

23rd Regulatory and pharmacovigilance conference

Programme

14 – 16 September 2026 | Novo mesto, Slovenia

KRKA

Living a healthy life.

GENERAL INFORMATION

Date
The conference will be held from 14 to 16 September 2026 at KRKA, d. d., Novo mesto headquarters in Slovenia (Novo mesto) and online.

Accommodation
The participants will be accommodated in Krka's capacities at **Hotel Šport Otočec.**
Full-board service (with breakfast, lunch and dinner) will be organised for all the participants at hotel and in KRKA, d. d., Novo mesto.
For more information visit https://www.terme-krka.com/us/en/otocec/

Arrival & Departure
The official programme of Regulatory and pharmacovigilance conference begins on Monday, 14 September 2026 at 09.00, following the registration at 08.15.
The pharmacovigilance part of the conference will be held on Wednesday, 16 September 2026.
All transfers will be arranged (from/to the airport, hotel, etc).
Departure is possible after 15.00 – after the last session on 16 September 2026.

Transport Information
We kindly ask the participants who depart on Wednesday, 16 September 2026 to leave their luggage in the morning at Krka Headquarters for easier transport organisation in the afternoon.

Please take into consideration when reserving the plane tickets, you have to calculate the time for departure from Krka Headquarters in Novo mesto to the airports as follows:
- Airport Jože Pučnik Ljubljana app. 3 hours,
- Airport Franjo Tuđman Zagreb app. 3 hours.

Please obtain all the necessary documents for staying in Slovenia (passports, visas, Letters of Guarantee ...), if needed. If you have any further questions about the accommodation or transport, please contact us by e-mail: Regulatory.Affairs@krka.biz

Social Event
On **Monday, 14 September 2026, the Regulatory Awards ceremony** will be held at **Krka Hall.**
On **Tuesday, 15 September 2026, a social event** will take place **in Bled,** one of Slovenia's most picturesque destinations. Further details about the social event schedule will be provided during the conference.
We recommend comfortable clothing/shoes. More information about the location is available at Bled Tourism.

Organising Committee
Nataša Eržen Vrščaj, Simona Podlesek Sumina, Bernarda Bevc, Eva Črepinšek Ožbolt, Anja Fortuna, Nina Kramar, Anja Vidrih, Tjaša Može, Bernarda Padovan, Jožica Valenčak and Nina Staniša.

Cost
KRKA, d. d., Novo mesto will settle all the expenses for the accommodation and meeting facilities, meals, coffee and refreshments that will be served during the morning and afternoon breaks and social events during this conference. Colleagues from Krka companies will receive Invoices to their headquarters.

The accommodation per person per day is:

Hotel		Bed and breakfast	Half board	Full board
Hotel Šport Otočec ****	1/1 – Standard room	94.24	98.24	128.24
Hotel Šport Otočec ****	1/2 – Standard room	75.24	79.24	109.24
Hotel Šport Otočec ****	1/1 – Superior room	101.84	105.84	135.84
Hotel Šport Otočec ****	1/2 – Superior room	82.84	86.84	116.84
		Tourist tax per day is **2.50 €.**		

Other expenses, such as mini-bar, room service, laundry, telephone calls are not covered by Krka. You should pay for these either by cash or card when you check out of the hotel.

PROGRAMME

Monday, 14 September 2026 **Present: All participants** **Krka, d. d., Novo mesto, Slovenia – Krka Hall / Online**	
08.00	*Departure/Transport of Local regulatory colleagues from the hotel to Krka's HQ*
08.15 – 09.00	**REGISTRATION** *(Krka, d. d., Novo mesto, Slovenia – Krka Hall)*
09.00 – 09.45	**INTRODUCTION / OPENING SPEECH** *(Suzana Kolenc, Director of New products)*
09.45 – 10.00	**New members of Krka Regulatory & Pharmacovigilance team** – short presentation
10.00 – 10.45	**Strategy, Corporate Finance and Investing: The Krka Perspective** *(Uroš Ožbolt, Finance director)*
10.45 – 11.15	*Coffee break*
11.15 – 12.00	**Text management and implementation** *(Ana Krstova, Technology elements for production /* *Blaž Krivec, Supply chain management / Klavdija Vertuš, HQ Regulatory Affairs)*
12.00 – 13.30	*Lunch break*
13.30 – 15.00	**Smart Use of AI / Artificial Intelligence in Regulatory Affairs -** *presentation and roundtable discussion* *(Matej Golob Managing Partner, CorpoHub; AI Expert /* *Round table participants: Kim Zelič, Bojana Ločičnik, Carsten Oelkers,* *Ilina Katsarova, Jelena Simić, Evgeniya Samlyukova)*
15.00	*Transport of Local regulatory colleagues to the hotel*

REGULATORY AWARDS

18.15	*Departure/Transport of Local regulatory colleagues from the hotel to Krka's HQ*
18.30	***Arrival to the Awards ceremony in Krka HQ***
19.00 – 21.00	**REGULATORY AWARDS FOR BEST REGULATORY MANAGERS** **Event & Dinner at Krka Hall**
21.00	*Transport of Local regulatory colleagues to the hotel*

Tuesday, 15 September 2026

Krka, d. d., Novo mesto, Slovenia – Krka Hall, Conference room 4/P / *Online*

08.00	*Departure/Transport of Local regulatory colleagues from the hotel to Krka's HQ*	
Parallel sessions:		
	Participants from EU, SEE and non-EAEU *Krka Hall*	***EAEU Participants*** *Conference room 4/P*
08.30 - 09.15	**New EU General Pharmaceutical Legislation** *(Špela Jenko, HQ Regulatory Affairs)*	**Overview of current situation per country** *(Sandra Hiti, Ruzanna Badalyan, Katsiaryna Khizhniak, Chynara Takinova, Arailym Abenova, Tatyana Tamkovich)* **+ plan EAEU variations and renewals** *(Gregor Hrovat, HQ Regulatory Affairs)* *Presentations/discussions will be partly held in RU language*
09.15 – 10.00	**One Data Source, Many Business Processes** *(Kim Zelič/Jaka Petrič, Informatics in Projects and Regulatory Affairs)*	
10.00 – 10.30	*Break*	
10.30 – 11.00	**The Patent Perspective: Key Patent Milestones on the Registration Path** *(Barbara Kunič, Head of Industrial Property)*	**EAEU Text and Mock-up preparation** *(Bernarda Padovan, HQ Regulatory Affairs/ Iza Pekle Simonič, Medical development)* **EAEU Veterinary procedures** *(Matija Krajnik, HQ Regulatory Affairs)* *Presentations/discussions will be partly held in RU language*
11.00 - 11.30	**Regulatory Management of Indication Patents: Key Challenges and Insights** *(Bernarda Bevc, HQ Regulatory Affairs)*	
11.30 - 12.00	**Individual meetings for local regulatory managers and HQ RP per country**	
12.00 – 13.00	*Lunch*	
13.15	*Departure to social event - location* ***Bled, Slovenia***	
21.00	*Departure to Novo mesto from Bled*	

Wednesday, 16 September 2026

Present: All participants
Krka, d. d., Novo mesto, Slovenia – Krka Hall, Conference room *4/P* / *Online*

07.45	*Departure/Transport of Local regulatory colleagues from the hotel to Krka's HQ*	
Participants: All participants (HQ New Products, local regulatory managers) + MRF:		
08.15 – 09.00	**Opening speech** *(Aleš Rotar, Member of the Management Board and Director of Pharmaceutical Research & Development and Production)*	
09.00 – 10.00	**Pharmacovigilance – novelties in human and veterinary pharmacovigilance** *(HQ Pharmacovigilance: Irena Orel, Rok Pejović)*	
Participants: LRP (local responsible persons for pharmacovigilance) + MRF:		
10.00 – 11.00	• **Inside Pharmacovigilance department** *(Teja Barle, HQ Pharmacovigilance)* • **Medical Assessment** *(Manca Urh, HQ Pharmacovigilance)* • **Personal data protection and use of AI** *(Meta Krek, HQ Pharmacovigilance)* • **PSMF** *(Ajda Kokalj, HQ Pharmacovigilance)*	
11.00 – 11.30	*Break*	
Parallel sessions:		
11.30 – 12.30	*Krka Hall* ***Participants from EU, SEE and non-EAEU*** • **Educational materials management - DAM project** *(Petra Tekavčič, HQ Pharmacovigilance, João Silva, Krka, Portugal)* • **MedDRA presentation** *(Nataša Nagelj Kovačič, Patricia Luštek, HQ Pharmacovigilance)*	*Conference room 4/P* ***EAEU Participants*** **EAEU Pharmacovigilance** • **EAEU novelties** *(Denis Makhnovskiy)* • **Kazakhstan inspection preparation** *(Denis Makhnovskiy, Anastassiya Yakhyayeva, Živa Turšič)*
All participants:		
12.30 – 13.30	*Lunch break*	
13.30 – 14.15	**Conclusions**	
14.15 – 15.00	**Individual meetings for local regulatory managers and HQ RP per country** *(HQ Regulatory Affairs, local regulatory managers)*	
15.00	*Departure / Transport to the hotel and/or Airport*	