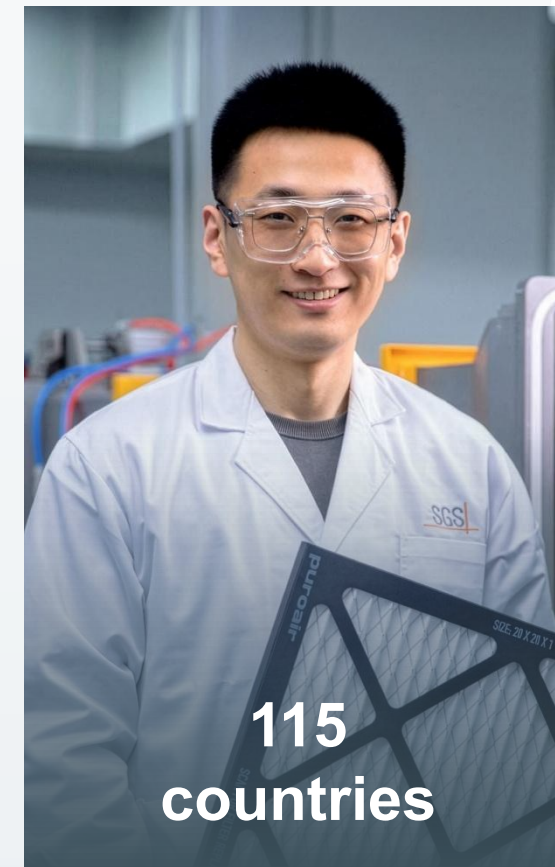
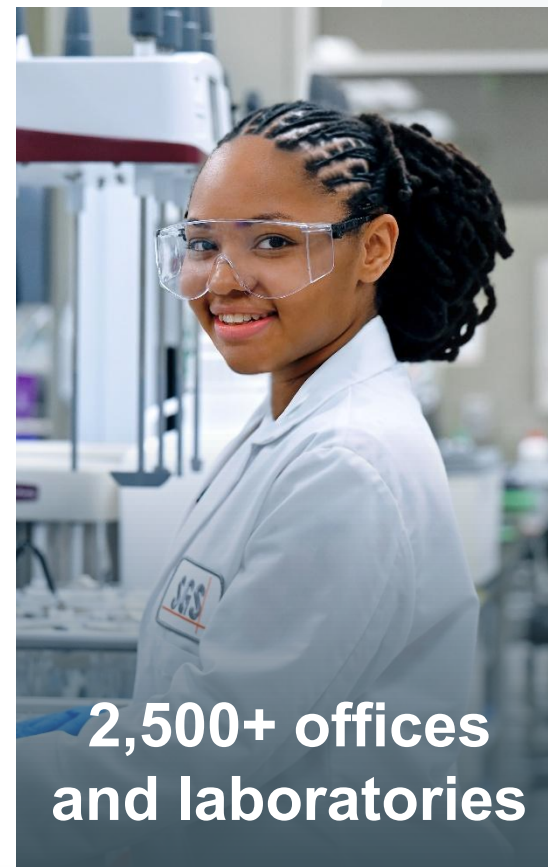
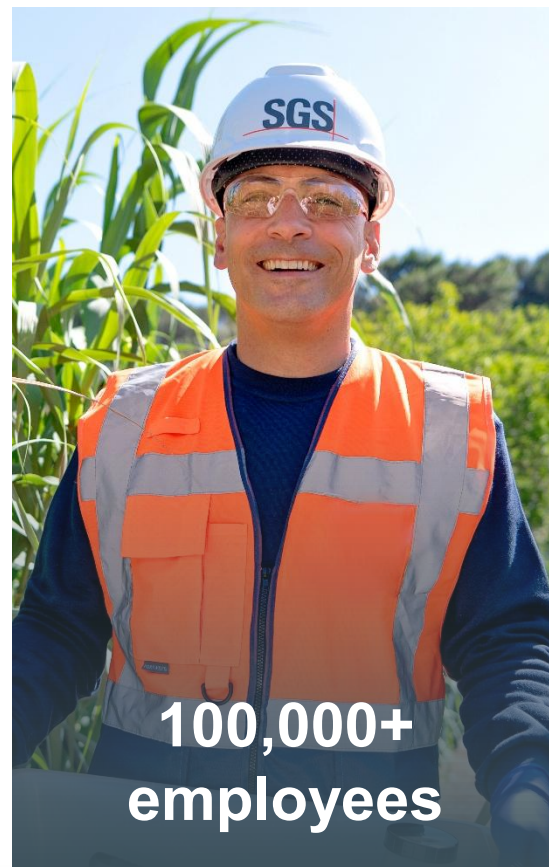


Integrated Services for the Pharmaceutical Industry

Supporting compliance, quality, and operational performance across the asset lifecycle

Client Presentation | 2026

SGS is the world's leader in testing, inspection and certification



SGS is the point of reference “when you need to be sure”

Global presence, local expertise

North America

13% of total sales
270 laboratories and business facilities
8,100 employees

Europe

33% of total sales
921 laboratories and business facilities
22,163 employees

Asia Pacific

34% of total sales
553 laboratories and business facilities
40,416 employees

Latin America

9% of total sales
230 laboratories and business facilities
17,162 employees

Eastern Europe, Middle East & Africa

11% of total sales
560 laboratories and business facilities
17,088 employees



Discover our Solutions for the Pharmaceutical Industry

From Project Delivery to Operational Performance

SGS supports pharmaceutical facilities across the lifecycle, helping manage compliance, quality and speed to market from CAPEX to OPEX

KEY STAKES

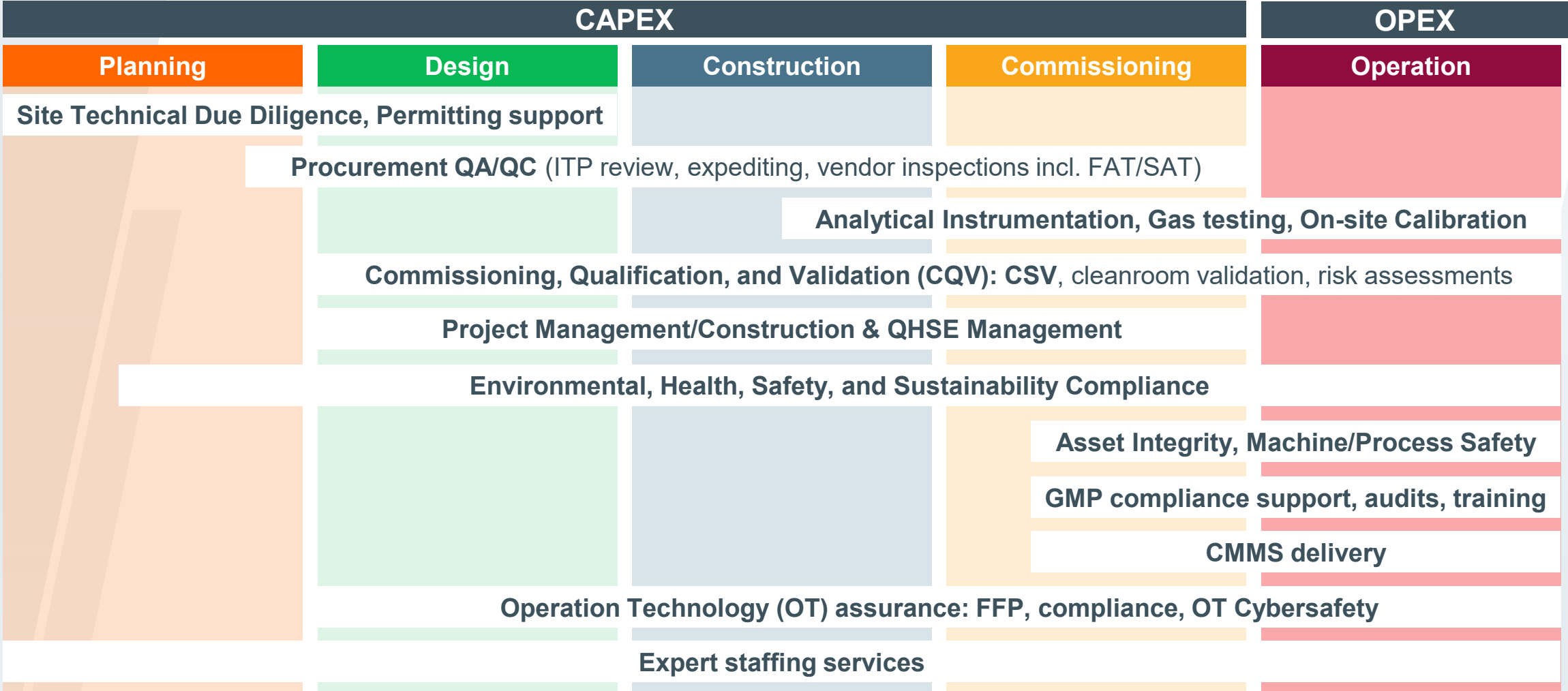
CAPEX

- **Fragmented assets impacting project integration**
Complex equipment, systems, utilities
- **Heavy validation workload delaying go-live**
Complex qualification & validation (DQ/IQ/OQ/PQ)
- **Risk of rework, audit findings & delayed approval**
Gaps between execution, documentation & compliance
- **In-process quality integration (PAT / RTRT)**
Embedding real-time quality control into manufacturing systems
- **High regulatory pressure on design & compliance**
FDA / EMA and global expectations
- **Pressure on timelines & cost overruns**
Need for right-first-time project delivery

OPEX

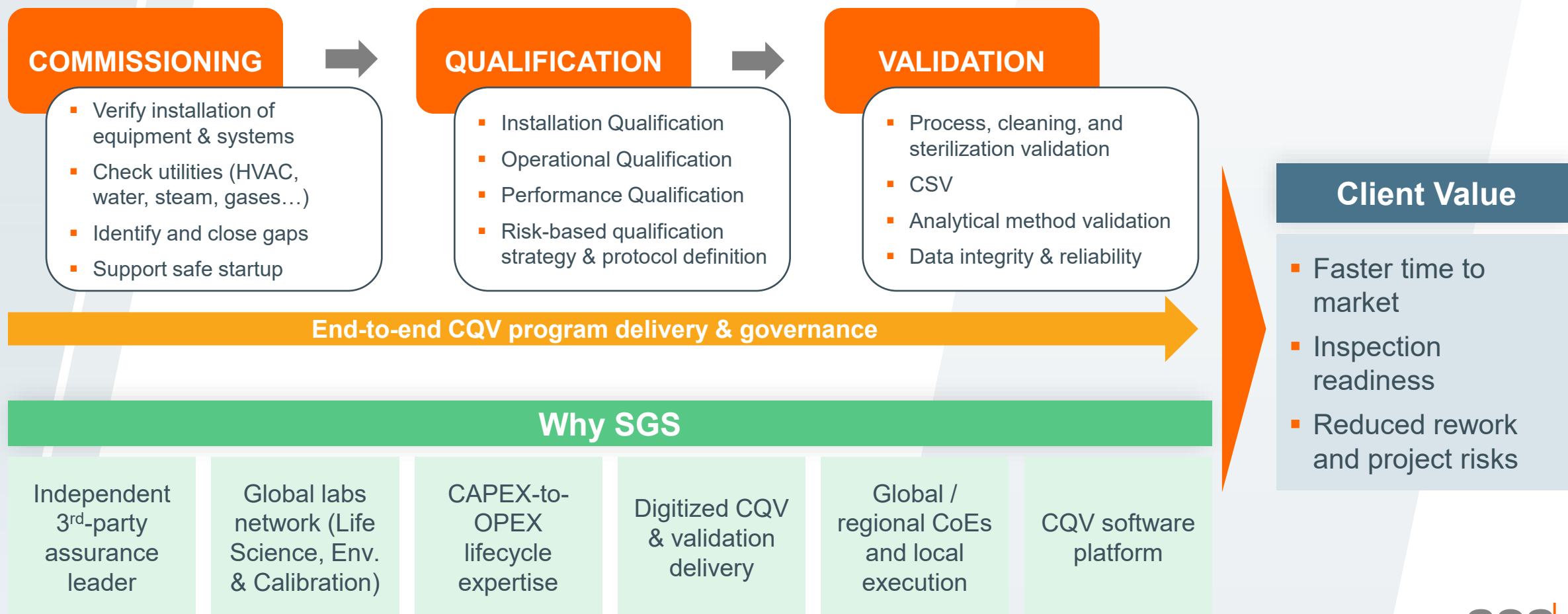
- **Maintaining validated state over time**
Plant, systems & process performance
- **Balancing compliance with operational constraints**
Managing compliance under production & business pressures
- **Shift to in-process & real-time quality monitoring**
From batch testing to continuous quality control
- **High requalification & periodic review burden**
Inspection workload and resource intensity
- **Deviation management & audit readiness**
Proactive risk management and inspection readiness
- **Cost, performance & uptime optimization**
Driving efficiency and continuous improvement

SGS Solutions Across the Pharma Asset Lifecycle



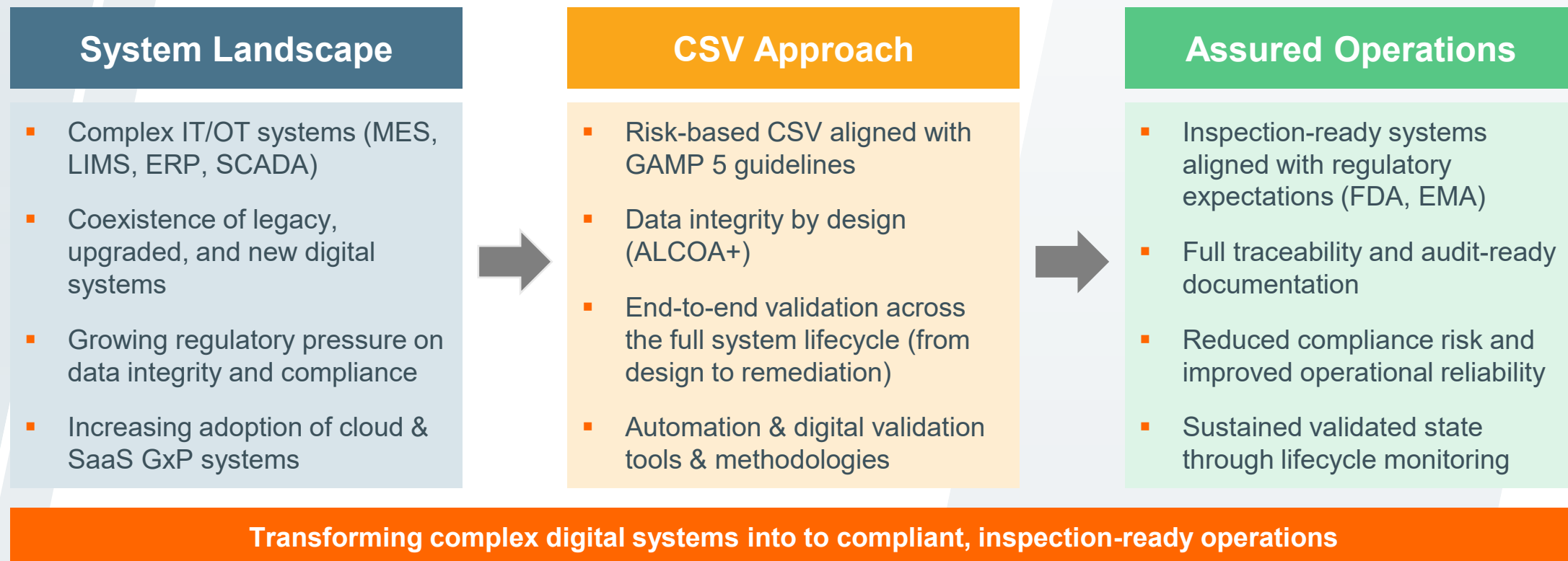
CQV – Commissioning, Qualification & Validation

Accelerating compliant start-up and time-to-market



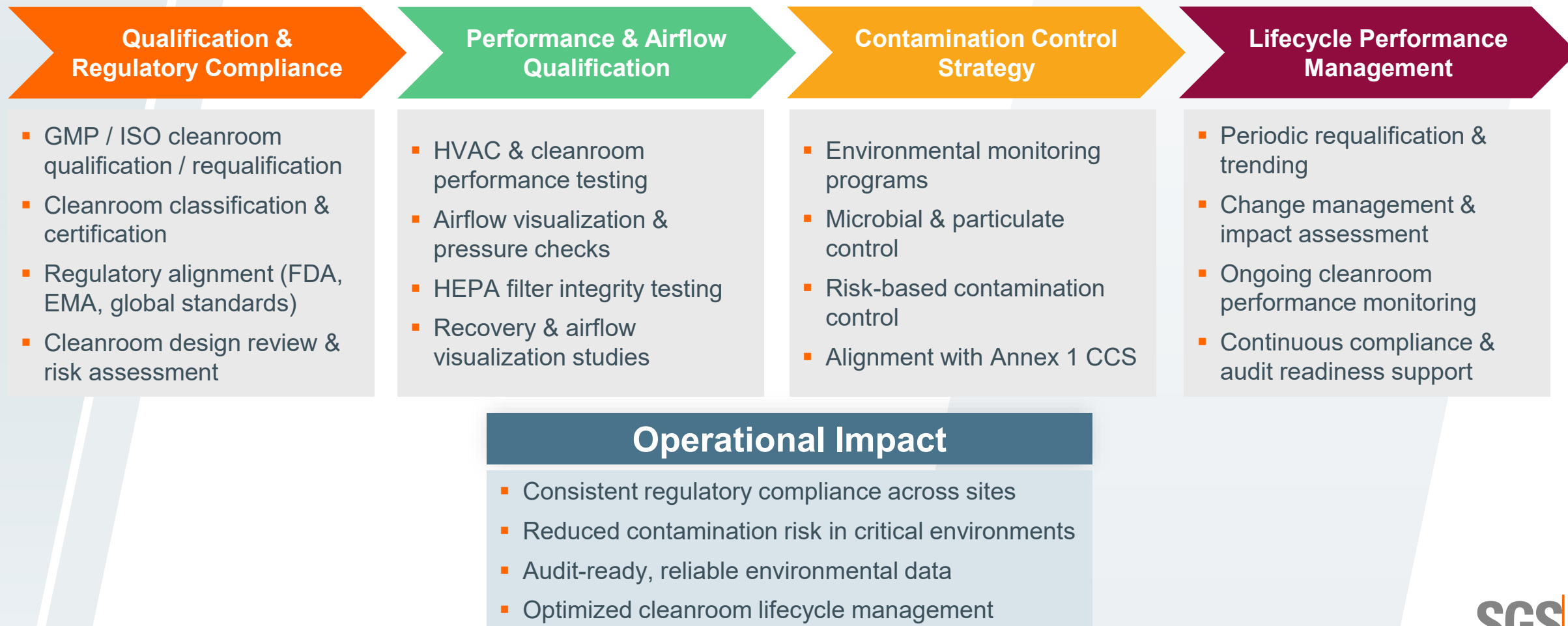
CSV – Computer System Validation

Ensuring data integrity and compliant digital operations



Cleanroom Validation

Ensuring compliant, high-performance cleanroom operations across your global footprint



Calibration & Measurement Assurance

Ensuring data integrity, product quality, and regulatory compliance

CAPEX

- **Calibration strategy & system definition**
(critical instruments & tolerances)
- **Commissioning & initial calibration of instruments**
(factory & site acceptance)
- **Traceability setup & documentation framework**
(GMP / ALCOA+)
- **Integration with CQV & validation strategy**

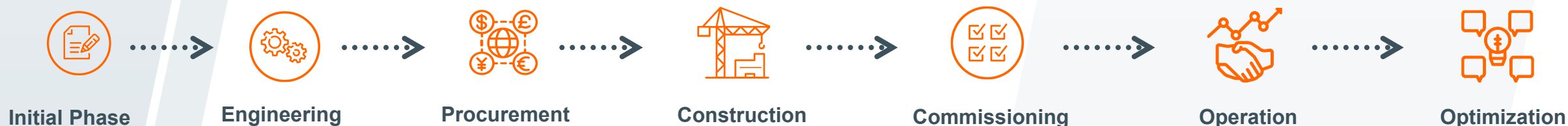
OPEX

- **Routine calibration & recalibration programs**
(GMP-compliant schedules)
- **Asset lifecycle management & performance tracking**
- **Deviation management & out-of-tolerance investigations**
- **Digital calibration platforms & automated data integrity controls**

Data integrity ensured | Audit-ready compliance (GMP/ALCOA+) | Improved product quality | Reduced deviations & risks

Construction support

Ensuring controlled execution and predictable GMP project delivery



SGS Value for CAPEX projects

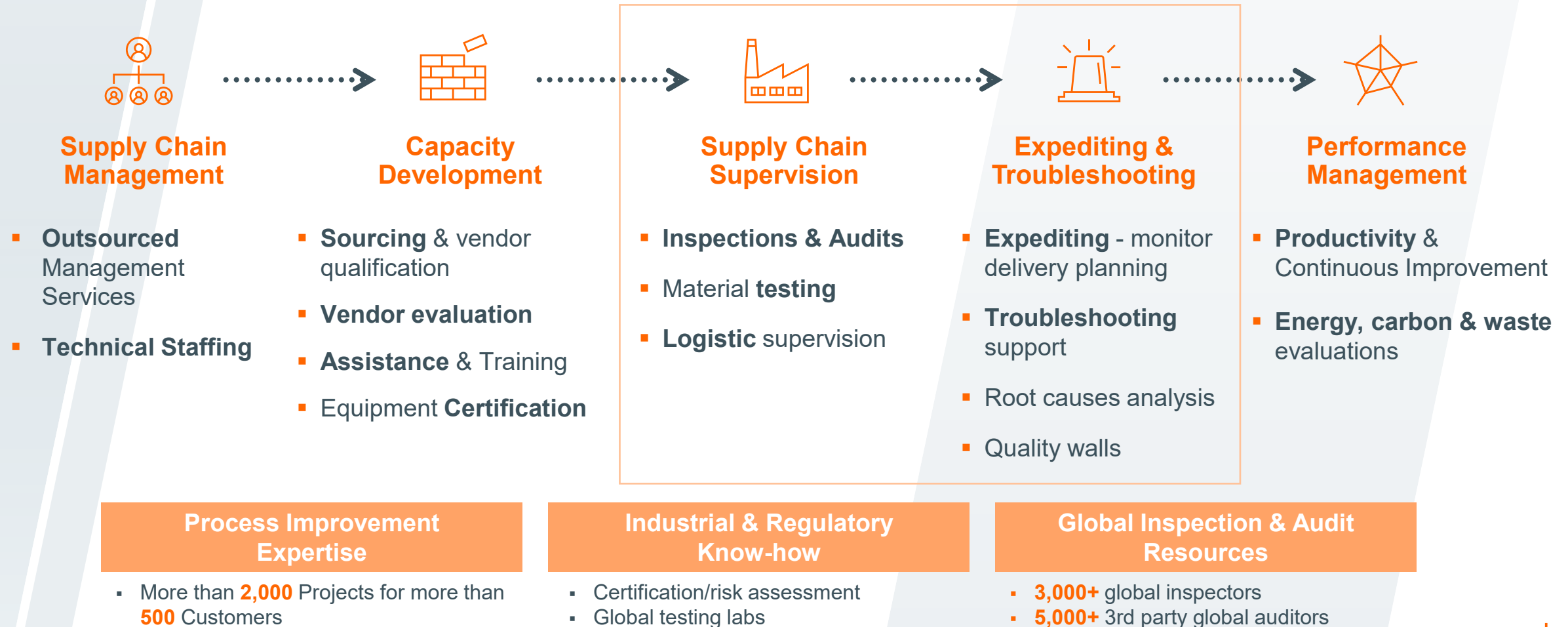
- **End-to-end project assurance**
- **Built-in GMP / GxP compliance** from design to qualification
- **Reduced project risk**, delays and cost overruns
- **Global expertise** with local presence
- **Predictable outcomes** and operational readiness

SGS Key Services

- **Project planning** – regulatory advisory, permitting support, site assessment, due diligence services...
- **Plant & equipment certification** – GMP compliant from design to final acceptance, management of compliance as a project
- **Procurement management** – sourcing support, tender management, supplier audits, inspections and development
- **Project / construction supervision** – planning, QA/QC, EHS, resource and budget management, controlling
- **Commissioning oversight** – final tests and reception
- **OT safety** – design review and system assessment
- **Expert staffing** – multidisciplinary support across all project stages

Supplier Assessments, Inspections, Improvement

Assuring Quality and Reliability Across the Supply Chain



GMP Technical Staffing & Compliance Support

Providing the right expertise, exactly when it's needed

Flexible deployment of GMP-Certified Experts

- Permanent placement & contractors
- Rapid deployment (local & expatriates)
- Payroll and tax compliant services
- Work permits and visas
- Complete in-country logistics support

Global reach & scalability

- 24 recruitment hubs worldwide
- Access to over 250,000 qualified experts



Qualification & Validation

- CQV engineers
- CSV specialists
- Qualification leads

Quality & Compliance

- QA/QC inspectors
- GMP documentation experts
- Audit & inspection readiness specialists

Engineering & Facilities

- Clean utilities engineers
- Cleanroom experts
- Automation & Control specialists

Supplier oversight

- FAT / SAT inspectors
- Expeditors
- Supplier QA specialists

Project & Operations

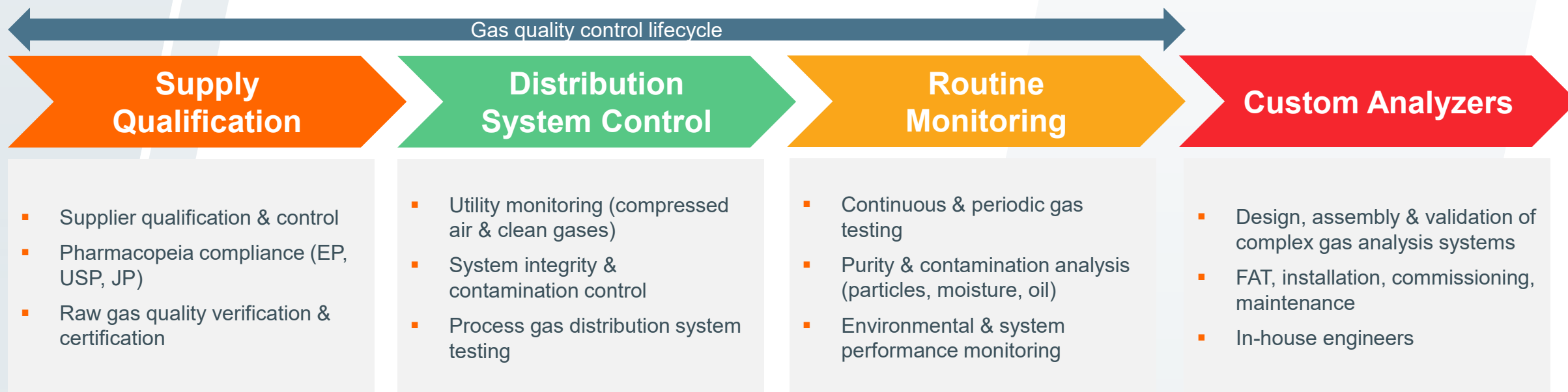
- GMP Project Managers
- Commissioning Managers
- Startup & Q Leads
- Project controls

Analytical Gas Testing

Ensuring gas quality from supplier to point-of-use

GAS

Member of the SGS Group



Controlled gas quality | Full system visibility | Early contamination detection | Audit-ready compliance | Reduced risk

What we test

- Purity & integrity testing of process gas systems
- Raw material analysis & certification of gases for regulated industries
- Process troubleshooting & engineering studies of gas systems

Gases tested

Compressed air, nitrogen, carbon dioxide, oxygen, argon, steam

Standards

USP, EP, JP, EIGA, ISBT, ISO8573, HTM0201, EN285, EudraLex, ISO14644...

Asset Integrity & Safety

Ensuring compliant, reliable, and resilient pharmaceutical asset performance

INTEGRITY MANAGEMENT

- Asset Integrity Programs
- Risk-Based Inspection (RBI)
- Corrosion & Structural Assessment
- Conventional & Advanced NDT
- Fitness-for-Service (FFS) & Remaining Life Assessment

SAFETY & COMPLIANCE

- Mech., Process, Elect., Fire Safety
- ATEX / Hazardous Areas
- GMP & EHS Regulatory Readiness
- Pressure Equipment
- Certification (CE marking, ASME...)

DIGITAL & OPERATIONAL ASSURANCE

- OT Cybersecurity Assessments
- Asset Data & Monitoring
- Digital Inspection & Analytics
- Remote & Advanced Technologies
- Predictive Maintenance & Performance Optimization

Assess → Inspect → Assure → Optimize

Reduced risk & incidents | Extended asset life & reliability | Audit-ready compliance | Optimized maintenance costs

Environmental Services

Managing environmental risk across pharmaceutical assets & operations

Key challenges

EMISSIONS & AIR QUALITY	WATER & EFFLUENTS	SOIL & WASTE	SUSTAINABILITY & ESG
- Stack emissions & air pollutants - Workplace air quality	- Process water & wastewater - Effluent compliance & discharge	- Hazardous & non-hazardous waste - Site contamination risks	- Carbon footprint & resource use - ESG reporting obligations

Monitor → Assess → Comply → Improve

How SGS Supports

Environmental
monitoring & testing

Impact
assessments &
compliance support

Permitting &
reporting

ESG &
sustainability
programs

Reduced environmental risk | Compliance assured | Improved ESG performance | Audit-ready reporting | Sustainable ops

Occupational Health & Industrial Hygiene

Protecting people while enabling safe and compliant pharmaceutical operations

Key challenges

Protecting workers
from APIs & HPAPI
exposure

Verifying
containment
performance

Generating
regulatory-defensible
exposure data

Demonstrating
compliance with
OEL/OEB limits

Managing exposure
risk during scale-up
& tech transfer

What this requires

- Exposure monitoring & Health Risk Assessment
- Containment Verification & SMEPAC Studies
- Occupational Exposure Banding (OEB)
- Exposure data interpretation & reporting
- Compliance Assessment & Program Management

Worker protection | Regulatory Compliance | Defensible data | Operational Continuity | Global Consistency

From Facility Compliance to Product Quality

SGS Industrial & Environment

- CQV/CSV/Facilities
- Cleanroom/Utilities/HVAC
- In process quality integration (PAT/RTTR)
- Digital validation/OT/CSV

SGS Pharma

- Analytical method development, validation & QC release
- Environmental Monitoring & Analytical Data Reliability
- Quality monitoring & Impurity Profiling
- Predictive models & AI-driven Method Development

Combined Proposition Value

- Process performance and analytical methods are co-developed to ensure consistent, measurable and releasable product quality
- Controlled environments enable reliable testing, while analytical monitoring confirms environmental performance and product integrity
- Real-time process data and analytical insights combine to enable deep product understanding and control strategies
- Validated digital systems ensure trusted data, while advanced analytics and AI transform data into predictive quality and process optimization

Reliable process & environment

Data, insights & release decision

Industrial & Analytical Excellence

Product quality emerges from the continuous interaction between manufacturing systems and analytical science

Why Choose SGS for your Pharma solutions?

Global Technical Expertise



- Experts across CQV, CSV, cleanrooms, engineering and GxP systems
- Deep capability in Pharma manufacturing, utilities, equipment and computerized systems
- Strong command of global regulatory frameworks (FDA, EMA, WHO) and compliance standards

Proven Delivery



- Proven track record in complex regulated pharma projects
- Consistent delivery across greenfield, brownfield and shutdown/upgrade projects
- Standardized, audit-ready methodologies with strong governance and validation discipline

Lifecycle Assurance



- End-to-end support from design through qualification, operation and maintenance
- Integrated CQV, CSV and asset integrity ensuring continuous compliance
- Independent verification for quality, compliance and inspection readiness

Global Reach, Local Expertise



- Presence in key global pharma manufacturing hubs
- In-house technical teams with global mobilization capability
- Global mobilization capability for fast deployment on critical projects

Client Confidence



- Trusted partner to global pharma and biotech manufacturers
- Ensures compliance, quality and inspection readiness of critical GMP assets
- Reduces regulatory risk and improves audit performance

—
Thank you!

Do you have any questions?

Contact

Youri Kouniniotis

Global Key Account Manager – Pharmaceuticals

Mobile: +966 54 753 6187

E-mail: youri.kouniniotis@sgs.com



When you need to be sure



Case Studies

Non-Destructive Testing

New Eli Lilly state-of-the-art pharmaceutical manufacturing facility in Alzey, Germany, with a total investment of approx. €2.3 billion and planned commissioning in 2027.

Need/Challenges

- Construction of a large-scale pharmaceutical manufacturing plant under demanding quality & regulatory requirements
- Inspection and verification of critical hygienic and utility piping systems across multiple contractors
- Maintaining installation quality while supporting project schedule and commissioning objectives

SGS Solution

- Non-Destructive Testing (NDT) incl. Visual Testing (VT), Radiographic Testing (RT), and endoscopic inspections
- Continuous welding surveillance and witness inspection of field welding activities
- Verification of welder qualifications, weld samples and installation compliance
- Inspection documentation and quality records management in accordance with project requirements

Impact / Benefits

- Reduced commissioning and validation risk through early identification of installation issues
- Improved piping quality assurance for hygienic and clean utility systems
- Independent quality oversight across multiple contractors and construction activities
- Support for GMP-ready facility delivery through continuous inspection presence and compliance verification

Project snapshot

- €2.3 B investment
- Alzey, Germany
- Pharmaceutical Manufacturing Facility
- Planned commissioning: 2027
- NDT & welding Quality Assurance Services



Gas System Qualification

A leading biopharmaceutical client required support to ensure process gas systems were fully qualified and compliant before manufacturing start-up across multiple gas distribution systems – N₂, O₂, CO₂ and Compressed Air

Need/Challenges

- Validate critical process gas systems prior to manufacturing start-up
- Manage a complex, multi-phase testing and qualification program across multiple gas systems
- Ensure compliance with strict pharmaceutical, cleanroom, and regulatory requirements
- Establish long-term control of critical gas quality and system performance

SGS Solution

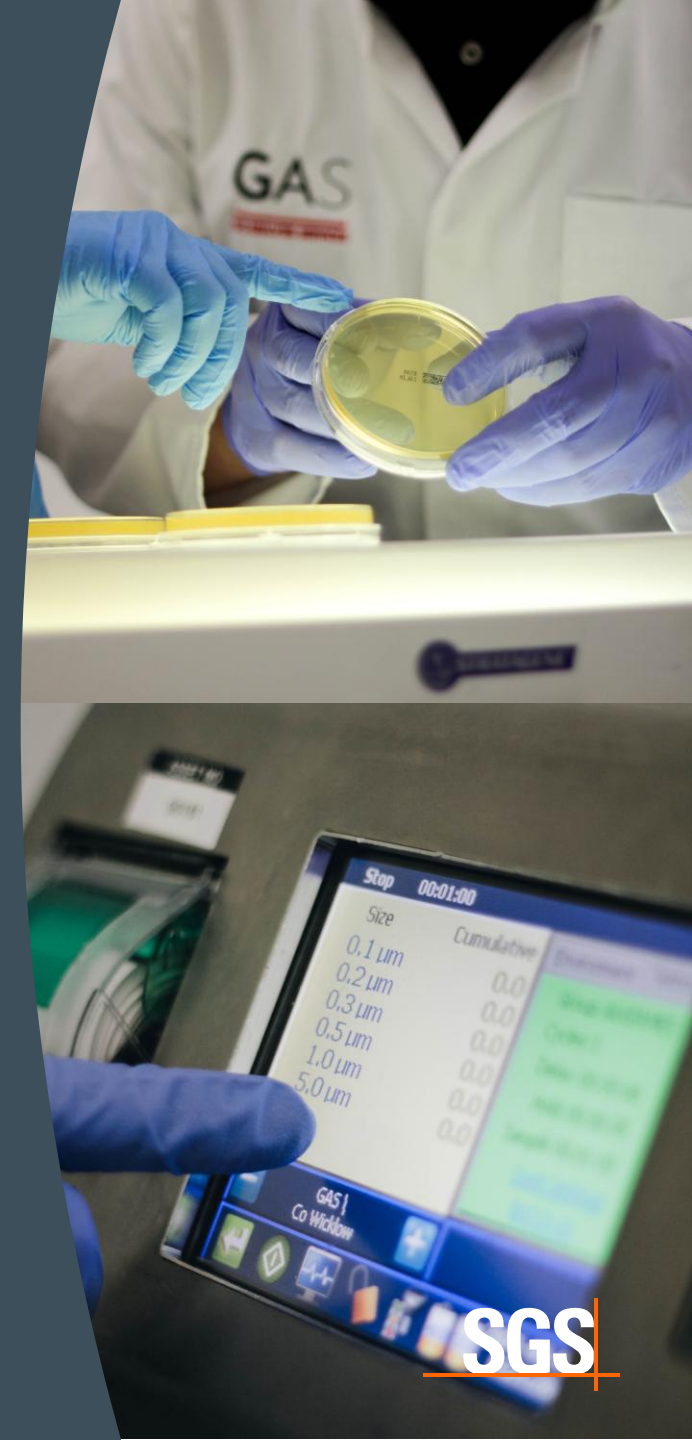
- Delivered end-to-end gas system qualification support from commissioning through routine operations
- Executed IQ/OQ/PQ testing to verify performance, reliability, and compliance
- Performed chemical and particulate testing in accordance with USP and EP requirements
- Verified critical gas quality through raw material certification and testing programs
- Implemented lifecycle monitoring and requalification strategies to maintain validated status

Impact / Benefits

- Achieved fully qualified gas systems ahead of production start-up
- Demonstrated compliance with pharmaceutical and cleanroom standards
- Enabled seamless transition from project commissioning to routine operations
- Established a sustainable lifecycle monitoring program to maintain compliance
- Reduced qualification risk through proven biopharmaceutical expertise and methodologies

Project Outcome

Qualified N₂, O₂, CO₂ and Compressed Air systems delivered on schedule, enabling manufacturing readiness and regulatory compliance prior to production start-up



Inertion Control Systems

SGS designed and validated a continuous oxygen monitoring system integrated with the clients' process controls, improving process safety, product quality, and operational reliability in critical pharmaceutical manufacturing operations.

Need/Challenges

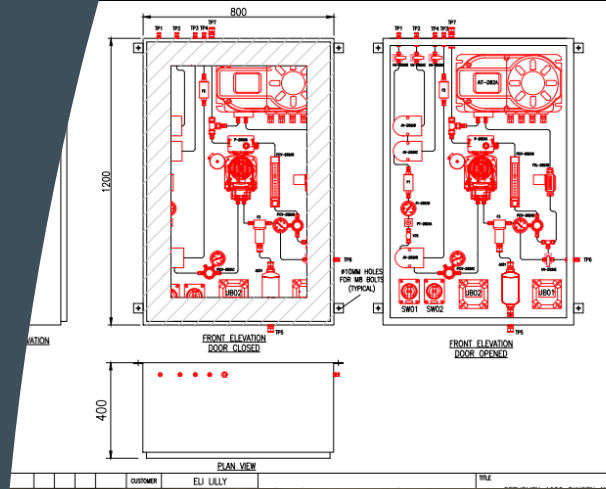
- Control oxygen levels in reactors, centrifuges and dryers during API manufacturing
- Prevent product degradation and contamination risks in sensitive processes
- Improve process safety while ensuring efficient and reliable production
- Achieve continuous monitoring without disrupting operations

SGS Solution

- Engineered a customized continuous oxygen monitoring system for critical process equipment
- Integrated analytical monitoring with existing plant control systems
- Delivered fabrication, installation, validation, and commissioning services
- Provided ongoing calibration, maintenance and lifecycle support

Impact / Benefits

- Improved GMP compliance and process safety through continuous monitoring
- Reduced risk of product degradation, batch rejection and associated costs
- Enhanced reliability and accuracy compared to traditional monitoring approaches
- Lowered maintenance requirements and unplanned downtime
- Increased confidence in critical manufacturing operations



Automation & CSV Support

End-to-end automation and CSV (Computer System Validation) support delivered to MSD Animal Health (New Zealand), enabling secure system modernization, regulatory compliance, and reliable GMP pharmaceutical operations

Need/Challenges

- Full automation lifecycle & CSV support in a GMP-regulated environment
- Modernization of legacy automation and network infrastructure
- Strengthening of cybersecurity architecture
- Compliance with GAMP5 and CFR 21 Part 11
- Maintain uninterrupted batch production during system upgrades

SGS Solution

- Delivered end-to-end automation & CSV services (initiation, design, validation, operations)
- Developed risk assessments and QA/validation documentation
- Authored User Requirement Specifications (URS) and Design Specifications aligned with GAMP5
- Executed IQ/OQ/PQ protocols to ensure compliance with CFR 21 Part 11
- Upgraded network infrastructure from a flat closed network to a secure, integrated architecture
- Migrated from Wonderware SCADA to FactoryTalk View SE, PI Historian, and Win-911

Impact / Benefits

- Strengthened regulatory compliance and validated system integrity
- Improved cybersecurity and system resilience
- Enhanced production data visibility and traceability
- Reduced operational risk during and after transition
- Ensured stable operations and on-time batch completion
- Delivered a scalable, future-ready automation platform aligned with pharmaceutical best practices

CSV for EMS/BMS

SGS delivered full lifecycle Computer System Validation (CSV) for EMS/BMS supporting GMP cleanroom operations in Suzhou, China, ensuring compliance with China & EU GMP, 21 CFR Part 11, and GAMP 5 while strengthening data integrity, environmental control reliability, and audit readiness.

Need/Challenges

- Commissioning of a GMP-regulated facility requiring validated EMS/BMS
- Evaluation of WinCC-based system architecture, integration, and configuration
- Verification of compliance with data integrity and electronic records requirements (21 CFR Part 11)
- Assurance of cleanroom environmental monitoring reliability (temperature, humidity...)
- Full traceability from user requirements to qualification to support regulatory inspections

SGS Solution

- Delivered end-to-end validation lifecycle documentation and execution
 - Risk Assessment (RA) aligned with GAMP 5 principles
 - Design Qualification (DQ) to confirm GMP-compliant system architecture
 - Installation & Operational Qualification (IOPQ)
 - Requirements Traceability Matrix (RTM) ensuring full lifecycle traceability
 - Validation Summary Report (VSR) for regulatory submission readiness

Impact / Benefits

- Achieved full compliance with China GMP, EU GMP, and 21 CFR Part 11
- Strengthened data integrity and electronic records control
- Improved environmental monitoring reliability and facility operational stability
- Reduced validation and compliance risks through structured traceability
- Enhanced readiness for regulatory inspections and customer audits

Cleanroom Validation

SGS delivered end-to-end Cleanroom Validation for a new sterile biopharma facility in Hangzhou, China, ensuring full compliance with China/EU GMP, ISO 14644, and GB standards while securing environmental performance and operational stability.

Need/Challenges

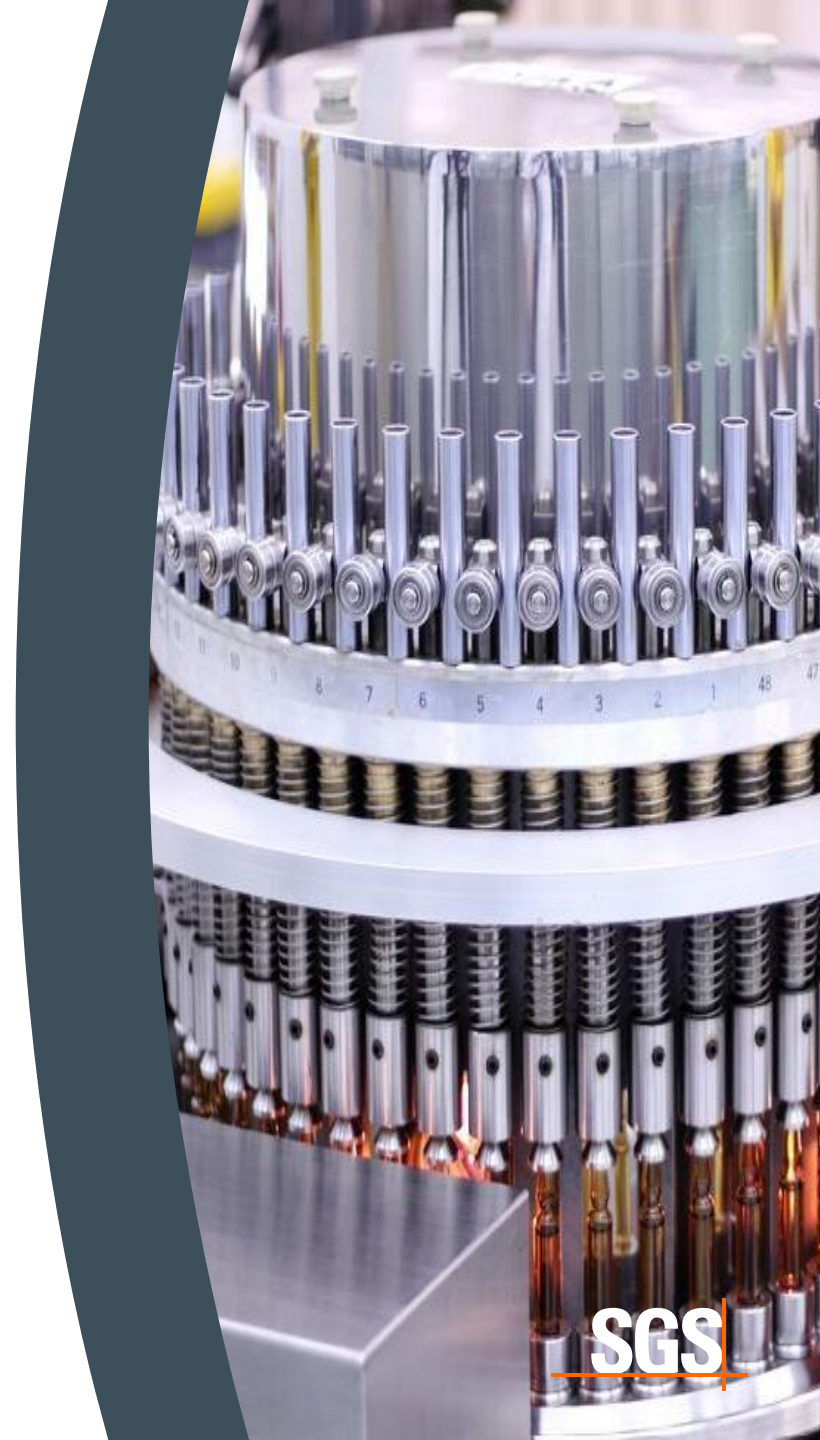
- Commissioning of new sterile production and biopharma laboratory areas
- Qualification of HVAC systems, cleanrooms, and critical utilities
- Verification of environmental performance (particles, microbiological control, humidity, etc.)
- Assessment of static and dynamic operational conditions
- Risk control across physical systems and computerized monitoring components

SGS Solution

- Executed full validation lifecycle including:
 - Validation Plan (VP) and Risk Assessment (RA)
 - Design Qualification (DQ)
 - Factory & Site Acceptance Testing (FAT / SAT)
 - IQ / OQ / PQ execution
 - Requirements Traceability Matrix (RTM)
 - Preventive maintenance and requalification planning

Impact / Benefits

- Achieved compliance with China GMP, EU GMP, ISO 14644, and GB standards
- Verified static and dynamic environmental performance
- Improved cleanliness control and facility operational stability
- Strengthened cross-system risk management (HVAC, utilities, monitoring systems)
- Enhanced regulatory inspection and audit readiness



Inspection & Quality Oversight

Ongoing inspection and quality oversight project supporting Lilly's Suzhou cartridge filling line. Services ensure compliance with GMP regulations and enhance process reliability across multiple water and steam generation systems.

Need/Challenges

- Ensure GMP and EMS compliance across critical water, steam, and PCA systems
- Minimize installation errors and protect materials during assembly
- Build local capabilities for future site projects

SGS Solution

- Performed welding and borescope inspections, piping verification, and installation checks
- Oversaw assembly with dimension, orientation, and in-process control checks for traceability and surface protection
- Witnessed pressure/leak testing, pickling, passivation, and drainability tests
- Conducted raw material inspections and continuous quality oversight via update meetings

Impact / Benefits

- Full compliance with Lilly EMS and GMP regulations
- Improved material traceability, installation quality, and process reliability
- Strengthened local inspection and quality capabilities for future projects



Supervision & Quality Control

SGS provided expert site supervision and welding quality control across multiple Chugai Pharma projects, ensuring GMP compliance and seamless coordination between contractors and vendors.

Need/Challenges

- Lack of specialized welding expertise for critical pharmaceutical piping systems
- Inconsistent quality across multiple subcontractors and fabrication vendors
- Strict GMP, safety, and construction compliance requirements
- High timeline pressure due to phased construction schedules
- Limited internal technical oversight capability

SGS Solution

- Deployed 4 welding specialists and 2 mechanical inspectors (AWS CWI & Japanese welding certified)
- Supervised on-site construction and off-site vendor spool fabrication
- Implement structured quality checks, welding qualification verification, and standardized reporting
- Coordinated vendors to ensure alignment with GMP and project specifications
- Conducted proactive risk assessments and early non-conformance detection
- Delivered knowledge transfer to strengthen client in-house capabilities

Impact / Benefits

- Ensured high-quality welding and full GMP compliance
- Reduced risk of defects, rework, and schedule days
- Improved multi-vendor coordination and construction efficiency
- Increased project transparency through structured documentation
- Strengthened client technical capabilities for future projects



Global Asset Integrity program

SGS has been working with a Global Agri Processing leader for several years, in 25 countries, on an International Asset Integrity Program

Need/Challenges

- Deployment of a global asset integrity program across multiple regions
- Limited internal resources and experts at central and local level
- Need for consistent methodologies and reporting
- Avoid multiplication of international travel and central oversight burden

SGS Solution

- Co-definition of global procedures, RBI and Mechanical Integrity standards aligned with international codes (API 510/570/653) and adapted to client operational risks
- Set-up of a global governance model with local execution teams to deploy services
- Assignment and training of local teams in line with client guidelines
- On-site deployment of integrity services (boilers, tanks, silos, pressure vessels...)
- Central technical supervision and consolidated operational reporting
- Flexible provision of specialized staff based on site needs

Impact / Benefits

- Successful deployment of a harmonized integrity program across countries
- Reduced reliance on central travel and internal resources
- Standardized service delivery across all sites
- Improved asset reliability and risk control
- Flexible access to highly specialized expertise worldwide



Scientific Insourcing

SGS supported a global Pharma leader through a scientific insourcing model, providing skilled QC analysts for method validation, product release, and stability testing

Need/Challenges

- Increasing workload driven by pipeline acceleration
- Stringent GxP and regulatory requirements
- Limited availability of qualified QC talent
- Need for rapid scalability without increasing internal headcount risk

SGS Solution

- Tailored scientific insourcing model integrated within the client's QC organization
- Strategic workforce planning: defined scope aligned with operational priorities & quality standards
- Targeted recruitment: developed customized job profiles and conducted joint candidate interviews
- Fast deployment: first QC team mobilized within 6-8 weeks
- Scalable model: expanded from 8 to 40 FTEs in 12 months
- Fully integrated onsite analysts under client systems & procedures, managed by SGS
- Robust governance: performance oversight, KPIs, continuous improvement, technical supervision

Impact / Benefits

- 6+ year partnership
- Fully integrated, SGS-managed QC workforce
- Scalable and compliant operational model
- High-performing team with strong retention
- Reduced recruitment burden for the client
- Improved operational continuity and delivery reliability
- Continuous value creation through structured governance and results-driven management



GMP-Compliant Calibration services

SGS has been supporting a global Biologics CDMO leader with GMP-compliant Calibration services as part of large-scale biologics CAPEX projects in Singapore, from pre-commissioning through handover to Operations

Need/Challenges

- On-site GMP calibration of critical instruments prior to Commissioning & Qualification (C&Q)
- Tight CAPEX timelines with no tolerance for delays to IQ/OQ activities
- Ensuring data integrity, traceability and audit-ready documentation from Day 1

Scope of Instruments (critical GMP utilities & process equipment)

- Pressure & temperature transmitters and gauges, flow meters and conductivity probes (PW/WFI & utilities), particle counters and chlorine analysers, safety and ultrasonic sensors, peristaltic pumps and critical process instrumentation...)

SGS Solution

- Deployment of a regional, harmonized calibration model to deploy services
- Qualified GMP Calibration teams mobilized from Singapore and China
- Standardized procedures, certificates and documentation aligned with client QA and global stds

Impact / Benefits

- Accelerated commissioning and IQ/OQ execution, supporting on-time facility start-up
- Reduced compliance and validation risk for GMP manufacturing areas
- Immediate audit readiness (FDA / EMA / local authority inspections)
- Improved operator and process safety at start-up
- Optimized CAPEX execution costs through efficient resource deployment
- Clean, documented handover to Ops, enabling smooth transition to routine GMP production



Containment verification | Isolator System

SGS conducted Containment Verification (CV) for an isolator system to support an upgrade to higher containment performance (e.g. $\leq$ OEB 3), ensuring safe handling of potent compounds.

Assessment conducted using SMEPAC-aligned methodology under representative operating conditions.

Need/Challenges

- Upgrade to higher containment performance (e.g. OEB 3)
- Verification of modified engineering controls
- Demonstration of effective operator exposure control
- Requirement for quantitative, SMEPAC-aligned data under tight timelines

SGS Solution

- Testing under representative / worst-case conditions
- Simulation of material handling and transfer tasks
- Air monitoring: PBZ (personal) & area/static
- Surface contamination checks (as applicable)
- Lactose surrogate testing with laboratory analysis

Impact / Benefits

- Achieved required containment performance (e.g. OEB 3)
- Confirmed effectiveness of isolator controls
- Reduced operator exposure risk
- Supported QA / EHS approval
- Audit-ready, defensible results