



SMART SOLUTIONS

Mastering Due Diligence & achieving Success in Vendor Outsourcing

Presented by

Dr Shripadaraja R - CEO

GPLACO Solutions



SMART SOLUTIONS

What and how much to present?



Most common questions

- ❖ How to identify and shortlist vendors for outsourcing?
- ❖ What should be the framework and duration?
- ❖ How to implement an effective and robust QMS?
- ❖ What should be the KPIs and how to decide them for:
 - CROs, BPOs, Consulting firms, Importers/distributors?
 - MAH - Subsidiaries/affiliates?
- ❖ What are the best databases/tools/applications?
- ❖ What should be the BCP?
- ❖ How to manage and improve the vendors performance?



Most clients look for:

- Organisational culture & leadership
 - Reputation and track record
 - Quality management system (QMS)
 - Areas of expertise and capabilities
 - Infrastructure and Technology
 - Customer engagement & service coverage
-

THE KEY DECISION FACTORS!!



PV outsourced activities:

- ICSRs monitoring and processing
 - Literature surveillance
 - Aggregate reporting – DSUR/PSUR/PBRER/PADER
 - Signal detection & management
 - Risk management activities
 - Quality Assurance (QA)
 - Training process
-

**WELL ORGANISED PROCESSES,
POLICIES, PROCEDURES AND
DOCUMENTS ARE THE KEY!!**



ICSRs monitoring and processing:

- ❑ Clear and detailed standard operating procedures (SOPs) and work instructions (WIs) forms the core and integral part of due diligence which defines the process and structure of the organisation.
- ❑ All the SOPs, policies, procedures and WIs shows how organised is your processes and procedures.
- ❑ Effective workflow process and operations demonstrates the volume handled by the resources and delivery timelines
- ❑ Display the documents in general and not “project specific” comparing the other clients processes.



Literature surveillance:

- ❑ Detailed standard operating procedures (SOPs) and work instructions (WIs) on the literature search and review process and procedures.
- ❑ Workflow process and operations demonstrating the volume handled by the resources and delivery timelines.
- ❑ Databases, frequency and quality of the process in detail to be highlighted.



Aggregate reporting:

- ❑ Detailed standard operating procedures (SOPs) and work instructions (WIs) gives an idea and about the process and procedure.
- ❑ Workflow process and operations to demonstrate the volume handled by the resources and delivery timelines. Separate reference documents and WIs for different reports:
 - DSUR/PSUR/PBRER/PADER
- ❑ Schedule, DLP, preparation, tools and submission in detail must be highlighted.



Signal detection & management:

- ❑ Detailed standard operating procedures (SOPs) and work instructions (WIs) gives an idea and about the process and procedure.
- ❑ Workflow process and operations to demonstrate the volume handled by the resources and delivery timelines.
- ❑ Signal methodology, preparation, tools and review board in detail must be highlighted.



Risk management activity:

- ❑ Detailed standard operating procedures (SOPs) and work instructions (WIs) gives an idea and about the process and procedure.
- ❑ Workflow process and operations to demonstrate the volume handled by the resources and delivery timelines.
- ❑ Schedule, DLP, preparation, tools and submission in detail must be highlighted.



Quality assurance (QA):

- ❑ One of the most important and significant check point for any project. The process of internal monitoring must be explicit and well established with related metrics.
- ❑ The following must be implemented: Key performance Indicators (KPI), Key Risk Indicators (KRIs), Key Control Indicators (KCIs), Key Result Areas (KRA), Service Level Agreements (SLA); as appropriate to measure performance and avoid non-compliance/non conformity.
- ❑ Independent QA process to monitor compliance must be in place. This is one of the key determining factor for vendor selection, and outsourcing due to direct business impact, client satisfaction and retention of business.



Training: most important

- Training is one of the most critical part of decision making process for clients and a back bone of any organisation. Most organisations neglect to showcase and not much importance is given during due diligence.
- A robust training process in place assures that the members are professionally trained and qualified to carry out activities and ensure excellent quality.
- Most problems arise due to inadequate and ineffective training which leads to judgmental errors and quality issues. Investing more in training the team, rather than much time improving and fixing would be a better option.



Common noted findings:

- QMS ISO certification (frequently asked)
- Ineffective Quality management system (QMS)
- Inefficient workflow process and management
- Untrained and under qualified professionals
- Under delivered – Quality and productivity targets
- Compliance/Metrics - Not met
- BCP is not up to the mark
- Service coverage not satisfactory
- Budget and cost/price not matched



SMART SOLUTIONS

Factors that influences the client's decision



SOLUTION - 1

- ✓ Clear and detailed organisational chart with hierarchy, verticals & functions, cross-functional departments and resources
- ✓ Quality manual with an effective QMS implementation
- ✓ Highlighting the core competencies, capabilities and therapeutic areas of expertise
- ✓ Qualification, training and knowledge of the team, hands-on experience on specific databases/tools/application
- ✓ Business continuity plan locations with back up and disaster recovery tested results



SOLUTION -2

Some important items to be in your presentation slides:

- ✓ Learning management system (LMS)
- ✓ Document management system (DMS)
- ✓ Quality management system (QMS)
- ✓ Clinical trial management system (CTMS)
- ✓ Electronic data capture (EDC)
- ✓ eCTD management and submission system
- ✓ Safety database
- ✓ Project management tools – workflow & performance reports



Other deciding factors

Each clients have different requirements and preferences. They may look at different aspects based on their convenience:

- ✓ Geographical location and outreach
- ✓ Native language
- ✓ Data security and confidentiality
- ✓ Budget and ease of business
- ✓ Financial Stability
- ✓ Insurance and liability
- ✓ References and Client Feedback



Accomplishments:

Consulted and advised over 20+ clients globally for the US & EU processes and achieved high quality and compliance on:

- ICSR (2M+ cases processed and reported)
- 150+ aggregate reports
- 100+ Signal detection and management reports
- 90+ execution of global PV audits
- 14 Due diligence for outsourcing PV operations



Results:

This is how we supported and helped global clients with:

- Successful due diligence process for PV & QA outsourcing
- Set-up of global PV operations for affiliates in 13 countries
- Global audit strategy and Risk management for an MAH
- Selection of vendors, performance and delivery management
- Customization of safety databases, testing and implementation
- Pain areas resolution – Quality, productivity and compliance



How to ace due diligence?

Attend the “2hours” workshop on preparing a high-impact presentation. The discussion will cover the following :

- ✓ What are the important documents to be in the QMS?
- ✓ How to implement an effective QMS?
- ✓ What should be the risk assessment and audit strategy?
- ✓ How to decide on budget, resources and operations?
- ✓ How to assure the Business impact and the contingency plan?
- ✓ How to decide on the parameters on performance indicators for CRO, BPO and Consulting firms?



Target audience

Small and medium sized:

- **Pharma and biotech companies**
- **Sponsors, CROs & Consulting firms**

Designations:

- **QPPV and Deputy QPPV**
- **VP, Senior directors and Directors – PV & QA**
- **VP, Senior directors and Directors - Marketing & BD**
- **Senior managers & Managers – PV & QA**



SMART SOLUTIONS

Quarterly scheduled sessions

- Conducted from 6.30 to 8.30 PM IST (Online–remote)

To register and for any questions/clarifications related to the workshop:

Email – Client@globalplacosolutions.com

Registered companies will be provided with the login details by email.



SMART SOLUTIONS

How can we help you?

Connect with us:

**To prepare or perform a thorough due diligence for
Outsourcing:**

www.Globalplacosolutions.com



SMART SOLUTIONS

Thank you!!