovanja za rešavanje stvarnih industrijskih problema.

Tokom nekoliko godina je boravila na *ICI plc's Wilton* istraživačkom centru gde je osnovala i rukovodila timom za modelovanje materijala koji je razvio rešenja za većinu poslovnih projekata *ICI* centra. Tokom 1990-ih godina je postala prestižni naučni rukovodilac *ICI* centra kao jedna od prvih žena koja je obavljala tu funkciju.

1993. godine odlazi iz *ICI* centra i osniva *Oxford Materials Ltd.* sa fokusom na dizajn i primenu raznolikih alatki za simulaciju modelovanja materijala. Pored toga, predvodila je uvođenje *CAD/Chem* sistema, koji je prethodio *INForm*-u, na tržište Ujedinjenog kraljevstva. Iz ove delatnosti se dalje formirana okosnica *Intelligensys*-a.

Kanađanka rođenjem, autor je preko 50 recenziranih radova u naučnoj literaturi kao i velikog broja popularnih članaka. Diplomirala je hemiju na *Queen's* univerzitetu u Kanadi sa posebnim priznanjima, a doktorirala je na teorijskoj hemiji na *UK's* univerzitetu u Oksfordu. Član je Kraljevskog društva hemičara kao i Američkog društva hemičara a aktivno učestvuje u recenzentskim aktivnostima Saveta za inženjerstvo i fizičke nauke Ujedinjenog Kraljevstva.

Biopharmaceutical aspects of oral drug delivery

Jelena Parojčić, Faculty of Pharmacy, University of Belgrade

Biopharmaceutical aspects of oral drug delivery refer to a number of physicochemical, pharmaceutical and physiological factors related to drug substance properties, dosage form characteristics, the conditions encountered in vivo, as well as their interactions, determining the rate and extent of drug absorption. Identification of the time course of drug input in vivo is essential for the (i) understanding of absorption mechanisms and the interactions encountered, (ii) design of the dosage forms with targeted product profiles, (iii) development of biorelevant dissolution testing and (iv) in vitro – in vivo correlation modelling. The shifting paradigm of drug absorption: from pH-partition hypothesis to the contemporary views on the fluid flow across intestinal barrier and the role of molecular transporters will be addressed, as well as the available methods for drug absorption analysis and prediction.

Dr Jelena Parojčić

Dr Jelena Parojčić is a Senior Lecturer in the Institute of Pharmaceutical Technology, Faculty of Pharmacy, University of Belgrade. She received a BSc in Pharmacy, MSc and PhD in Pharmaceutical Technology from the Faculty of Pharmacy, University of Belgrade. In 2005, Dr Parojčić was a Visiting Research Scientist in the Department of Pharmaceutics and Pharmaceutical Technology, Trinity College Dublin with Prof. Owen I Corrigan. Her research interests include biopharmaceutical characterization of oral drug delivery systems, dissolution method development and optimization and in vitro – in vivo correlation.

She has published 24 papers in international scientific journals, more than 60 abstracts on international conferences and the monograph „*In vitro – in vivo correlation: basic considerations and importance*“.

In 1997, Dr Parojčić has received the Annual ICN Yugoslavia Award for her MSc thesis entitled „*In vitro evaluation of commercially available paracetamol tablets with an attempt on establishing in vitro – in vivo correlation*“ and KRKA Annual award 2004 for the PhD thesis entitled „*Biopharmaceutical characterization of paracetamol extended release matrix tablets based on novel Carbopol® polymers*“.

Dr Jelena Parojčić is project coordinator of the Project TR23015: *Biopharmaceutical characterization of the selected BCS class 2 and 3 model drugs: in vitro and in silico methods evaluation* funded by the Ministry of Science and Technological Development, Republic of Serbia.



Biofarmaceutski aspekti oralne primene lekova

Jelena Parojčić, Farmaceutski fakultet, Univerzitet u Beogradu

Biofarmaceutski aspekti oralne primene lekova podrazumevaju brojne fizičko-hemijske, farmaceutske i fiziološke faktore koji se odnose na karakteristike lekovite supstance, farmaceutskog oblika leka, uslova koji postoje u organizmu, kao i njihovih interakcija od kojih zavisi obim i brzina apsorpcije leka. Poznavanje kinetike apsorpcije leka je neophodno da bi se utvrdio mehanizam apsorpcije leka, kao i moguće interakcije kao osnov za razvoj odgovarajuće formulacije leka, razvoj biorelevantnog testa za ispitivanje brzine rastvaranja i uspostavljanje in vitro – in vivo korelacije. U okviru prezentacije biće prikazana najnovija saznanja vezana za uticaj transportnih molekula, kao i protoka tečnosti unutar gastrointestinalnog trakta na apsorpciju lekova. Takođe će biti razmotrene mogućnosti primene matematičkih metoda za modelovanje i predviđanje procesa apsorpcije leka.

Dr Jelena Parojčić

Dr Jelena Parojčić zaposlena je kao docent u Institutu za farmaceutsku tehnologiju i kozmetologiju Farmaceutskog fakulteta u Beogradu, gde je odbranila i magistarski rad i doktorsku disertaciju. U toku 2005. godine, Dr Jelena Parojčić boravila je kao gostujući saradnik u Institutu za farmaceutsku tehnologiju, Farmaceutskog fakulteta, Trinity College, Dablin kod profesora Owena Corrigana. Istraživački interes Dr Parojčić usmeren je ka biofarmaceutskoj karakterizaciji oralnih lekovitih preparata, razvoju i optimizaciji metoda za ispitivanje brzine rastvaranja i uspostavljanje in vitro – in vivo korelacije. Dr Parojčić objavila je 24 rada u međunarodnim naučnim časopisima, više od 60 prezentacija na međunarodnim naučnim skupovima, kao i monografiju pod nazivom „*In vitro – in vivo korelacija: osnovna razmatranja i značaj*“.

Magistarski rad Dr Parojčić pod nazivom „*Farmaceutsko – tehnološka ispitivanja preparata sa paracetamolom i mogućnost uspostavljanja in vitro – in vivo korelacije*“ nagrađen je godišnjom nagradom ICN Jugoslavija za 1997. godinu. Za doktorsku tezu pod nazivom „*Biofarmaceutska karakterizacija hidrofилnih matriks tableta sa usporenim oslobađanjem paracetamola*“ Dr Parojčić je dobila godišnju nagradu KRKA, Novo mesto za 2004. godinu.

Dr Jelena Parojčić je rukovodilac projekta TR23015 *Razvoj i primena in vitro i in silico metoda u biofarmaceutskoj karakterizaciji lekova BSK grupe 2 i 3* koji finansira Ministarstvo za nauku i tehnološki razvoj Republike Srbije.



Recent advances in formulation of poorly soluble drugs

Svetlana Ibrić, Faculty of Pharmacy, University of Belgrade

It has been estimated that anywhere from 40 to 70 percent of all new chemical entities (NCE) identified in drug discovery programs are insufficiently soluble in aqueous media to allow for adequate and reproducible absorption from the gastrointestinal tract. Lipid-based dosage forms may provide new solutions for delivery of many new drugs demonstrating poor solubility and absorption. As with any novel approach, new questions may have to be addressed and extra measures to be taken to ensure the quality, safety, and efficacy of these systems. However, a considerable gap exists between the need for this technology, as justified by the preponderance of poorly water-soluble compounds filling drug discovery pipelines, and its application. As with any drug delivery technology, there are practical limitations to the successful application of oral lipid-based formulations. This discussion will explore some of the reasons for the gap between the need for lipid-based formulations and the reluctance to more fully exploit their considerable potential.

Dr Svetlana Ibrić

Dr Svetlana Ibrić is a Senior Lecturer in the Institute of Pharmaceutical Technology, Faculty of Pharmacy, University of Belgrade. She received a BSc in Pharmacy, MSc and PhD in Pharmaceutical Technology from the Faculty of Pharmacy, University of Belgrade. Her research interests include formulation of oral drug delivery systems, application of design of experiment and artificial neural networks in drug formulation as well as in dissolution method development and drug stability.

She has published 25 papers in international scientific journals, more than 80 abstracts on international conferences and two monographs: „Application of artificial neural networks in pharmaceutical technology“ (2003) and „Design of experiments in pharmaceutical technology“ (2006).

In 1998, Dr Ibrić has received the Annual ICN Yugoslavia Award for her MSc thesis entitled „*In vitro evaluation of commercially available diclofenac sodium tablets using the design of experiments*“. In 2002, she received PhD thesis entitled „*Application of artificial neural networks in formulation of aspirin extended release matrix tablets*“.



Novi pristupi formulaciji slabo rastvornih lekova

Svetlana Ibrić, Farmaceutski fakultet, Univerzitet u Beogradu

Poznato je da je 40 do 70 procenata svih novih hemijskih entiteta koji su identifikovani u programima razvoja lekova slabo rastvorni u vodenim medijumima što otežava adekvatnu i reproduktivnu apsorpciju iz gastrointestinalnog trakta. Farmaceutski oblici zasnovani na lipidima (lipidne formulacije) predstavljaju novi pristup za mnoge lekovite supstance koje karakteriše slaba rastvorljivost. S obzirom da lipidne formulacije predstavljaju novi pristup u formulaciji lekova, neophodno je obratiti posebnu pažnju na obezbeđivanje njihovog kvaliteta, bezbednosti i efikasnosti. Kao i kod primene drugih tehnologija, postoje praktična ograničenja za uspešnu primenu oralnih lipidnih formulacija. U prezentaciji će biti diskutovani razlozi za primenu ovog pristupa u formulaciji slabo rastvornih lekova, kao i za njihovu nedovoljnu primenu u farmaceutskoj industriji.

Dr Svetlana Ibrić

Dr Svetlana Ibrić, zaposlena je kao vanredni profesor u Institutu za farmaceutsku tehnologiju i kozmetologiju Farmaceutskog fakulteta u Beogradu, gde je odbranila i magistarski rad i doktorsku disertaciju. Istraživački interes Dr Ibrić usmeren je ka primeni optimizacionih tehnika u razvoju formulacije čvrstih doziranih oblika, razvoju in vitro testa za ispitivanje brzine oslobađanje lekovite supstance iz lekovitih preparata i stabilnosti lekova. Dr Ibrić je objavila 25 radova u vodećim međunarodnim časopisima, više od 80 prezentacija na međunarodnim naučnim skupovima, kao i dve monografije pod nazivom: „Primena veštačkih neuronskih mreža u farmaceutskog tehnologiji“ (2003) i „Primena matematičke teorije eksperimenata u farmaceutskoj tehnologiji“ (2006).

Magistarski rad Dr Ibrić pod nazivom „Primena eksperimentalnog dizajna u ispitivanju brzine rastvaranje dikofenak natrijuma iz tableta“ nagrađen je godišnjom nagradom ICN Jugoslavija za 1998. godinu. Doktorsku disertaciju po nazivom „Primena veštačkih neuronskih mreža u formulaciji matriks tableta sa kontrolisanim oslobađanjem acetilsalicilne kiseline“ odbranila je 2002. godine.



POSTAPPROVAL CHANGES AND DRUG BIOAVAILABILITY: INDUSTRIAL VS. REGULATORY PERSPECTIVE A. SOLID DOSAGE FORMS

Homšek Irena, Ivić Branka, Petrović Ljiljana, R&D Institute, Galenika ad, Belgrade
Ilić Marija, Medicines and Medical devices Agency of Serbia, Belgrade

The main reason for most postapproval changes is to implement the latest developments in pharmaceutical sciences into production of a drug product which is already on the market. Sometimes these need to be performed because of a minor change in the manufacturing process or changed active pharmaceutical ingredient/exipients manufacturer, equipment, production plant, etc.

Each of such changes requires proving that the quality of the finished product will be assured throughout the predicted shelf life. At the same time the product must remain its efficacy and safety. In the presence of certain changes in formulation and/or technological procedure, the therapeutic equivalence with reference product needs to be reconfirmed through bioequivalence study or appropriate *in vitro* testing, with the tests properly justified and explained in detail.

All the above suggests that a close collaboration between the industry and regulatory authorities needs to be established at the very beginning of the formulation development process, as well as during preformulation research, preparation for bioequivalence study, scale-up from laboratory to pilot and manufacturing plant, process validation and especially following postapproval changes in order to ensure the expected efficacy and safety of a drug product.

Dr Irena Homšek

Dr Irena Homšek is working in the pharmaceutical company Galenika ad, as director of R&D Institute. During eighteen years with the company she has developed a number of technologies for manufacturing drug preparation, and 16 of these, based on the personal verified procedure, have introduced into production and are available on the Serbian market. She received a BSc in Pharmacy, MSc and PhD in Pharmaceutical Technology from the Faculty of Pharmacy, University of Belgrade. During summer 2009, dr Homšek was a Visiting Research Scientist in the Department of Pharmaceutical Technology, Faculty of Pharmacy, University of Ljubljana.

Her research interests are in the field of formulation and *in vitro* and *in vivo* evaluation of solid dosage forms as well as establishment of *in vitro-in vivo* correlation, i.e. application of dissolution testing as a prognostic tool for *in vivo* behavior of drug products. She has published 9 papers in national and international scientific journals, more than 80 presentations on international and national meetings and 5 patent applications.

Marija Ilić, MSc

Marija Ilić graduated at Faculty of Pharmacy, University of Belgrade in 2000. She worked as teaching and research assistant at Department of Pharmaceutical Technology and Cosmetology, Faculty of Pharmacy, from January 2001. In July 2005, she became MSc in Pharmacy with thesis "Pharmaceutical-technological characterization of poly(acrylamide-co-itaconic acid) hydrogels as the potential drug delivery systems".

From 2005, she is working in Medicines and Medical Devices Agency of Serbia. Her present position is Senior Associate in National Pharmacovigilance Centre. She is involved in assessment of need for bioequivalence studies during processes of marketing authorisation/renewal/variations. Marija Ilić is author or co-author of 20 research articles and publications.

POSTREGISTRACIONE IZMENE I BIORASPOLOŽIVOST LEKOVA: INDUSTRIJSKA VS. REGULATORNA PERSPEKTIVA. A. ČVRSTI DOZIRANI OBLICI

Homšek Irena, Ivić Branka, Petrović Ljiljana, Institut za istraživanje i razvoj, Galenika ad, Beograd
Ilić Marija, Agencija za lekove i medicinska sredstva Srbije, Beograd

Postregistracione izmene najčešće se sprovode sa ciljem da se savremena dostignuća iz oblasti farmacije primene na proizvod koji se nalazi na tržištu. Nekada ih je u industriji neophodno sprovesti zbog manjih izmena u procesu proizvodnje, promene proizvođača aktivne ili pomoćnih supstanci, opreme, mesta proizvodnje i sl.

U svakom od ovih slučajeva neophodno je potvrditi da je kvalitet lekovitog preparata ostao nepromenjen u toku predviđenog roka trajanja, da je proizvod efikasan i bezbedan za pacijenta. Prilikom određenih izmena u formulaciji i/ili tehnološkom postupku neophodno je potvrditi terapijsku ekvivalentnost proizvoda nakon izmena sa referentnim preparatom, sprovođenjem studija bioekvivalencije ili odgovarajućim *in vitro* ispitivanjima koja moraju biti na adekvatan način obrazložena i argumentovana.

Sve ovo ukazuje na potrebu uspostavljanja bliske saradnje između industrije i regulatornih organa već na samom početku razvoja formulacije, tokom preformulacionih ispitivanja, prilikom planiranja studije bioekvivalencije, transfera tehnologije sa laboratorijskog na pilot i nivo proizvodnje, validacije procesa, a posebno po sprovođenju postregistracionih izmena, sa ciljem da se obezbedi očekivana efikasnost i bezbednost leka.

Dr Irena Homšek

Dr Irena Homšek je zaposlena u Galenici ad kao direktor Instituta za istraživanje i razvoj. Tokom 18 godina razvila je veliki broj tehnologija za izradu lekovitih preparata, a 16 formulacija, zasnovanih na sopstvenim tehnologijama, uvedeno je u proizvodnju i nalazi se na srpskom tržištu.

Završila je Farmaceutski fakultet Univerziteta u Beogradu gde je odbranila i magistarski rad i doktorsku disertaciju. Tokom leta 2009, dr Homšek je boravila kao gostujući saradnik na Zavodu za farmaceutsku tehnologiju, Farmaceutskog fakulteta Univeziteta u Ljubljani.

Njen istraživački rad usmeren je na formulisanje, *in vitro* i *in vivo* ispitivanje čvrstih doziranih oblika, kao i uspostavljanje *in vitro- in vivo* korelacije. Dr Homšek je objavila 9 radova u nacionalnim i međunarodnim časopisima, više od 80 prezentacija na međunarodnim i nacionalnim skupovima, kao i 5 patentnih prijava.

mr sc. Marija Ilić

Marija Ilić je diplomirala na Farmaceutskom fakultetu u Beogradu 2000. godine. Od januara 2001. godine je bila zaposlena na Farmaceutskom fakultetu u Beogradu kao saradnik, a zatim i asistent-pripravnik u Institutu za farmaceutsku tehnologiju i kozmetologiju. Titulu magistra farmaceutskih nauka je stekla u julu 2005. godine odbranom magistarskog rada pod nazivom "Farmaceutsko-tehnološka karakterizacija hidrogela poli(akrilamida-ko-itakonske kiseline) kao potencijalnih nosača lekovitih supstanci".

U Agenciji za lekove i medicinska sredstva Srbije je počela da radi u novembru 2005. godine. Trenutno radi kao viši stručni saradnik u Nacionalnom centru za farmakovigilancu. Uključena je u poslove procene potrebe sprovođenja ispitivanja biološke ekvivalentnosti u postupku dobijanja /obnove/ izmene dozvole za stavljanje leka u promet. Marija Ilić je autor ili koautor 20 objavljenih naučnih radova i saopštenja.



The First Symposium of Faculty of Pharmacy: Advanced Topics in Pharmaceutical Sciences

Friday, October 23, 2009
Faculty of Pharmacy

Koordinatori:

Dr sc. Vladimir Savić, van. prof.
Prof. dr Vera Kapetanović
Prof. dr Danica Agbaba



The First Symposium of Faculty of Pharmacy: Advanced Topics in Pharmaceutical Sciences

Friday, October 23, 2009

Faculty of Pharmacy

Programme

- | | |
|----------------------|---|
| 10.00 | Professor dr Nada Kovacevic
Opening remarks |
| 10.10 – 10.30 | Professor dr Danica Agbaba
Research at Faculty of Pharmacy: The Last Decade |
| 10.30 – 11.30 | Professor dr Ian Bates
Global Trends in Pharmacy Education |
| 11.30 – 12.30 | Professor dr Hugo Kubinyi
Chemical Biology and Chemogenomics in Drug Discovery |
| 12.30 – 13.30 | Pause: Lunch |
| 13.30 – 14.30 | Professor dr Pat Sandra
The Impact of Recent Innovations in Fluid-Based Separation Techniques on
Pharmaceutical Analysis |
| 14.30 – 15.30 | Professor dr Daan J.A. Crommelin
Nanotechnology and Drug Therapy: Will We Do Better in the Future? |
| 15.30 – 15.45 | Pause |
| 15.45 – 16.45 | dr Branislav Musicki
The World of Bioluminescence: Remarkable History of Photoproteins and Fluorescent
Proteins |

Professor dr Danica Agbaba

*Department of Pharmaceutical chemistry, Faculty of Pharmacy,
University of Belgrade, 11000 Belgrade Serbia*

Biography

In 1999, Danica Agbaba was appointed Professor of Pharmaceutical Chemistry at the School of Pharmacy, University of Belgrade. Dr Agbaba took her first degree in pharmacy in 1978, and then went to work for three years for pharmaceutical industry. In 1981, she started her academic career at the School of Pharmacy, University of Belgrade. In that time, Dr Agbaba has got the long-term professional training from the Drug Control and Teaching Center, King's College, University of London, London, UK and from the Center for Bio-Pharmaceutical Sciences, Leiden University, Leiden, The Netherlands. Currently, Dr Agbaba acts as Section Editor for *Acta Chromatographica*, as Guest Co-Editor for *J. AOAC Int.*, and as the Editorial Board member for *Arhiv za Farmaciju*. From 2006, she has been acting as principal investigator for the two national projects and from 2004, for the two bilateral projects (Serbia & Slovenia). Dr Agbaba's scientific work has resulted in more than 100 publications and her research interests are focused on drug analysis and more recently, on QSAR/QSPR and the drug design studies.

Research at Faculty of Pharmacy: The Last Decade**Abstract**

Due to an increasingly multidisciplinary nature of pharmacy observed in the last two decades, this presentation will focus on the main scientific achievements of scientists from our Faculty in various different areas such as chemistry, medicinal chemistry, biochemistry, biology, bio-pharmacy, medicine etc. Apart from the fundamental research, the applied research has also been pursued, mostly through participation to many national and some international research projects. Scientific cooperation with industry and with other scientific institutions, both in Serbia and abroad, will be also discussed.

**Professor dr Ian Bates**

*School of Pharmacy, University of London, 29/39 Brunswick Square, London
WC1N 1AX, UK*

Biography

Ian Bates is Professor of Pharmacy Education at the School of Pharmacy, University of London and Head of Educational Development. He is Director of the Global Education Taskforce, a team jointly sponsored by the International Pharmaceutical Federation (FIP), WHO and UNESCO, and additionally Editor-in-Chief of *Pharmacy Education*, an international journal for pharmaceutical education, which publishes peer reviewed research and development in both undergraduate and postgraduate fields.

Professor Bates is Vice President of the European Association of Faculties of Pharmacy (EAFF), a Fellow of the Royal Statistical Society, Director of the Global Education Taskforce (FIP-WHO-UNESCO), and a Trustee for the European Pharmaceutical Students' Association.

Ian has a first degree in pharmacy, and went on to further advanced studies in neuro-pharmacology, biopharmacy and toxicology before settling down to work for a living in the National Health Service. He was later tempted into an academic career, and teaches on a wide range of subjects from clinical pharmacokinetics to medical sociology, which has subsequently fuelled his reformist tendencies in higher education.

Global Trends in Pharmacy Education

Professor dr Hugo Kubinyi

University of Heidelberg (retired), c/o Donnersbergstrasse 9,
D-67256 Weisenheim am Sand, Germany

**Biography**

Hugo Kubinyi is a medicinal chemist with 35 years of industrial experience in Knoll AG (now Abbott Laboratories) and BASF SE, Ludwigshafen, Germany. Since 1987, until his retirement, he was responsible for the Molecular Modelling, X-ray Crystallography and Drug Design group of BASF, since early 1998 also for Combinatorial Chemistry in the Life Sciences. He is associate Professor of Pharmaceutical Chemistry at the University of Heidelberg, former Chair of The Cheminformatics and QSAR Society, and IUPAC Fellow. In 2006 he received the ACS Herman Skolnik Award in Chemoinformatics (CINF section, ACS) and in 2008 the Nauta Award in Pharmacology (EFMC). From his scientific work resulted more than 100 publications and seven books on QSAR, 3D QSAR, Drug Design, Chemogenomics, and Drug Discovery Technologies

Chemical Biology and Chemogenomics in Drug Discovery**Abstract**

Chemical biology [1] and chemogenomics [2-4] are recent strategies in the systematic search for new lead structures. Chemical biology studies the influence of chemical libraries on simple biological systems, e.g. stem cells, yeast and other cellular systems, parasites, or small animals, like *Caenorhabditis elegans*, *Drosophila* or the zebrafish, *Danio rerio*. If a new phenotype is discovered by the action of a certain substance, the next step is the identification of the respective target.

Chemogenomics aims to discover selective ligands of a certain target within a family of proteins or to shift biological activity and/or selectivity from one target to a related one. This is achieved by testing libraries of chemically related compounds in classes of evolutionary related targets (GPCRs, integrins, nuclear hormone receptors, aspartyl, metallo-, serine and cysteine proteases, kinases, phosphatases, ion channels, etc.). In lead optimization, one should cover the chemical space around the current lead as completely as possible, in order not to lose any interesting candidate and to obtain a solid intellectual property position. Know-how from lead optimization at one target can be transferred to another target; in addition, several analogs of non-specific compounds may show significantly different selectivities. Another systematic method for the discovery of new leads is the SOSA (selective optimization of side activities) approach, recently proposed by Camille Wermuth [5].

Typical chemogenomics applications will be presented and the advantages of these approaches, as compared to classical screening, will be highlighted.

Professor dr Pat Sandra

Department of Organic Chemistry, Ghent University,
Krijgslaan 281, S4, B9000, Ghent, Belgium

**Biography**

Pat Sandra is Professor in Separation Sciences at the Ghent University, Belgium. In 1986 he founded the Research Institute for Chromatography (RIC) in Kortrijk, Belgium, a center of excellence for research and education in chromatography and mass spectrometry. He is currently also extraordinary professor at the Department of Chemistry at the University of Stellenbosch, South Africa, at the Department of Analytical Chemistry, Evora, Portugal and director of the Pfizer Analytical Research Center at the Ghent University and of Metablys, an institute concentrating on metabolic studies.

Pat Sandra is active in all fields of separation sciences and is author or co-author of more than 500 scientific papers. He received several awards for his contributions to separation science including honorary doctorates in Pharmacy and in Food Safety.

The impact of recent innovations in fluid-based separation techniques on pharmaceutical analysis**Abstract**

The current trend of liquid chromatographic (LC) analyses, "the" technique of choice in pharmaceutical analysis, is biased toward high throughput, high productivity and high resolution. In response to these increasingly demanding requirements, over recent years, innovative technologies and improvements in instrumentation have emerged which are having a significant impact on our daily work.

On the other hand, a renaissance has been noted in supercritical fluid chromatography (SFC) and enhanced fluidity chromatography (EFC).

This lecture will review the features of LC, SFC and EFC in extending speed, productivity and peak capacity for pharmaceutical analyses. Special emphasis will be given to robustness and the introduction of the principles of green chemistry in state-of-the-art fluid-based separation techniques. Considering the present shortage and high price of acetonitrile, this is also important from a practical and economical point of view.

Professor dr Daan J.A. Crommelin

Department of Pharmaceutics, Utrecht Institute for Pharmaceutical Sciences, PO Box 80.082 TB, 3508 TB Utrecht, Sorbonnelaan 16, The Netherland

Biography



Prof. Daan Crommelin is presently scientific director of the Dutch Top Institute Pharma in Leiden. He is also professor at the Department of Pharmaceutics at Utrecht University. He is adjunct professor at the Department of Pharmaceutics and Pharmaceutical Chemistry at the University of Utah. Crommelin is co-founder of OctoPlus, a Leiden based company specialized in the development of pharmaceutical product formulations and advanced drug delivery systems. He published extensively and is on the editorial board of 10 peer reviewed journals in the pharmaceutical sciences. He also advises venture capital groups. He chaired the Board of Pharmaceutical Sciences of the International Pharmaceutical Federation (F.I.P.), was chair of the organizing committee of the Pharmaceutical Sciences World Conference 2007 in Amsterdam. He is past-president of the European Federation of Pharmaceutical Sciences (EUFEPS) and vice chair of the scientific advisory board of the European Innovative Medicines Initiative (IMI).

Nanotechnology and drug therapy: Will We do better in the future?

Abstract

Nanotechnology refers to a field of applied science and technology whose theme is the control of matter on the atomic and molecular scale, generally 100 nanometers or smaller, and the fabrication of devices or materials that lie within that size range' (Wikipedia). Nanomedicines are pharmaceutical products (including imaging devices for diagnosis and monitoring) based on nanotechnology.

Examples of first generation nanomedicines are cytostatic-liposome combinations. At present, nanomedicines are under development with a level of tissue specificity for the treatment of chronic inflammatory diseases. Active targeting techniques to improve target tissue specificity are now being integrated with nanotechnological approaches (lipid based or polymer based carrier systems). Groups of modern therapeutics that specifically call for these advanced drug delivery systems are siRNA and DNA for gene therapy. The nanotechnology toolbox offers tools that should improve the performance of these large and highly charged molecules. Finally, a new trend is the combination of imaging and therapy. MRI probes are combined with nanomedicines to monitor delivery at target tissue/cell level. Other interesting developments in the world of nanotechnology that impact therapy come from the field of microflu-

idics ('lab-on-a chip') and electronics bringing individualization of therapy closer by through these 'smart' technologies (maybe a better term than nanotechnology?).

In conclusion, nanotechnology provides many opportunities to improve the treatment of patients. Translational, cross-cutting approaches are essential to be successful in the clinic and for the individual patient: different disciplinary experts ranging from physicist to physician should be involved in the thought process and ensuing actions to fully exploit the potentials of nanomedicine.



dr Branislav Musicki

Galderma R&D, Chemical Development, Les Templiers, 2400 route des Colles, 06410 Biot, France

Biography

Dr Musicki is presently Group leader at Galderma R&D, responsible for development and optimization of synthetic routes for active pharmaceutical ingredients. This current position was preceded by various positions, from Research Scientist to Head of Laboratory, with Aventis, where dr Musicki was involved in a range of medicinal chemistry projects.

Dr Musicki obtained BSc degree in chemistry at Belgrade University and PhD at Harvard University under supervision of Professor Kishi. After postdoctoral period at Harvard and Indiana Universities he returned to Europe. Since then, he has been publishing extensively in various medicinal chemistry areas.

The World of Bioluminescence: Remarkable History of Photoproteins and Fluorescent Proteins

Abstract

The Nobel Prize for chemistry was shared last year by three scientists: Osamu Shimomura, who is an emeritus professor with the Marine Biological Laboratory in Woods Hole, Massachusetts and Boston University Medical School, Martin Chalfie, who is professor of biological sciences with Columbia University; and Roger Y. Tsien, a pharmacology professor with the University of California in San Diego. Each of whom had a contributing part in the discovery and application of GFP – green fluorescent protein – the protein that gives jellyfish their green glow. But the main difference between GFP and others like luciferase, which is found in Fireflies, is that unlike the latter, the GFP's ability to glow is not dependent on a specific chemical that gets used up in the process. GFP makes it possible for researchers to watch biological processes, such as the development of nerve cells in the brain or how cancer cells spread. Simply by shining ultraviolet light on cells that have been "tagged" with the protein, researchers can now see what was previously invisible. Bioluminescence field considered as seemingly esoteric as glow-in-the-dark jellyfish fifty years ago, was finally recognized as a true scientific discipline that can lead to a great discoveries and breakthroughs. During my seven years as a graduate student and post-doctoral fellow under the guidance of Prof. Y. Kishi's an emeritus professor with University of Harvard we had a privilege to collaborate with Prof. Shimomura working on the mechanism of action of photoprotein Aequorin a close cousin of GFP. We developed a variety of Aequorin analogues that have widespread use and applications in cellular science. The lecture will cover the story of bioluminescence during the last fifty years.



Round Table

Towards the More Intensive Industry and Academia Collaboration in the Serbian Pharmaceutical Sector: Challenges and Opportunities

Friday, 23 October, 2009
Faculty of Pharmacy



Round Table

Towards the More Intensive Industry and Academia Collaboration in the Serbian Pharmaceutical Sector: Challenges and Opportunities

Friday, October, 23rd 2009

Faculty of Pharmacy

Programme

- 17:00 – 17:40** **Part I: TI Pharma: A role model of public-private cooperation and partnership**
Part II: EUFEPS And European Initiatives in Pharmaceutical Sciences
Daan J. A. Crommelin,
EUFEPS President
Department of Pharmaceutics, Utrecht University
Dutch Top Institute Pharma/TI Pharma, Scientific Director
- 17:40-17:50** **University-Industry Partnership as an Integral Part of the Scientific and Technological Development Strategy of the Republic of Serbia 2009 to 2014**
Viktor Nedović *Ministry of Science and Technological Development*
- 17:50-18:00** **Industry Perspective**
Dragomir Marisavljević, *Chairman of the Pharmaceutical Manufacturers Group Council*
- 18:00-18:10** **Crossing the Border between Academic Research and Industrial Applications: University Perspective**
Nada Kovačević, *Dean of the Faculty of Pharmacy, University of Belgrade*
- Discussion**