QUALITY

COMPLIANCE

COMPETITIVE ADVANTAGE

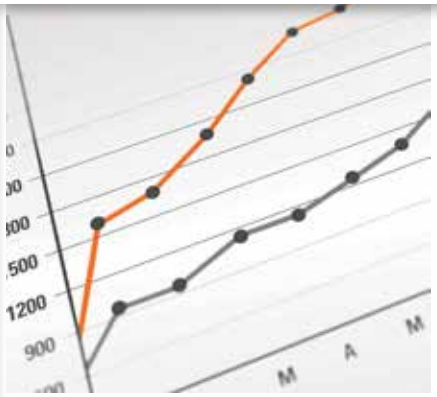
SUSTAINABILITY

FURTHER EXCELLENCE

SUPPLIER MANAGEMENT

RISK MANAGEMENT

TRACEABILITY



BUSINESS CONTINUITY

HOW CAN YOU EFFECTIVELY MANAGE QUALITY AND SAFETY THROUGHOUT YOUR SUPPLY CHAIN?

PHARMACEUTICAL AUDIT, CERTIFICATION AND TRAINING SOLUTIONS

SGS

EFFECTIVELY MANAGE AND CONTINUOUSLY IMPROVE YOUR PHARMACEUTICAL SUPPLY CHAIN

With today's pharmaceutical supply chains stretching from developed to emerging markets, confidence in quality and safety management and adherence to regulatory obligations is critical to the end product as well as to the reputation of the organisations involved.

A trusted global partner, who provides a comprehensive set of solutions that touch all parts of the pharmaceutical supply chain providing expertise in quality and safety management, Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP) has never been needed more. SGS delivers audits, certification and training solutions across a global network, giving you the knowledge to decipher the complexity and breadth of today's regulatory environment in a consistent manner.

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 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 and safety throughout is an enormous task. Drug companies conducting GMP and GDP audits of their extended supply chains are faced with the sheer complexity and volume of the supplier audits that must be performed.

SGS DECIPHERS REGULATORY OBLIGATIONS AND PROVIDES GUIDANCE ON THE EFFICACY, QUALITY AND SAFETY OF PHARMACEUTICAL SUPPLY CHAINS.

A RELIABLE PARTNER

As the global leader in quality management audits and certifications, SGS helps parties across the entire pharmaceutical supply chain to manage and improve the quality of their products in a globally consistent, reliable, and efficient manner.

SGS runs the world's largest network of independent auditors that are focused on US Food and Drug Administration (FDA), European Commission directives and regulations through the European Medicines Agency (EMA), and provides outsourced GMP and GDP audits and certifications to customers around the world.

Operating a global network of offices and laboratories, SGS works as one worldwide company, 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 provides a wide range of audit, certification and training solutions for the entire pharmaceutical supply chain, including finished dosage manufacturers, their suppliers of raw materials and (non-) active ingredients, primary packaging materials, and also third party logistics providers.

EUROPEAN DRUG COMPANY RELIES ON SGS TO MONITOR COMPLIANCE IN ASIA

A European based pharmaceutical multinational needed to monitor the compliance of their active pharmaceutical ingredient (API) suppliers in Asia. The company turned to SGS to verify the actual quality status of their API supplier base, which SGS performed during GMP third party audits of all suppliers against the harmonised global standards, ICH Q7 for API Manufacturers, and ICH Q9 on Risk Management. The drug company was able to use the SGS GMP audit reports during standard regulatory agency inspections by the European authorities.

SGS PROVIDES A SINGLE POINT OF CONTACT WITH SERVICES THAT SPAN ACROSS OUR GLOBAL NETWORK.

PHARMACEUTICAL AUDIT, CERTIFICATION AND TRAINING SOLUTIONS

PRE-INSPECTION ASSESSMENTS

For local and foreign regulatory bodies, e.g. US FDA, EU EMA, JPAL, SFDA, etc.

COMPLIANCE CONTROL OF SUPPLIERS

Such as manufacturers of active and non-active ingredients (excipients) and primary packaging materials following internationally accepted GMP guidance, such as ICH Q7, the EXCiPACT™ and ISO 15378 certification standards.

COMPLIANCE AUDITS

Of transporters, distributors and wholesalers of medicinal products following good storage and distribution practices (GSDP, e.g. EU publication 2013/C 68/01).

SHARED AUDITS

Share audit results of common suppliers among other pharmaceutical marketing authorisation holders for optimal cost.

TRAINING SERVICES

FURTHER EXCELLENCE

WHY SGS?

SGS is the world's leading inspection, verification, testing and certification company. SGS is recognised as the global benchmark for quality and integrity. With more than 75 000 employees, SGS operates a network of over 1 500 offices and laboratories around the world.

Enhancing processes, systems and skills is fundamental to your ongoing success and sustained growth. We enable you to continuously improve, transforming your services and value chain by increasing performance, managing risks, better meeting stakeholder requirements, and managing sustainability.

With a global presence, we have a history of successfully executing large-scale, complex international projects. Our people speak the language, understand the culture of the local market and operate globally in a consistent, reliable and effective manner.

SGS is also the global leader in quality management systems audits and certifications with over 110 000 organisations certified across a wide variety of industry segments. SGS GMP auditors are trained and qualified following the latest standards and requirements for Third Party certification programmes as published by regulatory bodies such as the US FDA and EU EMA in combination with the rules as set out by international bodies like ISO, PIC/S, APIC, IPEC, and WHO.

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 selected and trained based on their technical expertise as well as their business acumen, and their objectivity, ethics and confidentiality are beyond reproach.

TO LEARN MORE ABOUT SGS AUDIT, CERTIFICATION AND TRAINING SOLUTIONS FOR PHARMACEUTICAL SUPPLY CHAINS VISIT WWW.SGS.COM OR CONTACT GMP-AUDITS@SGS.COM FOR MORE INFORMATION

WWW.SGS.COM

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WHEN YOU NEED TO BE SURE

SGS