Gordana Pejović (rođ. Savić)

Obrazovanje	• 1995 – 2001 Farmaceutski fakultet, Univerzitet u Beogradu – **Diplomirani farmaceut** • 2002 – 2007 Farmaceutski fakultet, Univerzitet u Beogradu – **Magistar farmaceutskih nauka** • 2004 - 2008 Farmaceutski fakultet, Univerzitet u Beogradu – **Specijalista ispitivanja i kontrole lekova** • 2009 – 2012 Fakultet organizacionih nauka, Univerzitet u Beogradu - **Doktor tehničkih nauka – upravljanje kvalitetom**
Dodatne obuke	• April, 2002. Training course: QM – Quality Management System according to ISO 9001:2000, prepared and presented by "Research and Technology Center", Novi Sad • April, 2002. Training course: Introduction to GMP, prepared and presented by Mr. Hans Persson and Euro Health Group, held at "Srbolek a.d.", Belgrade. This was the part of the EU project "Rationalization of Pharmaceutical Section in Serbia". • May, 2002. Training course: Continued GMP training I, prepared and presented by Mr. Hans Persson and Euro Health Group, held at "Galenika a.d.", Belgrade. This was the part of the EU project "Rationalization of Pharmaceutical Section in Serbia". • May, 2002. Training course: Continued GMP training II, prepared and presented by Mr. Hans Persson and Euro Health Group, held at "Galenika a.d.", Belgrade. This was the part of the EU project "Rationalization of Pharmaceutical Section in Serbia". • September, 2002 Training course: Accrediting of testing and calibration laboratories (ISO 17025),

	prepared and presented by “Research and Technology Center”, Novi Sad • October, 2002 Training course: Drug stability testing, prepared and presented by Mr. Marksperson and Euro Health Group, held at the Military Medical Academy, Belgrade • December, 2002 Training course: Internal audits according to ISO 9001:2000, prepared and presented by “Research and Technology Center”, Novi Sad • February, 2003 HPLC – intensive course: Robust HPLC-methods, prepared and presented by Mr. Molnar, PhD, from Molnar Institute – Berlin • June, 2003 Training course: Medicines assessment – Safety and Efficacy, prepared and presented by Mr. Graham Dukes and Euro Health Group, held at Faculty of Pharmacy, University of Belgrade • September, 2003 Training course: The creation of business plan, prepared and presented by “Research and Technology Center”, Novi Sad • November, 2003 CEE Summit: “2004. Accession – Is industry ready for it and what regulatory hurdles remain?”, organized by IIR, held in Prague, Czech Republic • April, 2004 Training course: Marketing authorization procedure and regulatory requirements, prepared and presented by Mrs. Koblar from Crown Agents, an EU – funded project, managed by the European Agency for Reconstruction • December, 2004 Training course: Introductory Overview of Pharma Industry, organized by Management Forum, held in London, UK • December, 2004 Traning course: Off-shoring clinical trials, organized by IIR, held in London, UK • April, 2005 “OMCL Network Quality Assurance Training Session”, organized by European Directorate for the Quality of Medicines (EDQM), held in Strasbourg, France • May, 2005 OMCL Annual Meeting, organized by EDQM and OMCL Network, held in Rome, Italy.

	• June, 2005 ECPD International Summer School – Management of Health-Care Institutions, organized by the European Center for Peace and Development of the University for Peace, established by the United Nations • October, 2005 Quality Assurance training visit, organized by EDQM and OMCL Network, performed in National Control Laboratories (OMCL laboratories) of Austria (BIFA – Vienna), Belgium (SIPH – Brussels) and France (EDQM-Strasbourg). • November, 2005 Symposium "EU Regulatory Environment, organized by Agency for Medicinal Product and Medical Devices of Croatia, held in Opatia, Croatia • May, 2006 OMCL Annual Meeting, organized by EDQM and OMCL Network, held in Limassol, Cyprus. • May, 2006 JUS ISO 9001:2000 Internal Auditor Training Course, organized by SGS Beograd. • July, 2006 Benchmarking workshop: Si&Si Company, Society impact, Strategy and Planning, organized by FQCE – Fund for Quality Culture and Excellence, held in Banja Vrujci, Serbia. • August, 2006 ISC 2006, 26th International Symposium on Chromatography, organized by Van Hauen Conferences and Incentives, Copenhagen, Denmark • December, 2006 ECA GMP education course "Documentation Systems in QA", organized by Concept Heidelberg and European Compliance Academy, held in Prague, Czech Republic • March, 2007 OMCL inventory database training session, organized by EDQM, held in Vienna, Austria • May, 2007 OMCL Annual Meeting, organized by EDQM and OMCL Network, held in Prague, Czech Republic.

	• July, 2007 Training course: Introduction to Integrated Management Systems, held by Lloyd'S Register Quality Assurance, Belgrade, Serbia • October 2008 Training course: Legal and Regulatory Strategies for product Lifecycle Management, held by IIR Lifesciences, London,UK • November 2008 Symposia: Bioequivalence and Bioavailability Studies – Regulatory and Practical Aspects, held by Medicines and Medical Devices Agency of Serbia, Vrsac, Serbia • November 2008 Symposium on Biosimilar Medicinal Products, held by Medicines and Medical Devices Agency of Serbia, Belgrade, Serbia • July 2010 IRCA certified training course for lead auditors, SGS Belgrade office, Belgrade, Serbia • November 2010 Pharma Quality Excellence, ICH Q10 and EU-GMP Chapter1 master class, organized by European Compliance Academy, London UK ▪ October 2011 European Directorate for the Quality of Medicines and HealthCare – "Training course for auditors of the MJA/MJV Scheme of the OMCL Network", Strasbourg, France ▪ October 2011 "Veština javnog nastupa", D.R.Gilbert Centar, Beograd, Srbija ▪ Mart 2012 DIA 24th Annual EuroMeeting, Copenhagen, Danska • Октобар 2012 Положен државни стручни испит за државне службенике, Министарство правде и државне управе, Република Србија
Radno iskustvo	• Novembar 2012 – Fakultet organizacionih nauka, Univerzitet u Beogradu **Docent na smeru logistika kvaliteta (10% radnog vremena)** • Septembar 2005. - Agencija za lekove i medicinska sredstva Srbije, Beograd, Srbija **Direktor upravljanja kvalitetom (90% radnog vremena)**

	• Mart 2002. – Septembar 2005. Zavod za farmaciju Srbije, Beograd, Srbija **Stručni saradnik u Sektoru za Upravljanje kvalitetom** • April 2001. – Februar 2002. Privatna apoteka "Euro-trend", Beograd, Srbija , **farmaceut**
Naučni radovi i prezentacije	**1.** **Savić G., M. Zecević , B. Jocić, Lj. Živanović -** *Validation of RP-HPLC method for the determination of valdecoxib and its impurity - a mixture of alpha- and beta- n-lactosyl sulfonamide anomers*, Chromatographia, Vol. 66, Number 1/2, p.29-35, 2007 **2.** **Zečević M., Savić G., Marković S., Živanović Lj.-** *Chemometrics approach in investigation of chromatographic behavior of valdecoxib and SC-77852, beta anomer as impurity*, 29th International Symposium on High Performace Liquid Phase Separations and Related Techniques, June 2005, Stockholm **3.** **Zečević M., Savić G., Živanović Lj. –** *Development and validation of liquid chromatography method for separation of valdecoxib and its SC-77852 impurity,* Analytical Letters, Vol. 39, Number 9/2006, p. 1875-1890 **4.** **Zečević M., Savić G., Živanović Lj -** Validation of RP-HPLC method for the determination of valdecoxib and impurity SC-77852 as mixture alpha- and beta- n-lactosyl sulfonamide anomers, 26th International Symposium on Chromatography, August 2006, Copenhagen **5.** **Savić G.,** Žigić G., Đurović D., Savković O., - Dijagram toka procesa registracije – mera za uspostavljanje i upravljanje sistemom menadžmenta kvalitetom, Arhiv za farmaciju Srbije, No.4, p.570-571 2002 **6.** Savković O., Đurović D., **Savić G.** Žigić G., **–** Prijemna kontrola kvaliteta podržana Informacionim sistemom – značajan elemet upravljanja kvalitetom usluga, Arhiv za farmaciju Srbije, No.4, p. 572-573, 2002 **7.** Žigić G., **Savić G.**, Đurović D., Savković O., - Procesna mapa: hemijsko ispitivanje i kontrola lekova, Arhiv za farmaciju Srbije, No.4, p. 574-575, 2002 **8.** Đurović D., Savković O., **Savić G.**, Žigić G., **-** Izveštaj o internoj proveri – važan dokument za unapređenje kvaliteta usluge u kontroli i ispitivanju lekova, Arhiv za farmaciju Srbije, No.4, p. 552-553, 2002 **9.** **Savić G.** – Mesto Nacionalne kontrolne laboratorije u OMCL mreži, Četvrti kongres farmaceuta Srbije sa međunarodnim učešćem, decembar 2006, Beograd **10.** **Savić G.**, **Mašković M. –** Agencija za lekove i medicinska sredstva Srbije – regulatorna uloga i razvoj, 50-ti simpozijum – Moderni aspekti upotrebe antibiotika, oktobar 2007, Beograd **11.** **Pejović G.,** - *A top level medicines agency,* Public service review: European Union, issue 17, Breaking down the bio-barriers: How biotechnology and research in reproduction are contributing to European innovation and economic growth, PSCA International Ltd,

p.224-225, 2009

12. **Pejović G**., - *CTD, eCTD and NeES from an agency view – what are current guidelines and expectations, current situation in Serbia* – 11th Infotehna Annual Pharmaceutical Conference "Everything you wanted to know about e-submissions, but you did not know whom and where to ask", 25-27 May 2009, Bled, Slovenia (usmeno izlaganje)
13. **Pejović G**., Đukić Lj., Solarović T. – *Medicines and Medical Devices Agency of Serbia performance improvement – Good regulatory practice principles implementation,* International Journal "Total Quality Management & Excellence", vol.37, No. 1-2, 2009 (UDK 658.5, ISSN 1452-0680)
14. Đukić Lj., **Pejović G**., Solarović T. – *Significance of reliable medicine database for promoting quality of pharmaceutical healthcare* - International Journal "Total Quality Management & Excellence", vol.37, No. 1-2, 2009 (UDK 658.5, ISSN 1452-0680)
15. **Pejović G –** *e-Submission infrastructure development in non-EU national regulatory authority – current situation in Serbia* – Drug Information Association (DIA) 22nd EuroMeeting, 8 – 10 March 2010, Monaco (poster abstract, ID 32095)
16. **Pejović G.** – *Pregled međunarodnih i nacionalnih zahteva za dokumentaciju o leku u obliku elektronskog Opšteg tehničkog dokumenta* - Arhiv za farmaciju, vol.60, No.1, 2010, p. 48-55
17. **Pejović G.** – *Local topic – e.g. challenges with preparing for EU membership* – ISOP training course: Basic concepts in pharmacovigilance, 28 – 29 maj 2010. Beograd (usmeno izlaganje)
18. **Gordana Pejović,** Biljana Otašević, Mira Zečević, Vesna Kuntić, Zorica Vujić – *Valdecoxib stability properties under forced degradation conditions,* Scientific Review in Pharmacy (Farmaceutyczny Przegląd Naukowy), No.9, 2010, p. 11-17
19. **Pejović G.** – *Readiness to accept eCTD application in non-EU countries – the way forward* - 6th EGA South East Europe Pharmaceutical Symposium: Meeting the European Challenge for National Drug Regulatory Agencies and the Generic Medicines Industry, Vršac, 29 Septembar – 1 Octobar 2010 (usmeno izlaganje)
20. **Pejović G., J.Filipovic, Lj. Tasic –** *Nacionalna infrastruktura kvaliteta – osnov za pristup EU i slobodnoj trgovini lekovima* – Peti kongres farmaceuta Srbije sa međunarodnim učešćem, Beograd, 2010, **predavanje po pozivu,** Arhiv za farmaciju, vol.60, No.5, 2010, p.818-824
21. **Pejovic G**., - *Primena benčmarking metodologije u unapređenju regulatorne performanse Agencije za lekove i medicinska sredstva Srbije* – Peti kongres farmaceuta Srbije sa međunarodnim učešćem, Beograd, 2010, **poster presentacija,** Arhiv za farmaciju, vol.60, No.5, 2010, p.930
22. **Pejović G.,** J.Filipovic, Lj. Tasic – *How to remove barriers to medicines trade in emerging economies: the role of medicines regulatory authority in Serbia,* Accred. Qual. Assur. Volume 16, Issue 4 (2011), Page 253.
23. **Pejovic G**., - *Current development and readiness to accept electronic submissions in ALIMS, Serbia* – 1st Regulatory Workshop: Electronic

	Submissions, Kranjska Gora, 31 March – 1April 2011, (invited lecture) **24.** **Pejovic G.,** - *Institucionalni razvoj i primena principa menadzmenta kvaliteta u radu nacionalnog regulatornog tela Srbije*. Srpsko lekarsko drustvo: Sekcija za kliničku farmakologiju i Akademija Medicinskih nauka, III *Nedelja Bolničke kliničke farmakologije, simpozijum sa medjunarodnim učešćem, 17-19 novembar 2011, Book of Abstracts CIP- katalogizacija u publikaciji Narodna Biblioteka Srbije 615- 03 (048)0(0036.2)* **25.** **Pejovic G**., *Quality management principles implementation – impact on Serbian medicines regulatory performance improvement* – Drug Information Association (DIA) 24th EuroMeeting, 26. – 28 March 2012, Kopenhagen, Danska (professional poster ID 45286) **26.** **Pejović, G**., Radonjić, V., *„Development of proper infrastructure for the improvement of regulatory performance – advertising of medicines and medical devices“*, FIP Centenial Congres of Pharmacy and Pharmaceutical Sciences 2012, (accepted poster presentation, abstract number 811), to be held in Amsterdam, October 2012. **27.** **Pejovic G.,** - *Farmaceutska legislativa: važan element za uklanjanje barijera u trgovini lekovima*. Srpsko lekarsko društvo: Sekcija za kliničku farmakologiju i Akademija Medicinskih nauka, IV Nedelja Bolničke kliničke farmakologije, simpozijum sa medjunarodnim učešćem, 30. novembar-1. decembar 2012, Book of Abstracts CIP- katalogizacija u publikaciji Narodna Biblioteka Srbije 615- 03 (048), 615.2(048), ISBN 978-86-6061-029-6 **28.** **Gordana B. Pejović**, Valentina D. Marinković, Jovan V. Filipović, Ljiljana M. Tasić - *Analiza uticaja farmaceutske legislative u unapređenju infrastrukture kvaliteta u Srbiji*, Savremene tehnologije, vol. 2 No. 1, 2012, pp. 58-66 **29.** **Gordana Pejovic**, Ivana Mijatovic, Gordana Jakic - *How to improve quality performance of medicines regulatory authorities – is TQM a solution?*, e-proceedings of 10-th Anniversary international conference “Standardization and related activities – a means of international and Balkan collaboration”, Sozopol, Bulgaria, 13 - 14 September 2013. **30.** Gordana Jakic, Gordana Zalad, Ivana Mijatovic, **Gordana Pejovic**, *"Harmonisation and standardisation of terminology in contemporary Europe – choice or must",* e-proceedings of 10-th Anniversary international conference “Standardization and related activities – a means of international and Balkan collaboration”, Sozopol, Bulgaria, 13 - 14 September 2013. **31.** **Pejović, G** and Filipović, J. - *Current Regulatory and Market Environment for Biosimilars in Serbia*, Slovenian Journal of Public Health. Volume 53, Issue 1, (2014), Pages 101–114 ISSN (Online) 1854-2476, ISSN (Print) 0351-0026 **32.** **Gordana B. Pejović,** Valentina D. Marinković - *Key performance indicators in drug regulatory authorities – case study: Serbian drug regulatory authority***,** INTERNATIONAL JOURNAL OF ADVANCED QUALITY. No.3, Vol 42 (2014), p. 37, UDC 658.5, ISSN 2217-8155 **33.** **Gordana B. Pejović**, Jovan V. Filipović, Ljiljana M. Tasić, Valentina D.

	Marinković – *Towards medicines regulatory authorities' quality performance improvement: value for public health*, International Journal of Health Planning and Management, Article first published online: 2 Jul 2014 | DOI: 10.1002/hpm.2265 **34.** Svetlana Goločorbin-Kon, **Gordana Pejović**, Momir Mikov – *Kako se borimo protiv falsifikovanih i substandardnih lekova*, Šesti kongres farmaceuta Srbije sa međunarodnim učešćem, Beograd, 2014, **predavanje po pozivu,** Arhiv za farmaciju
Univerzitetski udžbenici	1. Božanić, V., **Pejović, G.**, *Akreditovane laboratorije,* udžbenik za stude Fakulteta organizacionih nauka, Fakultet organizacionih nauka, Beograd, 20 ISBN: 978-86-7680-217-3 2. Marinković, V., Tasić, Lj., **Pejović, G.,** Večerkov-Vukmirović, S., Kocić-Pešić, Jović, S., *Kvalitet u farmaciji – od teorije do prakse,* pomoćni udžbe Univerzitet u Beogradu - Farmaceutki fakultet, Beograd, 2012. ISBN: 978-6273-002-2
Članstva u programskim odborima naučnih i stručnih konferencija	1. Regulatorni seminar Agencije za lekove i medicinska sredstva Srbije sa međunarodnim učešćem: „Savremena pitanja u farmaceutskoj regulativi", 11-12.04.2005. godine, Beograd 2. Regulatorni simpozijum Agencije za lekove i medicinska sredstva Srbije sa međunarodnim učešćem: "Ispitivanje stabilnosti farmaceutskih proizvoda", 25.-27. 10. 2006. godine, Vršac 3. Simpozijum Agencije za lekove i medicinska sredstva Srbije sa međunarodnim učešćem: "Nečistoće i degradacioni proizvodi u farmaciji", 31.10.-02.11.2007. godine, Vršac 4. Simpozijum Agencije za lekove i medicinska sredstva Srbije sa međunarodnim učešćem: "Ispitivanje biološke raspoloživosti i biološke ekvivalentnosti lekova – regulatorni i praktični aspekti", 05.-07. 11. 2008. godine, Vršac 5. Simpozijum Agencije za lekove i medicinska sredstva Srbije sa međunarodnim učešćem: „Bezbednost pacijenta - zajednički cilj farmaceutske industrije, regulatornih tela i zdravstvenih ustanova", 18-20. 11.2009. godine, Vršac 6. Šesti EGA (European Medicines Association) farmaceutski simpozijum za jugoistočnu Evropu u saradnji sa Agencijom za lekove i medicinska sredstva Srbije, 29.09.-01.10.2010.godine,Vršac 7. European Medicines Agency conference u saradnji sa Agencijom za lekove i medicinska sredstva Srbije : Human and Veterinary Pharmaceuticals' Regulation: Heading Towards EU Accession: Serbia's Regulatory Challenges, Expectations and Opportunities, 29.-30.11.2010. godine, Beograd
Učešće na projektima	1. EU Twinning project sa Francuskom agencijom za lekove (AFSSAPS), CARDS 2005 SR 05 SO 01: CAPACITY BUILDING OF THE NATIONAL MEDICAL PRODUCTS AGENCY, Beograd, jul 2006 – mart 2009. godine (**član projektnog tima sa srpske strane**) 2. Project No. ME-AF MHSIP-7819-ME–CQ-S--11-A-111.2: TECHNICAL ASSISTANCE

	for training, capacity building and skills transfer to Montenegrin agency for drugs and medical devices (CALIMS) and Medicines and medical devices agency of Serbia – ALIMS (**konsultant na projektu**)
Profesionalna udruženja	a. Drug Information Association (DIA) b. Farmaceutsko društvo Srbije c. Jedinstveno udruženje Srbije za kvalitet (JUSK)
Jezici	Engleski

Ostalo

- Magistarske studije upisala je školske 2002/03. godine iz Farmaceutske hemije, na Farmaceutskom fakultetu u Beogradu. Magistarska teza pod nazivom: **„Reverzno-fazna tečna hromatografija u analitici valdekoksiba, praćenju nečistoća i ispitivanju stabilnosti u farmaceutskim preparatima“** odbranjena je 10. oktobra 2007. godine.

- Specijalističke studije iz oblasti ispitivanja i kontrole lekova upisala je 2004. godine na Farmaceutskom fakultetu u Beogradu. Specijalistički rad pod nazivom: **„Ispitivanje stabilnosti nekih COX – 2 inhibitora pod uslovima forsirane degradacije primenom tečne hromatografije pod visokim pritiskom; Farmakoterapijska svojstva valdekoksiba“** odbranjen je 13. novembra 2008. godine, sa odličnim uspehom.

- Doktorsku disertaciju iz oblasti Upravljanja kvalitetom pod nazivom „Opšti organizacioni model agencije za lekove u infrastrukturi kvaliteta“ odbranila je 2012. godine na Fakultetu organizacionih nauka, Univerziteta u Beogradu. Novembra 2012. godine izabrana je u nastavno-naučno zvanje docent, od kada i predaje na Katedri za upravljanje kvalitetom Fakulteta organizacionih nauka.

- Član je redakcijskog odbora stručne publikacije „Farmakoterapijski vodič“, izdanje 1, 2, 3 i 4.

- Od maja 2006. godine Doc. dr Gordana Pejović je angažovana kao tehnički ekspert za pitanja sistema manadžmenta kvaliteta u vodećem međunarodnom sertifikacionom telu SGS, sa sedištem u Ženevi. Od jula 2010. godine je i IRCA sertifikovani vodeći ocenjivač za sisteme menadžmenta kvaliteta.
Takođe, od oktobra 2011. godine angažovana je kao ocenjivač (auditor) za zahteve koji se odnose na menadžment u okviru standarda ISO 17025:2006 – Opšti zahtevi za kompetentnost laboratorija za ispitivanje i laboratorija za etaloniranje, u okviru sistema akreditacije koji organizuje Evropski direktorat za kvalitet lekova i zdravstvene zaštite (European Directorate for the Quality of Medicines and Health Care) Saveta Evrope. Navedena procedura akreditacije se sprovodi u zvaničnim nacionalnim kontrolnim laboratorijama za lekove zemalja Evrope.

Udata je, majka jednog deteta.