

ENVIRONMENTAL RISK ASSESSMENT OF MEDICINAL PRODUCTS

Requirements and Implications of the New EMA Guideline

FREE WEBINAR

30th Sep 2026 • 45 min



DESCRIPTION

An Environmental Risk Assessment (ERA) is mandatory for all Marketing Authorization Applications (MAA) of medicinal products in the European Union, regardless of the legal basis. The ERA aims to assess the potential environmental risks arising from the use of a medicinal product and to identify appropriate precautionary and risk mitigation measures, with the objective of protecting aquatic and terrestrial ecosystems, as well as microbial processes occurring in wastewater treatment plants.

The new European Medicines Agency (EMA) guideline on ERA entered into force on 1 September 2024 and introduced a range of new orientations and specific requirements for the assessment of the environmental risk of medicinal products. Understanding the implications of this new guideline is therefore essential for the successful submission of MAAs and, most importantly, for ensuring the proper use and disposal of medicinal products.

OBJECTIVES

- Address the requirements of the new EMA guideline on Environmental Risk Assessment.
- Provide a comprehensive overview of environmental risk assessment and the evaluation of persistence, bioaccumulation, and toxicity (PBT) potential.

TARGET AUDIENCE

Professionals of pharmaceutical industry (regulatory affairs, medical writers, business developers)

TRAINER

Andreia Mónico (PharmD. PhD), Medical & Scientific Associate Director, Owlpharma – Consulting, Lda.

PROGRAMME CONTENT

1. Legal framework
2. Environmental Risk Assessment and PBT potential
 - a. Assessment phases
 - b. Use of environmental data previously generated by other marketing authorization holders.
 - c. Environmental studies required for the determination of environmental risk and PBT potential.

REGISTRATION

To register, please fill out the form on the following page: <https://page.owlpharma.pt/en-gb/webinar-environmental-risk-assessment-of-medicinal-products>

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