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)

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

<table>
<thead>
<tr>
<th>Methodology Definition</th>
<th>GxP Solving (Configuration &amp; Protection)</th>
<th>Data Collection</th>
<th>Documents Creation, Review and Approval</th>
<th>Testing and Collecting (On-Site) And Document Compiling (Off-Site)</th>
<th>Documentation Delivery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definition of documents format, methodology of testing, project organization</td>
<td>On-site support to site personnel for GxP projects (IT professionals and technical experts)</td>
<td>Collecting, editing documents and evidence</td>
<td>Large group of people digesting the collected data and writing the documents</td>
<td>Stream working is possible</td>
<td>Documentation Delivery to the site including review and approval of results</td>
</tr>
</tbody>
</table>

Effort of Site People

- Project Leader, QA & Collaboration: 1 - 3 days per system
- Technical gap closure is mostly performed by PQE but it is vital to prepare project managers and technicians
- Local IT officer: up to 1 day per system
- Local System Administrator: up to 1 day per system
- Local Key User: up to 1 day per system
- Site reference people will review and approve the documentation
- Project Leader, QA and Department: 1 - 3 days per system
- Effort of the review can be greatly reduced organizing a 1-2 days workshop driven by PQE

Support site audits
- Local IT officer: up to 1 day per system
- Local System Administrator: up to 1 day per system
- Local Key User: up to 1 day per system

Reference people will review the testing results and approve the Validation Report hence releasing the system. 6 days RPO (RPO is the maximum) if a review can be greatly reduced organizing a 1-2 days workshop driven by PQE.