



## EXECUTIVE SUMMARY

“A reliable Partner for Global PV”

Outsourcing crucial roles like Stufenplanbeauftragter und EU-QPPV to Xendo allows the customer to focus on developing his product pipeline.

## RESULT

compliant  
documents  
and processes

## RESULT

ideal use of  
internal  
know-how

# XENDO CASE STUDY | GLOBAL PHARMACOVIGILANCE (PV)

## CHALLENGES

- For the application of a marketing authorisation (MAA) of a centralized medicinal product (full application), the customer decided to outsource the complete PV process
- Customer expects the partner to assume responsibility for complete Global PV and aims to establish long-term partnership for future growth

## PROJECT EXECUTION

- Define roadmap based on risk analysis and deadlines to be fulfilled; ensure compliance with GVP and German laws; close cooperation and support of customer RA team; flexible project management to react to ad-hoc issues
- Xendo assumes role of EU-QPPV and deputy as well as German Responsible Person for PV (Stufenplanbeauftragter) and deputy; including communication with European authorities

## ADDED VALUE

- Access to Xendo's PV experience including global processes, e.g. signal detection, PSMF, RMP, PSUR and global PV partner network
- By relying on Xendo's comprehensive experience in Global PV for compliance with GVP and German laws, the customer could focus on developing his business for its first proprietary authorised medicinal product