

Digitalna transformacija regulatornih poslova za lekove *RIMS Varijacije, PMS (IDMP) i ePI*

22.09.2025. godine
PKS, Resavska 13-15, sala 1

9:30 – 10:00 **Registracija učesnika**

10:00 – 11:30 **RIMS Varijacije – Elektronsko podnošenje zahteva i postupanje**
Marko Erić, Agencija za lekove i medicinska sredstva Srbije
Darko Rančić, Abstract

11:30 – 12:00 **Pauza**

12:00 – 14:00 **RIMS PMS (IDMP) & ePI**

- **PMS arhitektura – implementacija ISO IDMP standarda i FHIR strukture**
- **Kreiranje IDMP podataka o leku uz primenu kontrolisanih rečnika (EU SPOR)**
- **Kreiranje ePI informacija o leku**
- **Dinamika prelaska na PMS i ePI i planovi za naredni period**

Marko Erić, Agencija za lekove i medicinska sredstva Srbije
Tanja Neđić, Agencija za lekove i medicinska sredstva Srbije
Zoran Dobrosavljević, Abstract
Aleksandar Marjanović, Abstract

14:00 – 14:30 **Diskusija**

Korisni akronimi

RIMS	Regulatory Information Management System
FHIR	Fast Healthcare Interoperability Resources
ISO	International Organization for Standardization
IDMP	Identification of Medicinal Products
SPOR	Data management services for substances, products, organisations and referentials
SMS	Substance Management Services
PMS	Product Management Services
OMS	Organisation Management Services
ORG ID	SPOR OMS Organisation identity
LOC ID	SPOR OMS Location Identity
RMS	Referentials Management Services
PLM	Product Lifecycle Management
ePI	Electronic Product Information
eAF	Electronic Application Forms