

FRONT END BACK END SERVICE MODEL

IS YOUR COMPANY AFFECTED
BY GEOPOLITICAL CIRCUMSTANCES?
DO YOU NEED TO ENSURE GXP
PROJECTS' CONTINUITY?

When on-site visits are not practical or hindered a front-end | back-end organization becomes effective in terms of risks and benefit.

Two teams working in parallel

- 1 — Front end:** small task force of local consultants on site. Focus on data collection and testing activities
- 2 — Back end:** big teams of international consultants, experts and SMEs. Focus on documents creation, review and compiling

SERVICE FEATURES:



High tech support with live streaming
From Consultants & Auditors



Night shift with remote support
from countries on different time zones



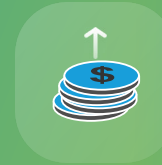
Multi countries organization
with local presences worldwide



Front/Back end planning of activities



Remote control option
testing and data gathering through remote connection



Cost effectiveness
(minimum/zero international travel expenses required)

APPLICABLE TO:

- GMP Compliance Activities**
CAPA Plans execution, post & pre inspection readiness
- Validation & Qualification Projects**
- Audits & Assessment**
- QMS Projects & Quality Control Services**

CASE STUDY

FRONT-END | BACK-END STRATEGY FOR GxP PROJECTS

(Below example belongs to a typical CSV Remediation Project however the concept is applicable, with different milestones, to all GxP Projects of Compliance, Qualification, IT and QMS)

MILESTONES	PQE ON-SITE	PQE OFF-SITE	PQE Activity Description	Effort of Site People
Methodology Definition			Definition of documents format, methodology of testing, project organization Can be either onsite or remotely executed (TC)	Project Leader, QA & Collaborators → 2-3 h (overall)
GAPs Solving (Configuration & Protection)			On-site support to site personnel for GAPs solving (PQE IT professionals and Validation experts)	Technical gaps closure is mostly performed by PQE but site IT and admin persone provide accounts and permissions: • Local IT officer → 0,5-1 days per system • Local System Administrator → Up to 0,5 days per system
Data Collection			Collecting data to write documents and protocols: • ON-Site task force (1 to 4 people) • To be executed in parallel with step 2	• Local IT officer → 1 h per system • Local System Administrator → 1 h per system • Local Key User → 1-2 h per system
Documents Creation, Review and Approval			Large group of people digesting the collected data and writing the documents	Site reference people will review and approved the documentation • Project Leader, QA and Department Managers → 1-5 days (overall) Effort of the review can be greatly reduce organizing a 1-2 days workshop driven by PQE
Testing and Collecting (On-Site) And Document Compiling (Off-Site)			2 teams working in parallel: • ON-Site task force (1 to 4 people) • Large group of people supporting evidence gathering, digesting and documents compiling	Support testing activities: • Local IT officer → 0,5 h per system • Local System Administrator → 0,5 h per system • Validation officer (assistant for PQE testers) → 1-2 days per system • Local Key User → 1-3 h per system (real analysis)
Documentation Delivery			Documentation Delivery to the sites including review and approval of results	Reference people will review the testing results and approve the Validation Report hence releasing the systems → 1-5 days Effort of the review can be greatly reduce organizing a 1-2 days workshop driven by PQE