## **LIFE SCIENCES**

LIFE INSPIRED, QUALITY DRIVEN

# **INSOURCING SOLUTIONS**

SUPPORTING THE INDUSTRY THROUGH SCIENTIFIC STAFFING SOLUTIONS





## INSOURCING SOLUTIONS

As organizations change constantly, there is an increasing need to adopt agile, scalable resourcing models within the life sciences industry. Having a global partner who can support operations through the provision of appropriately skilled resources, within regulated environments allows life science organizations to remain agile, while avoiding fixed costs and long-term liabilities.

#### **DELIVERY MODELS**

SGS has a range of delivery models to provide our clients with the appropriate resources for their project or scientific requirements:

- Fee-for-service: Testing activities carried out at SGS facilities on behalf of the client as per a pricing schedule which we provide for a scope of work
- Outsourced FTEs: Dedicated technical staff working exclusively on client activities within SGS facilities
- Scientific recruitment: Permanent recruitment, executive search, retained search, contract recruitment, local and international payroll solutions
- Insourcing solutions: An insourcing approach where SGS staff work for our clients in their facilities

#### **ABOUT SGS**

SGS is the world's leading inspection, verification, testing and certification company.

We are recognized as the global benchmark for quality and integrity. With almost 89,000 employees, we operate a network of more than 2,600 offices and laboratories around the world.

We offer an agile and responsive solution to help our clients overcome complex challenges, deliver innovative products and achieve efficiencies with:

- 40 years' experience in technical resourcing
- Access to international experts and GMP/GLP trained staff across our harmonized and digitalized network of laboratories throughout North America, Europe and Asia Pacific



## **INSOURCING SOLUTIONS**

A flexible insourcing business model that helps companies to focus on core competencies, improving their overall performance, as well as helping to contain costs by leveraging external management, quality, capability and capacity.

SGS are experts in providing technical, quality professionals and support staff for deployment in GXP, ISO environments within R&D and commercialization, manufacturing functions of biologics, pharmaceutical and medical device companies.

#### **KEY ELEMENTS**

- Assignments from 6 months to permanent
- Minimum 2 FTE's
- Global resourcing, general induction, contract and payroll infrastructure
- Project management and governance
- Technical oversight

### **CORE DISCIPLINES**

- Sample / reference standard management
- Microbiology QC
- Chemistry QC
- Biochemistry QC
- Method development and validation
- Environmental monitoring
- Manufacturing support
- Stability program management
- Regulatory administration and project management











# COMPLETE SUPPORT SERVICES







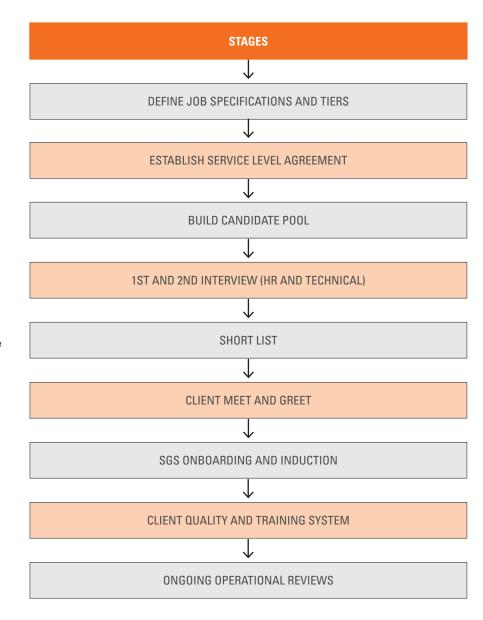


## **DRIVERS FOR INSOURCING**

- Risk mitigation
- Aligning resources to support preapproval phase activities
- Co-employment liability
- Transition from fixed to variable costs
- Transitional activities
- Facilities build and qualification
- Process validation
- Method establishment
- Clinical trials and transient technical projects
- Fixed headcount avoidance
- Downsizing
- Access to capabilities or capacities mid-term
- Mitigate overhead and administrative burden
- Regulatory and legislative compliance

## **WHAT SGS OFFER**

- Global proactive approach and candidate pooling
- Extensive profile database
- Technical recruiting
- Project management, induction and training facilities
- Technical gap analysis and training initiatives
- SLA, performance oversight and governance
- Regular SME engagement and market insight
- The only GXP/ISO service provider with global resource solutions infrastructure
- Unique platform for expedited talent pooling, identification and onboarding
- Governance and continuous improvement
- regulatory support
- Global employment legislation compliance





## INSOURCING CASE STUDY



## **SCENARIO**

A global pharmaceutical client was establishing analytical QC support for new product development. They required a team of QC analysts to perform analysis to support method validation, release and stability.

## **OUR SOLUTION**

- Scope of work agreed with client
- SGS provided candidate profiles and job descriptions for review by the client
- The candidates were shortlisted and interviewed
- The initial team was put in place over 6-8 weeks
- Once selected, the FTE's were placed on SGS payroll
- The team was expanded from 8 to 40 FTE's in one year
- The activities are now ongoing for over 3 years
- Ongoing team performance is managed by SGS within client's quality management and training environment
- SGS delivered performance and technical support to insourced teams
- Regular governance and business review cadence using Key Performance Indicators ensure value is delivered and pre-agreed service levels are achieved



## **VALUE**

- The team resource is on-boarded in industry best timeframes
- The administrative burden on the client is minimized with only on-boarding oversight and ongoing governance engagement required
- Performance and continuous improvement framework implemented
- Flexible terms for adjusting team size



## WHY PARTNER WITH SGS LIFE SCIENCES?

As the world's leading testing, verification and certification company, we offer our clients decades of experience in the field of life sciences. As a result, we are often a preferred partner for the top 20 pharmaceutical and biotechnology companies and perfectly placed to help clients:

- · Get products to market quickly, safely and more accurately
- Adhere to best practices and conform to national and international regulations
- Get vital support throughout every stage of the drug development cycle
- Access one of the largest networks of contract analytical laboratories in the world
- Benefit from expert knowledge of the medical device regulatory environment
- Gain testing and certification solutions for health, beauty and wellness products
- Provide our clients' staff with effective training in the areas of pharmaceutical and medical devices

## **GLOBAL REGULATORY AUTHORITIES** WE WORK WITH INCLUDE:

- FDA (US, China, India)
- EMA / MHRA / FAMHP
- Health Canada
- Swiss Medic
- ANSM
- PDMA

## HARMONIZED QUALITY MANAGEMENT SYSTEMS

SGS complies with the requirements of all global regulatory authorities necessary for approval and operates from GMP / GLP / GCP facilities.

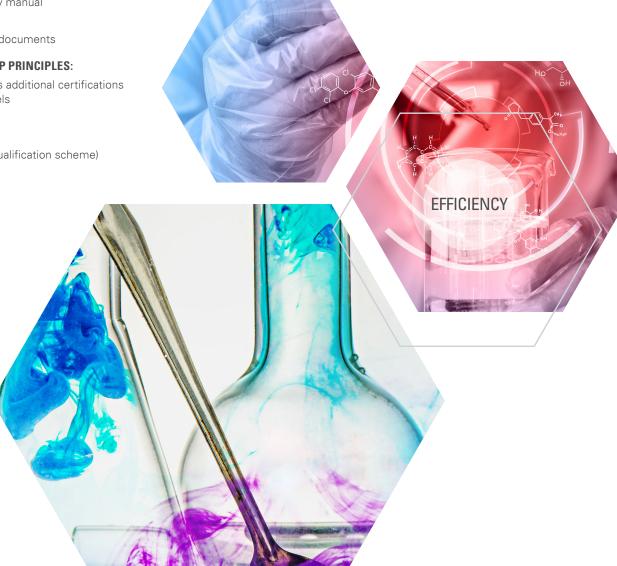
This expertise allows us to support our clients' local and global quality systems and ensure insourced teams are compliant.

#### **OUR 6 LAYER SYSTEM:**

- Global quality manual
- Global policies
- Global SOPs
- Local quality manual
- Local SOPs
- Site quality documents

## **BASED ON GXP PRINCIPLES:**

- Incorporates additional certifications on local levels
- ISO 17025
- ISO 9001
- WHO (prequalification scheme)



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