

Type:
Pharmaco-
vigilance

Geography:
European Union

Service Type:
FSP

Client:
Pharma

SERVICE TITLE:

“EU-QPPV service”

Service Challenges:

- MAHs SOPs and systems apply
- Several internal Client departments involved
- Participation in/keeping in loop of Client governance bodies
- Communication channel with MAH Management Board
- Stakeholder management
- Excelya project management

Benefits for the Client

- Strengthening of MAH procedures by incorporating Excelya experience
- Receive up-to-date information and insight, through the variable Excelya – Regulators interactions
- On-budget
- Ensuring service continuity

Excelya Solution:

- Project manager as contact point for oversight
- KPI monitoring for EU-QPPV activities
- Management Committee and Steering Committee meetings
- Participation of EU-QPPV in PV Quality Council, Benefit-Risk Board, Recall Committee etc.
- Periodic meetings with MAH LCPPVs (Local Contact Persons for PV)
- Review MAH SOPs and provide input
- Excelya EU-QPPVs board meetings to share knowledge and streamline solutions across projects