



Healthcare Assurance





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



**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, medical devices, cosmetic/personal care and food supplements industries**.

High **quality, safety and integrity** of healthcare 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.

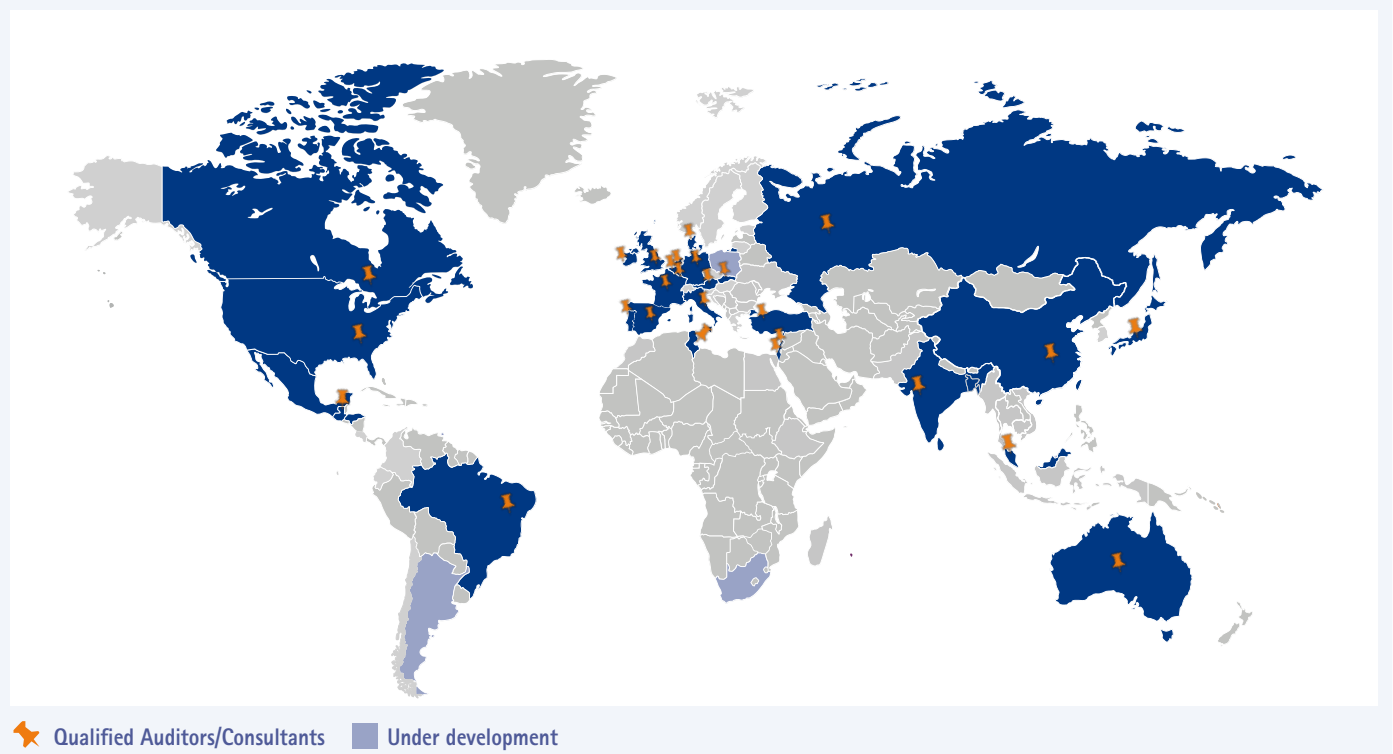
A large team of Eurofins **experts** can assist customers in the pharmaceutical, cosmetic/personal care, medical devices and food supplements industries to face the increasingly demanding and complex regulatory environment in which they operate, solving industry challenges and informing unbiased business decisions.

### Global network, local answer

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 where healthcare manufacturers, their supply chains and distribution flows are located.

More than 90% of audits are performed in local language.

### **Eurofins Healthcare Assurance Global Network**





## 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.

### Wide geographical coverage

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

### 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.

### Robust experience

Our team and all our auditors/consultants have on average 20 years of experience, with at least 10 years of practice in managing and working for healthcare industry projects.

### Flexibility and agility

We are committed to developing tailored solutions to make supply chain assessment easier, faster and more transparent for our customers.

### Several solutions

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

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



## Audits

Eurofins Healthcare Assurance offers audits to ensure compliance with internationally recognised standards and market requirements whether you are in the pharmaceutical, medical devices, cosmetic/personal care or food supplements industry.

### 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, Cosmetic Ingredients, Medical Device Components, Dietary Supplement Ingredients, 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 non-clinical 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 addition, our team provides:

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



Our experts provide supply chain and distribution audits in a cost-effective and time saving manner for customers and audited sites with the following options:

Individual audits	Shared audits	Purchase of existing reports
<p>Individual audits are carried out on behalf of one customer only, with our local auditors network.</p> <p>Individual audits are carried out on behalf of one customer only, with our local auditors network.</p> <p>They are fully customised and can be organised on-site or remotely.</p>	<p>Performing shared audits means that we are auditing one site, once, on behalf of several customers.</p> <p><b>Advantage for the customer:</b></p> <ul style="list-style-type: none"> <li>• the access to the audited site is easier and faster,</li> <li>• the price decreases with the number of involved customers,</li> <li>• entrance fees are lower or even cancelled.</li> </ul> <p><b>Advantage for the audited site:</b> less audit sessions to handle.</p> 	<p>Purchasing existing audit reports allows more customers to obtain assurance on their supplier sites without rescheduling or redoing an audit (with the agreement of the audited site).</p> 

 **GO DIGITAL WITH EUROFINS ASSURANCE ONLINE**

Eurofins Assurance On Line (EAOL) is designed to support our customers in the healthcare industry as a reliable partner for their digital journey.

- > Today you can purchase an existing audit report from our on-line library.
- > You can also make planning of your upcoming audit an easy step by checking our on-line calendar.

Get your access codes by contacting us directly [healthcareassurance@eurofins.com](mailto:healthcareassurance@eurofins.com).

Link to the platform <https://www.eurofins-aol.com>.





## Remote audits

During national or international crises such as the COVID-19 pandemic, on-site audits organisation may not be possible for several reasons such as travel restrictions, health risks or other restrictions imposed by authorities.

To support our customers, we are able to avoid the border-crossing issue with our local network of auditors.

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

Our process is compliant with the EMA's document "Guidance related to GMP/GDP and PMF distant assessments" dated Oct. 2020.





## Consulting

Whether you are in the pharmaceutical, cosmetic/personal care, medical devices or food supplements industry, your business processes may require varying levels of assistance or advice. Eurofins Healthcare Assurance gets you on-demand expertise through its consulting and advisory services.

### **Eurofins Healthcare Assurance experts offer:**

- 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.



## Training

Your employees' performance is key to your company's success. Our Healthcare Assurance experts provide training to your employees in the pharmaceutical, cosmetic/personal care, medical devices and food supplements industries.

### **Eurofins Healthcare Assurance training courses are about:**

- Regulatory evolution: keep your employees up-to-date with the latest legislation applicable to your business.
- 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 / in-the-field trainings at a defined date and location.

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



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