



# **THE COMPLETE GMP AUDIT SOLUTIONS KIT**

**SGS**

# WITH THE PHARMACEUTICAL SUPPLY CHAIN STRETCHING FROM DEVELOPED TO EMERGING MARKETS TODAY, THE **REGULATORY OBLIGATIONS** FACING ALL THOSE INVOLVED ARE **INCREASING.**

A trusted global partner, who specialises in quality management systems audits and certifications, with a firm base in Good Manufacturing Practices (GMP), and who can handle the volume, complexity and breadth of today's regulatory environment in a globally consistent manner, has never been needed more.

## **COMPLEX REGULATORY LANDSCAPE**

As the pharmaceutical industry continues to grow and developed markets evolve, more and more manufacturing is relocating to emerging markets. Regulatory obligations and guidance on efficacy, quality and safety throughout the entire product life cycle will continue to increase as industry regulatory bodies require drug companies to control and ensure the quality of their entire supply chain.

Considering the distributed nature of today's pharmaceutical supply chain, ensuring quality throughout is an enormous task. Drug companies wishing to conduct GMP auditing of their extended supply chains using their own resources are faced with the sheer complexity and volume of the supplier audits that must be conducted.

In addition, governments in emerging markets are tightening regulations for the pharmaceutical industry in their countries. This brings suppliers more in line with what is accepted as good manufacturing practice in Europe and North America and gives these suppliers

a valuable head start against their competitors as they vie for business from drug companies.

## **A RELIABLE PARTNER**

As the global leader in quality management systems audits and certifications, SGS can help parties across the entire pharmaceutical supply chain manage and improve the quality of their products in a globally consistent, reliable and efficient manner through services and solutions tailored specifically for pharmaceutical quality assurance.

SGS runs the world's largest network of independent auditors of Quality Management Systems that are focused on US Food and Drug Administration and European Commission regulations and directives on GMP and provides outsourced quality assurance and good manufacturing practice services to customers around the world.

Operating a network of offices and laboratories in 135 countries around the world, SGS works as one company globally, providing a single point of

contact for customers, while at the same time understanding and appreciating the cultural and regulatory differences from country to country.

SGS's provides a wide range of GMP solutions for the entire pharmaceutical and bio-tech industries supply chain, including drug manufacturers, suppliers and regulators.

### **EUROPEAN DRUG COMPANY USES SGS TO MONITOR COMPLIANCE IN ASIA**

A European based drug company needed to monitor the compliance of one of their active pharmaceutical ingredients (API) suppliers in Asia. The drug company turned to SGS to verify the actual quality status of the API supplier, which SGS performed during a two-day GMP audit of the supplier against the accepted and harmonised global standard for API manufacturers, ICH Q7A. The drug company was able to use the SGS audit report to their advantage during a standard regulatory agency inspection.

## WHY SGS?

For more than 120 years, SGS has built its brand as the world's leading inspection, verification, and testing and certification company. SGS is the global leader in quality management systems audits and certifications with over 100,000 organisations certified across a wide variety of industry segments.

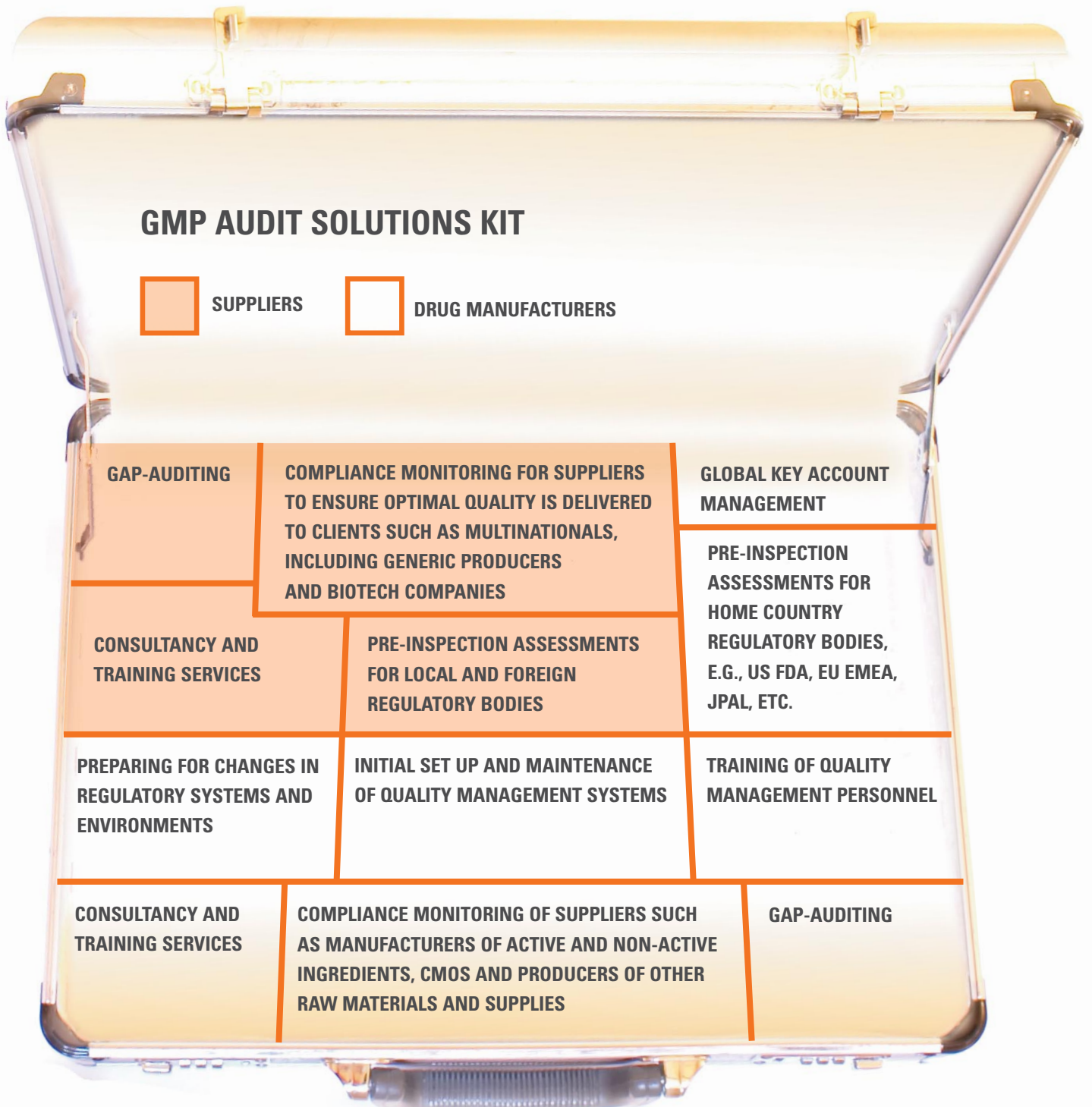
SGS provides a vast array of GMP compliant analytical techniques for the quality control of pharmaceuticals. The combination of strong technical expertise combined with more than 30 years of experience in GMP regulated contract services provides SGS's customers with a unique solution for their needs in pharmaceutical analysis.

The SGS approach is transparent and logical, which is what makes SGS the ideal independent partner to help you in your quest for continuous improvement. Our experts are hand-selected and trained based on their technical expertise as well as their business acumen, and like all SGS employees their objectivity, ethics and confidentiality are beyond reproach.

## FOR MORE INFORMATION

To learn more about SGS's GMP audit solutions, email [gmp-audits@sgs.com](mailto:gmp-audits@sgs.com) or call +41 22 739 9111. An SGS representative would be pleased to speak with you about your company's needs and to propose solutions.

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