

# ALIMS Simpozijum 2.0

## ALIMS Symposium 2.0



**2.0**dgovornost

**2.0**perativnost

**2.0**rganizacija

**2.0**pservacija

**2.0**bjectivity

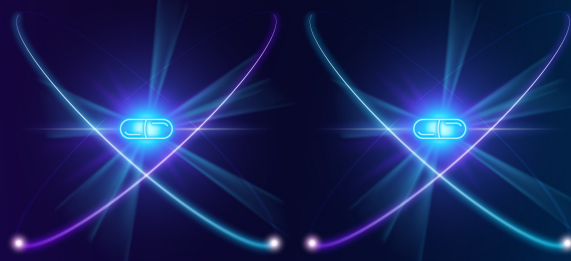
**2.0**perativness

**2.0**rganization

**2.0**bservation

24 – 26. 10. 2024.

Kopaonik, Srbija



## Predavači i moderatori / Lecturers and moderators





Aleksandra Bjelovuk	 SRB	Marija Kurćubić	 SRB
Aleksandra Labudović	 SRB	Marija Malešević	 SRB
Aleksandra Vujačić Simić	 SRB	Marko Erić	 SRB
Amy Rowland	 USA	Milan Đokić	 SRB
Ana Coelho	 POR	Mladen Bogdanović	 SRB
Biljana Andrić	 SRB	Nađa Milojković	 SRB
Biljana Latinović	 SRB	Pavle Zelić	 SRB
Biljana Stojanović	 SRB	Siniša Radulović	 SRB
Biljana Tubić	 BIH	Snježana Nikolić	 SRB
Dragana Avakumović	 SRB	Sonja Selić	 SRB
Dubravka Mišković	 SRB	Sophie Barreteau	 FRA
Gordana Boljević Stanojević	 MNE	Stana Ubavić	 SRB
Iva Klarica Domjanović	 CRO	Stefan Đurić	 SRB
Iva Prunić	 SRB	Stefan Mandić Rajčević	 SRB
Ivan Popović	 SRB	Svetlana Jovanović	 SRB
Ivan Soldatović	 SRB	Svjetlana Mihaljica	 SRB
Ivana Ferber	 CRO	Tanja Nedić	 SRB
Ivana Tadić	 SRB	Tatjana Stojadinović	 SRB
Jelena Anđelković	 SRB	Tijana Radojičić	 SRB
Jelena Čolović	 SRB	Vesna Ševaljević	 SRB
Jelena Stevanović Gročić	 SRB	Viktorija Dragojević Simić	 SRB
Katarina Todorović	 SRB	Violeta Ristić	 SRB
Katica Drljević Đurić	 SRB	Vladimir Burgić	 SRB
Maja Bašić	 CRO	Zoran Dobrosavljević	 SRB
Marija Čarapić	 SRB	Zorana Radonjić	 SRB



## Svečano otvaranje konferencije / Conference opening ceremony

Ana Popović	 SRB	Dragoş Guţu	 MOL	Nataša Grubiša	 BIH
Blerina Kaza	 ALB	Emer Cooke	 IRL	Petra Doerr	 SWI
Bogdan Kirilov	 BUG	Fabio Scano	 ITA	Saša Jačović	 SRB
Bojan Trkulja	 SRB	Maja Vučković Krčmar	 SRB	Sefedin Jonuzi	 NMK
Cecilia Müller	 HUN	Mirjana Vučićević	 SRB	Snežana Mugoša	 MNE

## Organizacioni odbor / Organizing Committee

Nenad Petronijević	Predsednik / <b>President</b>	 SRB
Pavle Zelić	Programski direktor / <b>Program director</b>	 SRB
Željko Jovanović	Finansijski direktor / <b>Financial director</b>	 SRB
Kristina Denčić	Direktor usluga / <b>Hospitality director</b>	 SRB

### Organizator



### Koorganizatori



### Pokrovitelj





# 01

## 24.10.2024.

Sala Izvor  
Hall Izvor

17:00–18:00 **Koktel dobrodošlice**  
**Welcome cocktail**

18:00–20:00 **Obeležavanje 20 godina rada ALIMIS:**  
Svečano otvaranje simpozijuma, pozdravni govor zvaničnika,  
interaktivna panel diskusija direktora  
i rukovodilaca regulatornih tela iz Evrope  
**Celebrating 20 years of ALIMIS:**  
Formal opening of the symposium, official welcome speech,  
interactive panel discussion with directors  
and managers of regulatory bodies from Europe

Moderator / Moderator:

**Jelena Mitrašinić**, ALIMIS

**Saša Jaćović**, direktor ALIMIS / **ALIMS director**

**Emer Cooke**, direktor EMA / **EMA director**

**Petra Doerr**, direktor EDQM / **EDQM director**

**Maja Vučković Krčmar**, Kancelarija EU delegacije u RS  
**Delegation of the European Union (EU)  
to the Republic of Serbia**

**Fabio Scano**, direktor Kancelarije SZO u RS  
**director of WHO office in Republic of Serbia**

**Mirjana Vučićević**, Privredna komora Srbije  
**Serbian Chamber of Commerce**

**Bojan Trkulja**, direktor INOVIA / **INOVIA director**

**Ana Popović**, direktor GENEZIS / **GENEZIS director**

**Predstavnik Ministarstva zdravlja Srbije**

**Representative of the Ministry of Health of Serbia**

Uvodno predavanje  
**Introductory lecture**

**Saša Jaćović**, direktor ALIMIS / **ALIMS director**

Panel visokih predstavnika  
**Panel of High Representatives**

Moderator / Moderator:

**Pavle Zelić**, ALIMIS

Panelisti / Panelists:

**Saša Jaćović**, direktor ALIMIS / **ALIMS director**

**Nataša Grubiša**, direktor ALMBIH / **ALMBIH director**

**Snežana Mugoša**, direktor CinMED / **CinMED director**

**Sefedin Jonuzi**, direktor MALMED / **MALMED director**

**Cecilia Müller**, direktor NNGYK / **NNGYK director**

**Bogdan Kirilov**, direktor BDA / **BDA director**

**Dragoş Guţu**, direktor AMDM / **AMDM director**

**Blerina Kaza**, direktor AKBPM / **AKBPM Director**

20:00–22:00 **Večera u restoranu hotela Gorski**  
**Dinner at hotel Gorski**







9:30–11:00	<b>RIMS - Sledeća ALIMS generacija</b> <b>RIMS - ALIMS Next Generation</b>	Moderatori / <i>Moderators:</i> <b>Marko Erić</b> , ALIMS <b>Tanja Nedić</b> , ALIMS
	ALIMS digitalna transformacija i RIMS revolucija <b>ALIMS digital transformation and RIMS revolution</b>	Predavači / <i>Speakers:</i> <b>Marko Erić</b> , ALIMS <b>Tatjana Stojadinović</b> , ALIMS
	Putokaz u eBudućnost - panel diskusija <b>Pathway to eFuture - panel discussion</b>	Panelisti / <i>Panelists:</i> <b>Svetlana Jovanović</b> , Fakultet organizacionih nauka, <b>The Faculty of Organisational Sciences</b> <b>Tatjana Stojadinović</b> , ALIMS <b>Tijana Radojčić</b> , PKS / <i>Chamber of commerce of Serbia</i> <b>Zoran Dobrosavljević</b> , Abstract <b>Marko Erić</b> , ALIMS
11:00–11:30	Kafe pauza / <i>Coffee break</i>	
11:30–13:00	<b>Umrežavanje u oblasti regulative i kontrole</b> - značaj saradnje sa međunarodnim i nacionalnim institucijama u obezbeđivanju kvalitetnih lekova <b>Networking in regulation and control</b> - importance of collaboration with international and national institutions in acquiring quality drugs	Moderator / <i>Moderator:</i> <b>Marija Malešević</b> , ALIMS
	Povlačenje leka iz prometa - Nacionalna i međunarodna saradnja u postupku povlačenja <b>Medicine recall from the market</b> - National and international cooperation in the recall process	<b>Svjetlana Mihaljica</b> , ALIMS
	Iskustva NKL u okviru OMCL mreže <b>NCL Experience within OMCL Network</b>	<b>Katica Drljević Đurić</b> , ALIMS
	Novi zahtevi u kvalitetu aktivne supstance i učešće ALIMS-a u CEP procedure <b>New requirements for the quality of active substance and ALIMS participation in the CEP procedure</b>	<b>Marija Čarapić</b> , ALIMS
	Značaj kvaliteta i ispitivanja ekscipijenasa u formulaciji leka: da li su ekscipijensi samo pomoćne materije? <b>Significance (Awareness) of quality and testing of excipients in drug formulation: Are excipients just auxiliary substances?</b>	<b>Stana Ubavić</b> , ALIMS

02

25.10.2024.



Sala Izvor  
Hall Izvor

13:00–15:00 Pauza za ručak / [Lunch break](#)

15:00–16:30 Regulatorni *reliance*: sadašnja praksa i buduće perspektive  
[Regulatory Reliance: Current Practice and Future Prospects](#)

Moderator / Moderator:  
**Dragana Avakumović**, ALIMS

Panelisti / [Panelists](#):

**Marija Malešević**, ALIMS

**Biljana Tubić**, ALMBIH

**Gordana Boljević Stanojević**, CinMED

**Ivana Ferber**, MSD Hrvatska / [MSD Croatia](#)

**Ana Coelho**, EMA

16:30–17:00 Kafe pauza / [Coffee break](#)



17:00–18:30	<p>Aktuelne teme iz oblasti regulative medicinskih sredstava, sa osvrtom na regulatorne zahteve u delu prometa i proizvodnje medicinskih sredstava u Republici Srbiji, uspostavljanja sistema menadžmenta kvalitetom (ISO 13485) i ocenjivanja usaglašenosti medicinskih sredstava u Republici Srbiji (srpski znak usaglašenosti)</p> <p>Current topics in the field regulation of medical devices, with reference to regulatory requirements in the area of marketing and production of medical devices in the Republic of Serbia, establishing a management system for quality (ISO 13485) and conformity assessment of medical devices in the Republic of Serbia (Serbian mark of conformity)</p>	<p>Moderator / Moderator: <b>Aleksandra Vujačić Simić</b>, ALIMIS</p>
	<p>Regulatorni zahtevi u oblasti prometa i proizvodnje medicinskih sredstava u Republici Srbiji</p> <p>Regulatory requirements in the field of circulation &amp; production of medical devices in the Republic of Serbia</p>	<p><b>Marija Kurćubić</b>, Ministarstvo zdravlja Republike Srbije / Ministry of Health of Republic of Serbia</p>
	<p>Regulatorni zahtevi za stavljanje na tržište "DDC (Drug-Device combination)" proizvoda</p> <p>Regulatory requirements for placing "DDC (Drug-Device combination)" products on the market</p>	<p><b>Vesna Ševaljević</b>, MD&amp;D Solutions</p>
	<p>Ocenjivanje usaglašenosti medicinskih sredstava za svrhe dobijanja 3A znaka (srpski znak usaglašenosti)</p> <p>- osvrt iz ugla imenovanog tela</p> <p>Assessment of the conformity of medical devices for the purposes of obtaining the 3A mark (Serbian mark of conformity)</p> <p>- a review from the designated body point of view of</p>	<p><b>Ivan Popović</b>, Kvalitet AD Niš</p>
	<p>Značaj uspostavljanja sistema menadžmenta kvalitetom</p> <p>- medicinska sredstva (ISO 13485)</p> <p>The importance of establishing a quality management system</p> <p>- medical devices (ISO 13485)</p>	<p><b>Vladimir Burgić</b>, QMS Consulting</p>
18:30–21:00	<p>Večera u restoranu hotela Gorski</p> <p>Dinner at hotel Gorski</p>	
21:00	<p>Koktel - restoran Nacionalna klasa</p> <p>Cocktail - Restaurant "Nacionalna Klasa"</p>	



10:00–11:30	<p>Panel diskusija</p> <p>- Praktični aspekti, izazovi i rešenja u primeni novih EU regulativa iz oblasti medicinskih sredstava u Republici Srbiji</p> <p>Panel discussion</p> <p>- Practical aspects, challenges and solutions in the application of new EU regulations in the field of medical devices in the Republic of Serbia</p>	<p>Moderator / Moderator:</p> <p><b>Biljana Stojanović</b>, ALIMS</p> <p>Panelisti / Panelists:</p> <p><b>Nađa Milojković</b>, NeoMedica d.o.o. Niš ispred Grupacije proizvođača medicinskih sredstava, PKS NeoMedica d.o.o. Nis, representative of Group of producers of medical devices, Chamber of commers of Serbia</p> <p><b>Jelena Čolović</b>, Medtronic Srbija d.o.o. ispred Grupacija uvoznika i distributera medicinskih sredstava, PKS Medtronic Srbija d.o.o. representative of Group of importers and distributers of medical devices, Chamber of Commerce of Serbia</p> <p><b>Vesna Ševaljević</b>, MD&amp;D Solutions</p> <p><b>Vladimir Burgić</b>, QMS Consulting</p>
11:30–12:00	Kafe pauza / Coffee break	
12:00–13:30	<p>Tragom globalnih trendova</p> <p>- od bioekvivalencije do međusobne zamenjivosti</p> <p>Following global trends</p> <p>- from bioequivalence to mutual substitutability</p>	<p>Moderatori / Moderators:</p> <p>Snježana Nikolić, ALIMS</p> <p>Mladen Bogdanović, ALIMS</p>
	<p>Abridged Application in the EU - a regulatory perspective</p> <p>Generički, hibridni i biološki sličan lek u EU - regulatorni aspekt</p>	<p>Ana Coelho, EMA</p>
	<p>Međusobna zamjenjivost lijekova i novosti vezane za ICH smjernicu za ocjenu bioekvivalencije</p> <p>Drug interchangeability and news related to the ICH guideline for bioequivalence assessment</p>	<p>Iva Klarica Domjanović, HALMED</p>
	<p>Klinička ispitivanja lekova ranih faza: šta je sa Srbijom?</p> <p>Early phase clinical trials: what about Serbia?</p>	<p>Viktorija Dragojević Simić, VMA / Military Medical Academy</p>
13:30–14:00	Zaključci simpozijuma / Symposium conclusions	
14:00–16:00	Ručak / Lunch	
	Kraj simpozijuma / End of Symposium	

03

26.10.2024.



Sala Pogled  
Hall Pogled

## Paralelna sesija / Parallel session

10:00–11:30 **Rezultati projekta na temu infodemije**  
**Results of the infodemic project**

Moderator i predavač / **Moderator & speaker:**

**Pavle Zelić**, ALIMS

Predavači / **Speakers:**

**Amy Rowland**, Emory Global Health

**Maja Bašić**, HALMED

**Stefan Mandić Rajčević**, Medicinski fakultet u Beogradu

**University of Belgrade - Faculty of Medicine**

