VALIDATION, CALIBRATION AND QUALIFICATION SERVICES

Since 1998, SGS has provided the pharmaceutical industry with Validation, Calibration and Process & Quality services in accordance with GMP and with the standards set by worldwide Agencies. SGS's experienced team of professionals works closely with the Quality Assurance departments of each client.

The validation activities are performed according to all modern EMA and FDA regulations including a perspective view of effective, integer and professional solution. Thus, we are glad to provide the Greek Market with the following services:

EQUIPMENT VALIDATION SERVICES

- Validation Master Plans review and preparation
- Gap Analysis & Risk / Impact Assessments
- Qualification / Validation (Validation Plans, Design – Installation – Operational and Performance Qualifications)
- Support for the implementation of a Remediation Program
- Equipment commissioning (Factory and Site Acceptance Tests)
- Analytical Lab Instruments

INSTRUMENT CALIBRATION SERVICES

- Metrology Plan review and preparation
- Field instruments calibration
- Reference instruments calibration in our accredited laboratories around Europe

INFORMATION TECHNOLOGY COMPLIANCE AND VALIDATION

- GxP Risk Assessment & Remediation Plan Management
- Computer System Validation (GAMP v.5)
- 21 CFR part 11 Compliance support and verification
- Support for IT Infrastructure Management & IT Networks Qualification

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PROCESS & QUALITY SUPPORT

- Third Party and Supplier's Assessment, Qualification and Auditing
- Remediation Plan Management
- Manufacturing Process Optimization & Validation
- Support on Risk & Gap Analysis
- Cleaning Validation
- Analytical Methods Validation
- Quality Reports and all necessary assessments
- Technology Transfer Support
- Processes and Primary Packaging Validation
- Inspections or Audits preparation
- GMP Support (i.e. CAPA Management)
- Internal Processes Analysis in order to improve efficiency and efficacy of the company
- Personnel training

METHOD DEVELOPMENT & VALIDATION

SGS life science laboratories have extensive knowledge and expertise in developing and validating methods for raw materials, API's, finished products and cleaning validation. SGS offers development and documentation of analytical protocols and reports for proprietary and non-proprietary test methods and manufacturing processes in compliance with the ICH Q2 (R1) guideline "Validation of Analytical Procedures: Text and Methodology" and FDA guidelines. Once a method is validated, it may require transfer. Method transfer may involve comparative testing, co-validation between two sites (Lab-to-Lab), complete or partial revalidation and comprehensive documentation (Transfer Plan, Protocol, Report). Whether SGS is the developing or the receiving laboratory, we can assist you with your method transfer requirements.

DEVELOPMENT:

- Identification
- Assay testing
- Dissolution
- Particle size distribution
- Testing for impurities
- Stability indicating methods
  - Humidity/temperature
  - Temperature
  - pH variation
  - Oxidative and reductive stress
  - Light stressing
  - Microbial testing

VALIDATION:

- Accuracy
- Precision
  - Repeatability
  - Intermediate precision
  - Reproducibility
- Specificity
- Detection limit
- Quantitation limit
- Linearity
- Range
- Robustness
- System suitability test

PHARMA CONSULTING AND QUALITY SERVICES

Through experienced consultants with many years in pharma business (production, APIs, MDFs, Medical Devices, Cosmetics) we form a robust and modern management system for clients' sustainability plan, facility upgrades, market authorization activities and regulatory audits.

- Conceptual Design for Modern GMP Facilities and Labs
- Quality Systems reviews, remediation and outline
- SOPs writing and implementation
- Personnel training
- SMFs, DMFs, Suppliers Support
- Contingency plans
- Machine Selection
- Lean Management
- Site/Line Upgrade
- Manufacturing solutions
- ERP & IT Infrastructure advancement
- TTS projects and WMS support
- GMP consultancy and audit preparation

STY, QUALITY AND ENVIRONMENTAL PROTECTION SUPPORT (SQE)

- Workplace Risk Assessment Report
- Emergency Plan
- Single document on the assessment of risk from interference (DUVRI)
- Risk Assessment of exposure to mechanical vibrations
- Preparation, support and implementation of measures for protection and prevention
- Noise impact assessment
- External Management of Head of the Prevention and Protection Department
- Fire protection and prevention management
- Support for drafting of the explosion protection report
- Taking charge of Work Supervision
- Taking charge of project design and work coordination

ABOUT SGS

With 21 laboratories offering GMP/GLP-compliant contract analytical and bioanalytical services, SGS leverages its wholly-owned global network, present in North America, Europe, and Asia, to deliver harmonized solutions to large pharmaceutical and biotechnology firms. From supporting drug development to performing quality control testing of raw materials and finished products, SGS's laboratory services include analytical chemistry, microbiology, stability studies, biosafety, and protein analysis. SGS also provides clinical trial management (Phase I to IV) and services encompassing data management and statistics, PK/PD modeling and simulation, pharmacovigilance and regulatory consultancy.

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