GXP and Quality Assurance services provided for the healthcare industry.





WE FOCUS
ON YOUR NEED



Sinhema's experience since 1999.

A BIT OF HISTORY...

Established in 2019, Eurofins Healthcare Assurance is part of the Eurofins Group which combines more than 25 years of experience in the testing, inspection and certification (TIC) industry.

In February 2022, Eurofins Healthcare Assurance has completed the acquisition of Sisthema, a reputable Quality Assurance and GxP audit player which was established in 1999.

Since 2011, Sisthema performs audits for the qualification of suppliers of APIs, raw materials, excipients, packaging materials, medicinal products, medical devices, cosmetics and food supplements, and also for providers of pharmacovigilance, analyses, and distribution/storage services.

Both companies have joined forces and will operate under the Eurofins Healthcare Assurance brand with the same high level and quality of service they are used to.



GLOBAL NETWORK, LOCAL ANSWER

Eurofins Healthcare Assurance is a global trusted partner providing business assurance services to identify and mitigate risks along the entire supply chain of customers, at their manufacturing sites and distribution channels in the pharmaceutical industry, medical, cosmetic/personal care and food supplements industries.

High quality, safety and integrity of pharmaceutical products can only be achieved by implementing robust and effective management systems and processes. Eurofins Healthcare Assurance provides

audit, certification, training and consulting services focused on quality management systems, process optimisation, risk and cost reduction and finally brand protection.

A large team of Eurofins experts can assist customers in the healthcare industry to face the increasingly demanding and complex regulatory environment in which they operate, solving industry challenges and informing unbiased business decisions.



STRENGTHEN THE CONFIDENCE IN YOUR SUPPLY CHAIN, MANUFACTURING SITES AND DISTRIBUTION FLOWS



Healthcare Assurance services are provided by a team of specialists from the Eurofins network and external qualified partners. Auditors and consultants are based in more than 30 countries in Europe, North & Latin America, Asia and Oceania in all strategic locations where healthcare manufacturers, their supply chains and distribution flows are located.

More than 90% of audits are performed by a local auditor.

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QUALITY ASSURANCE

AND GXP AUDITING

Eurofins Healthcare Assurance offers audits to ensure compliance with internationally recognised standards and market requirements.

Eurofins Healthcare Assurance audits supply chains (suppliers and CDMO), based on regulatory, international or customer standards:

- GMP (Good Manufacturing Practice): Finished Products, APIs and Excipients, Starting Materials, Cosmetic Ingredients, Medical Device Components, Food Supplement, Packaging Materials, Service Providers for Analytical Testing, Sterilisation, Maintenance, Validation, etc.
- GCP (Good Clinical Practice): Clinical Research Organisation, Investigation Center, Data Center.
- GLP (Good Laboratory Practice): Laboratories used to perform all nonclinical safety studies which are intended to support research permits or marketing authorisation.

Our auditors also provide distribution and post-market surveillance:

- GDP (Good Distribution Practice): Distribution centres, transportation.
- GVP (Good Pharmacovigilance, Materiovigilance, Cosmetovigilance Practices): Service providers for vigilance activities.

In case of need, we can also switch to our remote audit process since Eurofins Healthcare Assurance has a team of specifically qualified auditors for distant assessment.

In addition, our team provides:

- Internal audits programmes
- Health Canada audits for OTC (Over The Counter)
- Due diligence audits
- · GDPR audits
- and more



SHARED AUDITS AND AVAILABLE REPORTS!

Bring safe drugs to the market.

In order to stay compliant with stringent regulatory requirements of GxP regulated environments, drug manufacturers must regularly audit their suppliers. The increasing burden on suppliers for hosting many audits and the increasing costs for the audit sponsors can be avoided by using the shared audit process.

Eurofins Healthcare Assurance, as a 3rd party GXP and quality assurance audit provider offers the solution to smoothen the whole supplier audit process! With the agreement of audited sites, our customers can purchase existing reports from our extensive library of more than 700 available reports or they can join a planned shared audit.

	Join a shared audit	Purchase an existing report
Save money	•	•
Rely on us for the whole scheduling process	•	
Get a report tailored to your needs	•	•
Lower the audit burden on your suppliers	•	•
Get immediate access to the audit report		•
Available on our new online platform	•	•



SUPPLIER AUDITING MADE EASY!

USE OUR NEW MODERN AND INTERACTIVE PLATFORM

Our unique report library and list of planned audits is now fully digital and offers interactive new features!

Easy search, easy filter, easy request! In just a few clicks, our experts will be notified and you will get a detailed confirmation in your mailbox!

Accessible via our website by scanning the QR code below or via the URL:

www.eurofins.com/pharmasharedaudits



Easily find the supplier you are looking for and join a planned audit or purchase a report.

You don't find a particular audit for your supplier?
Request it!

You don't find a particular supplier? Request it!



WHY EUROFINS

HEALTHCARE ASSURANCE?



Large product scope

Our auditors and consultants' expertise covers all key healthcare products and applicable standards from R&D to distribution.



Robust qualification & experience

Our team and all our auditors and consultants have a strong experience in the healthcare industry and undergo an extensive qualification and continuous monitoring programme.



Wide geographical coverage

You can rely on a worldwide network of qualified auditors who speak local languages and know local cultures.



Digital solution

Our new digital platform offers powerful features to streamline and optimise your supplier auditing process.



Consistency and integrity

With Eurofins Healthcare Assurance's stringent quality, process and ethics management systems, our customers can expect the highest levels of consistency and integrity.



Several solutions

In order to best accomodate your audit needs, we offer several solutions:

- on-site or remote audits,
- individual or shared audits.
- purchase of existing audit reports.

WE ARE COMMITTED TO DEVELOPING TAILORED SOLUTIONS TO MAKE SUPPLY CHAIN ASSESSMENT EASIER, FASTER AND MORE TRANSPARENT FOR OUR CUSTOMERS.



We know your business processes may require varying levels of assistance or advice. Eurofins Healthcare Assurance gets you ondemand expertise through its consulting and advisory services.

- Gap-analysis, definition of CAPAs and support in implementation.
- Support in the implementation of new standards or regulations, and in the preparation for an inspection by health authorities, corporate or customer audits.
- Improvement of quality systems (CAPA, Deviation, Change control, Batch records, OOS, Risk Analysis...).
- Support on quality investigation, when industrial issues occur. Chemical and bio-contamination, lost productivity, on finished products, intermediates, raw materials or utilities.
- Support in review and regulatory filing requirements.

Your employees' performance is key to your company's success. Our Healthcare Assurance experts provide trainings to your employees.

- Regulatory evolution:
 - Review of EU GMP Annex 1 for sterile products manufacturing.
- Technical expertise and quality standards:
 - GXP, ISO.
 - Analytical methods (theory and practical application in one of our laboratories).
 - Sterilisation process.
 - Quality tools: audit, risk analysis, etc.

Our offer is tailored to your needs:

- e-Learning allows trainees to learn at their own pace.
- Interactive online trainings via a dedicated digital platform.
- Classroom: on-site trainings.

Our training offer can be customised or standardised, in English or local languages.

More details at:

www.eurofins.com/assurance/healthcare-cosmetics/services/consulting/

www.eurofins.com/assurance/healthcare-cosmetics/services/training/





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