SAFETY WRITING THROUGH PRODUCT LIFECYCLE

High-quality safety documents which fulfil global regulatory requirements

Asphalion counts with a team of PV medical safety writers with extensive experience in compiling and updating the necessary documents for both Medicinal products and Medical devices

ASPHALION
Knowledge from experience

Medicinal Products

Clinical development phase

Drug Safety Plan

DSUR Development Safety Update Report

Preparation for the marketing authorisation

RMP Risk Management Plan

Post Marketing phase

PSUR/PBRER
Periodic Safety Update Report
Periodic Risk Benefit Evaluation Report

ACO
Addendum to the Clinical Overview
Clinical Expert Statement

Signal detection report

Any Update of RMP

Any other safety report requested by authorities

Medical Devices

Clinical development & preparation for the marketing authorisation

Development → Conformity assessment → Clinical Data → CE certification

CDP Clinical Development Plan

CEP Clinical Evaluation Plan

CER Clinical Evaluation Report

RMP Risk Management Plan/ Risk Evaluation

PMS plan Post Market Surveillance Plan

PMCF plan Post Market Clinical Follow up Plan

Post Marketing phase

CE certification → Post Marketing Phase

PSUR Periodic Safety Update Report

PMS report

PMCF report Post Market Clinical Follow up Report

SSCP Safety Summary and Clinical Procedures (class IIb implantable and class III products)

Any Update of RMP and Plans (PMS/ PMCF plans, CEP….)