M E D

XX SIMPOZIJUM ALIMS

16-18.10.2025. | KOPAONIK

Agencija za lekove
i medicinska sredstva Srbije

DAN/DAY I

16.10.2025.

SALA IZVOR 1 i 2
HALL IZVOR 1 i 2

17.00-18.00	**KOKTEL DOBRODOŠLICE / WELCOME COCKTAIL**	
18.00-20.00	**SVEČANO OTVARANJE** Svečano otvaranje Simpozijuma, pozdravni govori zvaničnika OPENING CEREMONY Formal opening of the Symposium, official welcome speech	Konferansije/Master of Ceremonies: Jelena Mitrašinović, ALIMS Sanda Savić, Privredna komora Srbije / Serbian Chamber of Commerce Bojan Trkulja, direktor INOVIA / INOVIA director Ana Popović, direktor GENEZIS / GENEZIS director Maja Vučković Krčmar, Delegacija Evropske unije u Srbiji / Delegation of the EU to the Republic of Serbia Dorina Pirgari, regionalna kancelarija za Evropski region, SZO / Regional Office for European Region, WHO Saša Jaćović, direktor ALIMS / ALIMS director Predstavnik Ministarstva zdravlja Republike Srbije Representative of the Ministry of Health of the Republic of Serbia
	Panel diskusija: **“Svet zajedno protiv falsifikovanih i substandardnih medicinskih proizvoda“** Panel discussion: “The World Together Against Falsified and Substandard Medical Products”	Moderator: Pavle Zelić, ALIMS Učesnici panela / Panelists: Dorina Pirgari, regionalna kancelarija za Evropski region, SZO / Regional Office for European Region, WHO Ronny Berkovitz, Univerzitet u Jerusalimu, Ministarstvo zdravlja Izraela / University of Jerusalem, Ministry of Health of Israel Radoslav Ruitchev, Agencija za lekove Bugarske - BDA / Bulgarian Drug Agency - BDA David Kočović, Institut za lijekove i medicinske sredstva Crne Gore - CInMED / Institute for Medicines and Medical Devices of Montenegro – CInMED Predavanja / Lectures: Prof. Emil Bienvenu, generalni direktor, Agencija za lekove i hranu Ruande, predsednik komiteta za falsifikovane i substandardne medicinske proizvode SZO / Director General, Rwanda Food and Drugs Authority, Chair of the WHO Committee on Falsified and Substandard Medical Products Pol Huleat, Administracija za terapeutske proizvode Australije - TGA / Therapeutic Goods Administration - TGA Laila Mouawad, Agencija za regulativu zdravstva Brazila - ANVISA / Brazilian Health Regulatory Agency - ANVISA Mark Abdoo, Uprava za hranu i lekove SAD - FDA / US Food and Drug Administration - FDA
20.00-22.00	**VEČERA / DINNER**	

DAN/DAY II

17.10.2025.

SALA IZVOR 1 i 2
HALL IZVOR 1 i 2

09.30-11.00	**POKAZATI BIOLOŠKU EKVIVALENTNOST: KADA BIOWAIVER PRIČA CELU PRIČU?** **PROVING BIOEQUIVALENCE: WHEN A WAIVER SPEAKS FOR ITSELF?** Moderator: Tanja Nedić, ALIMS
	Mogućnosti izostavljanja studija BE u prisustvu hrane i pri primeni PPI **Waivers for the fed and PPI BE studies** Alfredo García Arieta, AEMPS
	Nova mapa - Isti lavirint: Ključne izmene u nacrtu smernice ICH M13B **New map - Same maze: Key updates in ICH M13B draft** Snježana Nikolić, ALIMS
	BCS Biowaiver ili ne: Slučajevi iz prakse pod lupom ALIMS **Waive it or leave it: Practical cases of BCS Biowaivers under the ALIMS lens** Tanja Vidojević, ALIMS
	Globalni razvoj liraglutida: Regulatorni uvidi i inovacije **Global development of liraglutide: Regulatory insights and innovation** Jose Luiz Donato, Rio Biofarma Brasil Ltda | Fabio Barros, Rio Biofarma Brasil Ltda
	Kratak prikaz projekta regionalne saradnje: Slučaj liraglutid **Regional collaboration project highlights: Liraglutide case study** Tanja Nedić, ALIMS | Biljana Tubić, Associate Professor, Deputy of Agency Director for Division of Medicinal Products Gordana Boljević Stanojević, CinMED
11.00-11.30	**KAFE PAUZA / COFFEE BREAK**
11.30-13.00	**ALIMS DIGITALNA TRANSFORMACIJA, ZDRAVLJE 5.0 & VEŠTAČKA INTELIGENCIJA** **ALIMS DIGITAL TRANSFORMATION, HEALTH 5.0 & AI** Moderator: Tatjana Stojadinović, ALIMS
	Uvodno predavanje - Prezentacija predavača i ključnih rezultata digitalizacije ALIMS **Introductory lecture - Presentation of lecturers and key results of digitization of ALIMS** Tatjana Stojadinović, ALIMS
	Digitalna inovativna infrastruktura RS u službi zdravstva **Digital innovative infrastructure of the RS in the service of healthcare** Prof. Mihailo Jovanović, PhD, Government of the Republic of Serbia, Director of Office for IT and eGovernment
	Health 5.0 **Health 5.0** Jelena Bojović, Director of C4IR Serbia
	"RIZIS" i uloga registara ALIMS-a **"RIZIS" and the role of ALIMS registers** Prof. Ilija Antović, PhD, The Faculty of Organizational Sciences, University of Belgrade
	Zaštita i bezbednost podataka - Pravni i etički izazovi digitalizacije u zdravstvu **Data protection and security - Legal and ethical challenges of digitization in healthcare** Svetlana Jovanović, PhD, The Faculty of Organizational Sciences, University of Belgrade
	Evolucija upravljanja regulatornim informacijama - Kodiranje budućnosti **The evolution of regulatory information management - Coding the future** Marko Erić, ALIMS
	Iza koda - Inteligentna usklađenost **Beyond the code - Intelligent compliance** Zoran Dobrosavljević, Abstract
13.00-14.30	**PAUZA ZA RUČAK / LUNCH BREAK**

DAN/DAY II

17.10.2025.

SALA IZVOR 1 i 2
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14.30-16.00	**UPRAVLJANJE SIGNALIMA U FARMAKOVIGILANCI** **SIGNAL MANAGEMENT IN PHARMACOVIGILANCE** Moderator: Jelena Anđelić, ALIMS
	Upravljanje signalima u EU: inovacije, saradnja i bolji ishodi za pacijente Signal management in the EU: Innovation, collaboration and better outcomes for Patients Viola Macolić Šarinić, EMA
	Od signala do ažuriranja bezbednosnih informacija o leku From signal to safety updates of PI Anita Rakić , Merck Healthcare KGaA
	Upravljanje bezbednosnim signalima u ALIMS-u Safety signal management within ALIMS Marija Mihailović, ALIMS
16.00-16.30	**KAFE PAUZA / COFFEE BREAK**
16.30-18.00	**TRANZICIONI IZAZOVI U REGULATIVI MEDICINSKIH SREDSTAVA U REPUBLICI SRBIJI I EU: PUT MEDICINSKOG SREDSTVA OD KLASIFIKACIJE DO VIGILANCE; REGULATORNI ZAHTEVI OD PROIZVODNJE DO TRŽIŠNOG NADZORA; USAGLAŠENOST, KVALITET I SIGURNOST - KLJUČNI ELEMENTI U PROMETU MEDICINSKIH SREDSTAVA** TRANSITIONAL CHALLENGES IN THE REGULATION OF MEDICAL DEVICES IN THE REPUBLIC OF SERBIA AND THE EU: THE PATH OF A MEDICAL DEVICE FROM CLASSIFICATION TO VIGILANCE; REGULATORY REQUIREMENTS FROM MANUFACTURING TO MARKET SURVEILLANCE; COMPLIANCE, QUALITY AND SAFETY - KEY ELEMENTS IN THE PLACING OF MEDICAL DEVICES ON THE MARKET Aleksandra Vujačić Simić, ALIMS
	Defekti kvaliteta i povlačenje medicinskih sredstava sa tržišta Quality defects and withdrawal of medical devices from the market Marija Kurćubić, Ministry of Health of the Republic of Serbia
	Regulatorni izazovi u oblasti graničnih proizvoda Regulatory challenges in the field of borderline products Marija Petrović Radović, ALIMS
	Vigilanca medicinskih sredstava, regulatorna praksa HALMED-a u okviru „EU Vigilance System“ Medical device vigilance, regulatory practice of HALMED within the “EU Vigilance System” Antonela Šimunović, HALMED
	Novine u EU vodičima iz oblasti medicinskih sredstava sa refleksijom na nacionalnu regulativu Innovations in EU guidance on medical devices with reflections on national regulations Vesna Ševaljević, MD & D Solutions
18.00-21.00	**VEČERA / DINNER**
21.00	**KOKTEL / COCKTAIL**

DAN/DAY II

17.10.2025.

SALA POGLED
HALL POGLED

09.30-11.00	**VETERINARSKI LEKOVI: JEDINSTVENO ZDRAVLJE - NEW ERA DIGITALIZACIJE** **VETERINARY MEDICINES: ONE HEALTH - NEW ERA DIGITALIZATION** Moderator: Gordana Žugić, ALIMS
	Jedinstveno zdravlje: Politike, digitalizacija i vještačka inteligencija One health: Politics, digitalization and Artificial Intelligence Prof. Nihad Fejzić, PhD, University of Sarajevo, BiH
	Od algoritma do dozvole za stavljanje leka u promet: AI kao pokretač novih pristupa u regulativi i registraciji lekova From algorithm to market authorization: AI as a driver of new approaches in drug regulation and registration Prof. Svetlana Ibrić, PhD, Faculty of Pharmacy, University of Belgrade
	Antimikrobna rezistencija - Prekomerna, nekontrolisana upotreba antibiotika u stočarskoj proizvodnji Antimicrobial resistance - Excessive, uncontrolled use of antibiotics in livestock productio Nenad Budimović, Chamber of Commerce and Industry of Serbia
	Klasične farmakološke metode u suzbijanju antimikrobne i antiparazitske rezistencije i mogućnosti primene veštačke inteligencije Classical pharmacological methods in combating antimicrobial and antiparasitic resistance and the possibilities of applying AI Prof. Saša Trailović, PhD, Faculty of Veterinary Medicine, University of Belgrade
11.00-11.30	**KAFE PAUZA / COFFEE BREAK**
11.30-13.00	**VETERINARSKI LEKOVI: REGULATORNI ZAHTEVI - KVALITET I KONTROLA KAVLITETA LEKA** **VETERINARY MEDICINES: REGULATORY REQUIREMENTS - PRODUCT QUALITY & QUALITY CONTROL** Moderator: Gordana Žugić, ALIMS
	Antimikrobna rezistencija - Procena rizika po javno zdravlje Antimicrobial resistance - Assessment of the risk to public health Jelena Anđelković, ALIMS
	Regulatorni zahtevi za kvalitet leka - tableta Regulatory requirements for medical product quality - tablet Aleksandra Labudović, ALIMS
	Regulatorni zahtevi za kvalitet leka - Intramamarna suspenzija Regulatory requirements for medical product quality - Intramammary suspension Jelena Stevanović Gročić, ALIMS
	Informacije na neposrednom ili spoljašnjem pakovanju veterinarskog leka - Obeležavanje (Nacrt pakovanja) Information on the immediate or outer packaging of a veterinary medicine - Labelling (Mock up) Svjetlana Mihaljica, ALIMS
13.00-14.30	**PAUZA ZA RUČAK / LUNCH BREAK**

DAN/DAY II

17.10.2025.

SALA POGLED
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14.30-16.00	**KLINIČKA ISPITIVANJA LEKOVA - NOVINE I IZAZOVI U ODOBRAVANJU KLINIČKIH ISPITIVANJA** **CLINICAL TRIALS OF MEDICINES - CHANGES & CHALLENGES IN CLINICAL TRIAL AUTHORISATION** Moderator: Biljana Andrić, ALIMS
	Izazovi u radu EOS-a od 2020-2025. **Challenges faced by EOS 2020-2025.** Prof. Darko Antić, PhD, The University Clinical Centre of Serbia and President of EOS
	Praćenje bezbednosti lekova u kliničkim ispitivanjima **Drug safety monitoring in clinical trials** Tijana Mićić, ALIMS
	Lekovi za naprednu terapiju (ATMP): Regulatorni okvir **Advanced therapy medicinal products (ATMPs): Regulatory framework** Jelena Mijailović, ALIMS
	Panel diskusija: Vaša pitanja - naši odgovori **Panel discussion: Your questions - ours answered** Panelists: Ana Lakobrija, ALIMS | Aleksandra Bjelovuk, ALIMS
16.00-16.30	**KAFE PAUZA / COFFEE BREAK**
16.30-18.00	**ICH GCP (R3) KONAČNO OTKROVENJE, IMPLEMENTACIJA I IZAZOVI 2025** **ICH GCP (R3) FINAL REVELATION IMPLEMENTATION VS CHALLENGES 2025** Moderator: Violeta Ristić, ALIMS
	Panel diskusija **Panel discussion** Panelists: Prof. Vladimir Janjić, PhD, Dean of the Faculty of Medical Sciences at the University of Kragujevac Nikola Bošković, Abbvie | Aleksandar Đurić, Parexel
18.00-21.00	**VEČERA / DINNER**
21.00	**KOKTEL / COCKTAIL**

*Napominjemo da je ograničen broj mesta na sesijama za klinička ispitivanja i veterinarske lekove i da zbog ograničenog kapaciteta sale, prednost na ovim sesijama imaju učesnici sa plaćenim kotizacijama za ovu kategoriju.
Sve sesije će biti snimljene i postoji mogućnost odloženog gledanja 3 meseca nakon simpozijuma.
*Please note that there are a limited number of places in the sessions for clinical trials and veterinary drugs and that due to the limited capacity of the hall, priority is given to participants with paid registration fees for this category.
All sessions will be recorded and there is a possibility of delayed viewing 3 months after the symposium.

DAN/DAY III

18.10.2025.

SALA IZVOR 1 i 2
HALL IZVOR 1 i 2

10.00-11.30	**PANEL DISKUSIJA** **- AKTUELNI REGULATORNI ZAHTEVI ZA STAVLJANJE NA TRŽIŠTE MEDICINSKIH SREDSTAVA** **- IZAZOVI IMPLEMENTACIJE, PRIMERI IZ PRAKSE I REŠENJA** **U PRIMENI NOVIH EU REGULATIVA IZ OBLASTI MEDICINSKIH SREDSTAVA U REPUBLICI SRBIJI** PANEL DISCUSSION - CURRENT REGULATORY REQUIREMENTS FOR PLACING MEDICAL DEVICES ON THE MARKET - IMPLEMENTATION CHALLENGES, PRACTICAL EXAMPLES AND SOLUTIONS IN THE APPLICATION OF NEW EU MEDICAL DEVICE REGULATIONS IN THE REPUBLIC OF SERBIA Moderator: Biljana Stojanović, ALIMS
	Panel diskusija Panel discussion Panelists: Ana Razić, B.Braun Adria RSRB, Grupacija uvoznika i distributera medicinskih sredstava, PKS Ivan Popović, Kvalitet AD Niš | Danilo Rajković, International Certification Group Beograd | Biljana Stojanović, ALIMS
11.30-12.00	**KAFE PAUZA** / COFFEE BREAK
12.00-13.30	**REGULATORNI IZAZOVI I INOVACIJE U FARMACEUTSKOJ INDUSTRIJI:** **OD RAZVOJA LEKA DO PACIJENTA** REGULATORY CHALLENGES AND INNOVATIONS IN PHARMACEUTICAL INDUSTRY: FROM DRUG DEVELOPMENT TO PATIENT Moderator: Stana Ubavić, ALIMS
	Najnovija regulatorna saznanja o ispitivanju stabilnosti aktivne supstance i gotovog leka - Novi predlog smernice ICH Q1 2025 The latest regulatory knowledge on stability testing of drug substance and drug products - New draft ICH Q1 2025 Marija Čarapić, ALIMS
	Specifični zahtevi za ekscipijense u dokumentaciji o kvalitetu leka: U kom pravcu ide regulativa za ekscipijense? Specific requirements for excipients in quality part of MA dossier: Potential regulatory pathway for excipients Stana Ubavić, ALIMS
	Pilot program za varijacije (EMA/WHO) - Novi regulatorni trendovi Pilot programme for variations (EMA/WHO) - Emerging regulatory trends Dragana Avakumović, ALIMS
	Lekovi sa živim mikroorganizmima (Live Biotherapeutic Products), regulatorni okvir i izazovi Live Biotherapeutic Products, regulatory framework and challenges Milanka Šetina, ALIMS
13.30-14.00	**ZAKLJUČCI SIMPOZIJUMA** / CONCLUSIONS
14.00-15.30	**PAUZA ZA RUČAK** / LUNCH BREAK

DAN/DAY III

18.10.2025.

SALA POGLED
HALL POGLED

10.00-11.30	**BENCHMARKING ALATI ZA UNAPREDJENJE POSLOVNIH PROCESA** **PROCESSES IMPROVEMENT USING THE BENCHMARKING TOOLS** Moderator: Dragana Šmidling Koruga, ALIMS
	Benchmarking alati za unapredjenje poslovnih procesa Processes improvement using the benchmarking tools Dragana Šmidling Koruga, ALIMS
	Primena Benchmarking alata u praksi Benchmarking tools in practice Jelena Rajić, ALIMS | Marija Žunjić, Ministry of Health of the Republic of Serbia | Marko Veljković, IZJZS Batut
11.30-12.00	**KAFE PAUZA / COFFEE BREAK**
12.00-13.30	**NOVINE I IZAZOVI U KONTROLI KVALITETA BIOLOSKIH LEKOVA I IMPLEMENTACIJA NOVOG INFORMACIONOG SISTEMA** **INNOVATIONS AND CHALLENGES IN QUALITY CONTROL OF BIOLOGICAL MEDICINAL PRODUCTS AND THE IMPLEMENTATION OF A NEW INFORMATION SYSTEM** Moderator: Dragana Šmidling Koruga, ALIMS
	Regulacija vakcina - Puštanje serije vakcine u promet Regulatory approach - Vaccines batch release Vera Simić, ALIMS
	Specifičnosti puštanja u promet lekova proizvedenih iz krvi krvne plazme Critical regulatory considerations for the batch release of plasma - Derived Medicinal Products Boško Mitrović, ALIMS
	Novo informatičko rešenje za puštanje serije biološkog leka u promet A new digital solution for batch release of biological medicinal products Katica Drljević Đurić, ALIMS
14.00-15.30	**PAUZA ZA RUČAK / LUNCH BREAK**