

EU SIGNAL MANAGEMENT

Recent Legislative Amendments and Regulatory Updates

INTERMEDIATE LEVEL

Live Online • 21/10/2026

DESCRIPTION

The signal management process, critical in Pharmacovigilance, consists of a set of activities carried out to determine whether new risks are associated with an active substance or medicinal product, or whether known risks have changed. Marketing Authorisation Holders (MAHs) of medicinal products approved in the European Union are legally required to continuously monitor product safety and maintain a signal management process. This training aims to present a comprehensive and integrated approach to the legal requirements applicable to signal detection within the European Union, its implementation, and recent/forthcoming changes to the process requirements.

OBJECTIVES

- Present the legal foundations underpinning signal management within the European Union;
- Analyse the legislative changes introduced in 2025/2026, including the updated version of the *Guideline on Good Pharmacovigilance Practices (GVP) Module IX – Signal Management*, expected to be released in the second quarter of 2026, and discuss the impact of these changes on the organisational structure and practices of MAHs.
- Describe the various stages of the signal management process and discuss possible methodologies;
- Highlight the importance of integrating EudraVigilance Data Analysis System (EVDAS) analysis into the signal detection process;
- Describe the importance of MAHs to monitor signals assessed by authorities and cooperate in safety evaluations.

TARGET AUDIENCE

Professionals from the pharmaceutical industry (Pharmacovigilance).

TRAINER

Daniela Gomes, Pharmacovigilance Manager, Owlpharma.

PROGRAMME CONTENT

1. Definitions and legal framework;
2. Changes to European legislation occurring in 2025/2026 and their impact on the signal management process.
3. Stages of the signal management process;
4. Methodologies applicable to signal management and analysis of their suitability to the MAH's organisation;
5. EVDAS as an essential tool in signal management;
6. The role of competent authorities in signal management.

REGISTRATION

Registration may be completed online at <https://www.owlpharma.pt/knowledge>. Alternatively, you may register by completing the attached form and sending it to knowledge@owlpharma.pt. You will receive an email confirming availability and providing payment details. Registration will only be considered complete upon confirmation of payment.

FEES

200 € + VAT

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REGISTRATION FORM

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Participant Details

Full Name	
Position	
Company	
Telephone	
Email	
Professional License Number (Ordem dos Farmacêuticos):	

Billing Details

Name or Company Name	
Address	
Tax Identification Number (TIN)	
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The information you provide will not be shared with third parties and will be used exclusively for the management of the training service and the issuance of participation certificates.