

DSUR and PSUR/PBRER

Aggregate Safety Reporting from Development to Post-Marketing



Interactive Training

- Importance of pharmacovigilance in patient safety
- Role of DSUR during clinical development
- Role of PSUR /PBRER in post-marketing surveillance
- Global regulatory frameworks: ICH, EMA, FDA, PMDA
- Signal detection and benefit-risk evaluation
- Submission timelines and regulatory expectations
- Challenges, harmonization, and future considerations

Speaker



Dr. Joan D'Souza
Chief Medical Officer, Attorney (JD), M.Sc- Pharmacovigilance and
Pharmacoepidemiology
Switzerland, Germany, US

Program

- Understand the purpose and structure of DSUR and PSUR/PBRER
- Differentiate between clinical development and post-marketing safety reporting
- Review global regulatory requirements and timelines
- Explore signal management and benefit-risk evaluation
- Discuss harmonization efforts and industry best practices
- Supports continuous monitoring of medicinal product safety
- Enables early detection of emerging safety signals
- Protects patients through proactive risk management
- Supports regulatory decision-making
- Ensures compliance with global pharmacovigilance regulations
- Strengthens benefit-risk evaluation throughout the product lifecycle

Who should attend

From practice for practice!

We are particularly addressing employees in the following areas:

- Pharmacovigilance professionals, Safety Writers, and Drug Safety Associates
- Regulatory Affairs, Clinical Research, and Quality Assurance professionals
- Safety Physicians, Medical Reviewers, and Risk Management teams
- Pharmaceutical industry professionals involved in DSUR, PSUR/PBRER, signal management, and regulatory compliance activities

Aims and Objectives

Prior to the introduction of DSUR and PSUR/PBRR frameworks, pharmaceutical companies encountered challenges due to fragmented regional safety reporting requirements, inconsistent reporting formats, and limited coordination across functions and regulatory regions.

The introduction of harmonized ICH and global regulatory requirements established standardized approaches for cumulative safety evaluation, signal detection, benefit–risk assessment, and periodic reporting timelines. Consequently, departments such as Pharmacovigilance, Regulatory Affairs, Clinical Operations, Quality, and IT had to adapt their processes through enhanced collaboration, integrated safety systems, stronger compliance oversight, and improved global data management.

Reasons to Join

- You receive immediately applicable implementation tips for your institute and department
- You clarify open questions for your department or institute with the speaker
- You receive valuable practical tips through exchange with other practitioners
- To gain updated knowledge on global pharmacovigilance requirements and evolving DSUR/PSUR/PBRR regulations
- To understand current industry best practices for safety reporting, signal management, and benefit–risk evaluation
- To strengthen cross-functional understanding of how regulatory changes impact pharmacovigilance, clinical development, regulatory affairs, and quality processes

Our Speaker



Dr. Joan D'Souza

Chief Medical Officer, Attorney (JD, US), M.Sc- Pharmacovigilance and Pharmacoepidemiology, Switzerland, Germany, US

Dr. Joan D'souza is a seasoned pharmacovigilance and regulatory affairs leader with extensive international experience across clinical development (Phase I-IV) and post-marketing safety in both biotechnology and pharmaceutical environments. She currently serves as Qualified Person for Pharmacovigilance (QPPV) and Regulatory Affairs Lead in Switzerland, Germany, Austria, and Liechtenstein, and supports interactions with major regulatory authorities including EMA, FDA, Swissmedic, BfArM, and MHRA. Dr. D'souza has broad expertise in global pharmacovigilance systems and safety governance, including signal management, aggregate safety reporting (DSUR, PSUR/PBRR), risk management planning, benefit–risk evaluation, safety surveillance, regulatory submissions, inspection readiness, SOP development, and PSMF oversight. Her experience spans the full product lifecycle, from early clinical development through post-marketing activities. With a unique multidisciplinary background that combines a medical degree, U.S. legal qualification, an MSc in Pharmacovigilance and Pharmacoepidemiology, and ongoing doctoral studies, she brings a comprehensive perspective to drug safety, regulatory compliance, and strategic decision-making. As Founder of JD Pharma Services and an active contributor to international pharmacovigilance and regulatory affairs initiatives including educational programmes for underprivileged students, Dr. D'souza has supported global safety and risk management teams, developed training programs, supported GVP/GCP audits/inspections, and advised organizations across multiple therapeutic areas, including oncology, immunology, cardiology, gastroenterology, rare diseases, endocrinology, immunology, dermatology, and neurology. She remains dedicated to advancing patient safety, benefit-risk assessment, and regulatory excellence in complex global healthcare environments.

Recommended Seminars

Beyond the Risk Management Plan

14. Juli 2026, Online-Veranstaltung

Klar, souverän und selbstbewusst

16. und 17. Juli 2026, Online-Veranstaltung

Pharmacovigilance Agreements

28. Juli 2026, Online-Veranstaltung

Leading Through Change and Mindful Transitions

11. August 2026, Online-Veranstaltung

Clinical Project Management – Success Factors, Communication and Leaderships

1. September 2026, Online-Veranstaltung

Was nicht im Risk Management Plan steht

10. November 2026, Online-Veranstaltung

► This and other seminar offers can be found online on our website: www.akademie-heidelberg.de/online-seminare

Further Information

I am happy to answer your questions about this seminar, in-house trainings and our entire program.



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Registration Form

DSUR and PSUR/PBRER

Last Name
First Name
Job Title
Company/Organization
Street Address/No.
Postal Code / City
Phone Number
Email Address
Assistant's Name
Date / Signature

Kindly send your registration to: anmeldung@akademie-heidelberg.de

Date and Time

Friday 4 December 2026

9 a.m. to 4.30 p.m.

Online access from 8:45 a.m.

Seminar code: 26 12 PS712 W

Fee

€ 690,- (plus VAT)

The fee includes access to the seminar as well as the presentation as a PDF file. After the seminar, you will receive a certificate confirming your attendance.

Special fee: € 590,- (plus applicable VAT) for registrations received by June 30, 2026.

General Terms and Conditions

Our general terms and conditions apply (as of 01.01.2010). If you wish, we can send these to you. An English version is available upon request. You can also view our general terms and conditions at any time on our website: www.akademie-heidelberg.de/agb

Procedure

- One day prior to the seminar you will receive an email with a link giving you direct access to the online seminar.
- In order to participate, you do not need to download and install any program. You can dial in directly via Zoom using your internet browser.
- You can ask questions at any time and discuss them with the speakers and other participants via your microphone and camera. Alternatively, you can use the chat to communicate.

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