

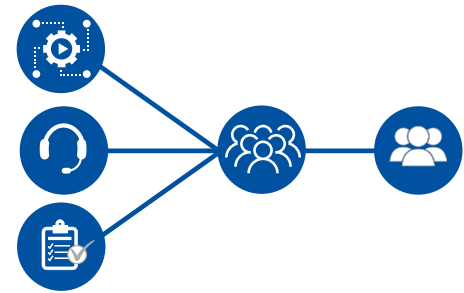


AVATAR

WE TAKE CARE OF IT

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

When site visits are impractical or hampered, our Frontend/Backend Service Model is very effective in terms of risk benefit.



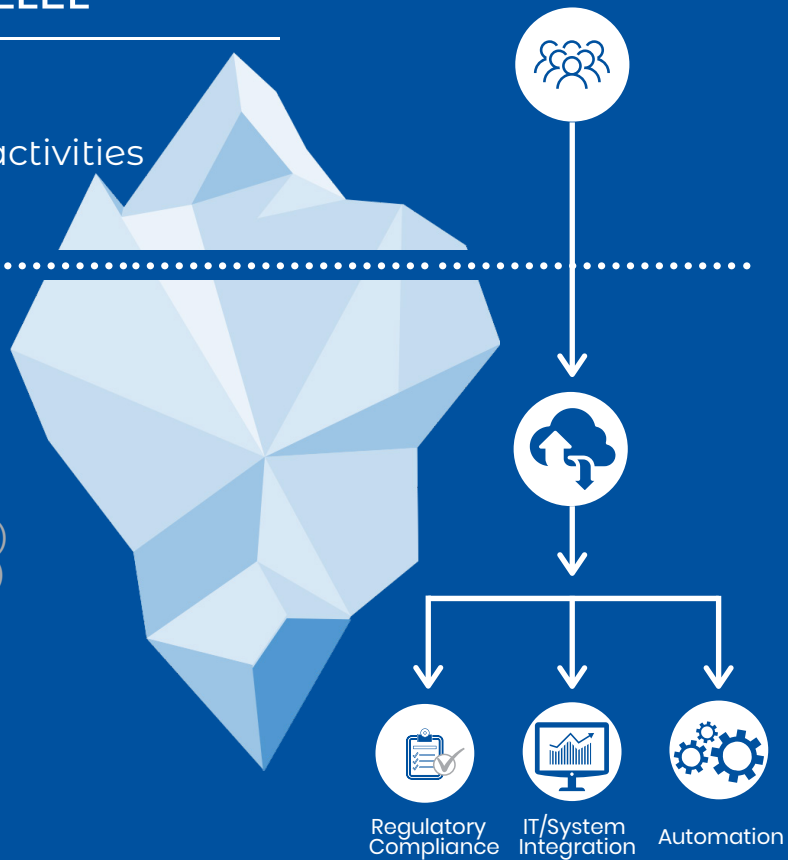
TWO TEAMS WORKING IN PARALLEL

Frontend

- Focused on data collection and testing activities
- Small group of local consultants on site

Backend

- Large group of international consultants, experts and SMEs
- Focused on creating, reviewing, and compiling documents
- ✓ Regulatory Compliance activities (cGMPs) (Qualification/Validation/Execution/CAPA)
- ✓ Audits and Evaluations
- ✓ QMS and Quality Control Services
- ✓ 21 CFR Part 11 / 21 CFR 820
- ✓ EU-MDR
- ✓ ISO 13485 / ISO 14921
- ✓ Data Integrity
- ✓ Quality Risk Management



SPECIAL FEATURES

- Support of the highest technology with live transmission of Consultants and Auditors
- Night Shifts with remote support (USA & PR) covering different time zones
- A Multi-Site Organization with Local and Global Presence
- Frontend/Backend approach when planning activities Offline Testing and Data Collection through remote Connections
- Zero Travel Expense Profitability (No travel necessary when working remotely)

PAST PERFORMANCE

- Parenteral Facilities Instrumentation & Controls
- BOHLE HMI Programming
- QRM - Quality and Risk Management
- MES/HMI 7x 24 Support Outsource
- Data Integrity Remediation
- DHL Line HMI Programming & Troubleshooting

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