14 September 2023
Information Management

Agenda: Informative Webinar on Regulatory Procedure Management for Product Lifecycle Management 1st roll-out on IRIS

15 September 2023, 10:00 – 11:30 (CEST)

Webinar: WebEx meeting

EMA is pleased to announce a **public webinar** for pharmaceutical industry companies (especially individuals with expertise in regulatory affairs) interested in learning more about the **Regulatory Procedures for medicinal products onboarding on IRIS.**

EMA is currently working on the onboarding of **human and veterinary regulatory procedures** on IRIS, with the aim to increase automation and efficiency, improve knowledge management and data security, and enhance transparency. The onboarding of regulatory procedures on IRIS will lead to **process simplification and standardisation for MAHs**, thus allowing the **decommissioning of SIAMED**.

The first procedures to be onboarded on IRIS are **Variations, Article 61.3 notifications and Marketing Authorisation Transfers** for a sub-set of Human and Veterinary medicinal products.

During the webinar, participants will have the chance to interact with the EMA product team, ask questions, and receive updates on the ongoing work related to regulatory procedures. The session will also include a demo of the Industry Portal in IRIS.

This is a valuable opportunity to enhance your understanding and stay informed about the latest developments in this area.

The **registration form** is available here.

Registration is open until the start of the meeting.

#	Item	Speaker	Mins
1.	**Welcome**	**Madalina Duta-Mare** *Regulatory Procedure Management for PLM Product Owner*	10:00 – 10:05 (5 min)

#	Item	Speaker	Mins
2.	**Introduction to Regulatory Procedure Management (RPM) for Product Lifecycle Management (PLM)**	**Madalina Duta-Mare** *Regulatory Procedure Management for PLM Product Owner*	10:05 – 10:15 (10 min)
3.	**RPM objectives & key changes**	**Sara Santos** *Regulatory Procedure Management for PLM Subject Matter Expert*	10:15 – 10:25 (10 min)
4.	**RPM Roadmap**	**Sara Santos** *Regulatory Procedure Management for PLM Subject Matter Expert*	10:25 – 10:30 (5 min)
5.	**1st roll-out impact on pharmaceutical companies**	**Madalina Duta-Mare** *Regulatory Procedure Management for PLM Product Owner*	10:30 – 10:40 (10 min)
6.	**Presentation of ongoing work for RPM (IRIS Industry Portal Demo)**	**Simona Griniene** *Regulatory Procedure Management for PLM Subject Matter Expert*	10:40 – 10:55 (15 min)
7.	**Next steps**	**Simona Griniene** *Regulatory Procedure Management for PLM Subject Matter Expert*	10:55 – 11:00 (5 min)
8.	**Q&A Session**	Moderator: **Joris Wiemer** *EMA Change Management Lead*	11:00 – 11:25 (25 mins)
9.	**Closing**	**Madalina Duta-Mare** *RPM for PLM Product Owner*	11:25 – 11:30 (5 mins)