ZENTIVA

PHARMACOVIGILANCE POLICY

Pharmacovigilance is a critical and highly regulated activity. Our organization is committed to ensuring compliance with all applicable international and local regulatory requirements. We will facilitate inspections by regulatory authorities and adhere to our corporate quality standards. Independent audits will be conducted based on a defined strategy and a risk-based approach to ensure that our pharmacovigilance activities align with Good Pharmacovigilance Practices (GVP) and other relevant regulations.

Ensuring Quality and Safety of Our Medicines

We maintain the quality and safety of all our products and control these parameters on a regular basis. Every step is traceable and properly recorded to ensure that our medicines are safe for patients. We monitor and review these processes regularly to ensure compliance with all regulations and safety standards.

Effective Pharmacovigilance and Continuous Improvement

We ensure an effective pharmacovigilance system, quality performance indicators and a quality system supporting regular reviews are in place.

We constantly strive for improvements. Our program includes regular feedback and covers comprehensive training for PV experts and any other company personnel who might as a first point of contact for safety data.

Responsible Oversight by Experts

The Pharmacovigilance system is established and maintained by the European Qualified Person responsible for Pharmacovigilance.

Ludmila Filipova
EU QPPV, European Qualified Person responsible for Pharmacovigilance

Jan Skrle
Head of Pharmacovigilance

April 2025