
mediconomics®
manage · research · improve
Pharmacovigilance
STEADILY WORKING ON
THE FUTURE OF HEALTH
Pharmacovigilance
Clinical Research
Regulatory Affairs
Data Management
Product Development
Medical Writing
www.mediconomics.com

We provide guidance and support at every stage

mediconomics®
manage · research · improve

Pharmacovigilance

Pharmacovigilance (PV) legislation was formalised by the EU in 2012 to regulate the detection, management and prevention of adverse reactions to medicines in patients. In line with these changes and to fulfil the obligations of PV, organisations authorised to produce a medicinal product for human use now require the services of a QPPV.

Mediconomics has the required expertise and approval of the EMA to provide your organisation with tailor-made PV solutions, saving you valuable time and expense.

Our services include evaluation of the current PV status (literature research, reporting, PSURs, alarm plans, etc.), implementation of PV systems, EU-conform electronic reporting (XEVPRM, ICSR), compilation of risk management plans (RMPs), training, internal audits and more.

General Oversight:
- Provision of EU-QPPV and/or Deputy
- PSMF creation and maintenance
- Support with PV integration

Operational Support:
- Development of SOPs
- Conduct of PV trainings
- Literature research
- Medical assessment of ICSRs

PV Solutions

Drug Saftey
- EudraVigilance registration
- Generation of narratives for SAEs and SUSARs
- Generation of Risk Management Plans
- Safety Reports

PV Audits
- Conduct of audits (vendors/internal)
- Support during inspections/audits

mediconomics gmbh
Misburger Straße 81 B
30625 Hannover
Germany
Tel. +49 (0) 511 560 998-0
Fax +49 (0) 511 560 998-20
info@mediconomics.com
www.mediconomics.com

mediconomics aps
Slotsbryggen 14 A-D
4800 Nykøbing F
Denmark

mediconomics UK
Spring Farm House
Wallingford Rd
Goring On Thames, Reading RG8 0HR
United Kingdom

mediconomics inc.
4141 1/2 Verdugo Road
Los Angeles CA 90065
USA