

Type:
Pharmaco-
vigilance

Geography:
Global

Service Type:
FSP

Client:
Top 20 pharma

PROJECT TITLE:

“Reduction of PSURs and PVAs”

Project Challenges:

- Client SOPs and systems apply
- Several internal Client departments involved
- PSURs (PBRER format) to meet global requirements and timelines
- PVAs with numerous global partners with constant update needs
- Stakeholder management included (internal and external)
- Excelya project management

Excelya Solutions:

- Project manager and deputy as single contact points for oversight and communication
- Flexible team to adapt to workload
- 8 Excelyates (experts) in project team
- Management Committee and Steering Committee meetings
- KPI monitoring for both PSUR/PVAs

Benefits for the Client

- Excellence in PV audits and no findings from regulatory PV inspections
- On-budget

Key metrics

Project agreement renewed twice

Only **minor** Findings in PV audit

8 Excelya team members

Feedback from Client

- Investigating to contract also DSUR/RMP reduction