Auditing of starting and raw materials and intermediates manufacturers

WE FOCUS
ON YOUR NEED

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SiSThema's experience since 1999.

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The pharmaceutical industry and its stakeholders face continuous and increasing requirements to comply with complex regulatory and international standards leading to an increasing need of audit and inspections procedures all along its supply chains.

Our worldwide network of auditors provides a complete range of services to help drug manufacturers and their suppliers stay compliant with stringent GMP requirements and up-to-date with the pharmaceutical regulatory standards, expectations and procedures.

Thanks to an extensive and recognised experience with starting and raw material suppliers, our teams of chemists have developed a tailored service for API and excipients manufacturers. Our experts can help companies to prepare external audits and inspections, audit and map supply chains, build risk analysis, train employees, etc.

Thanks to our shared audit offer, our customers save money and reduce the burden of the whole audit process: suppliers have less audit sessions to host, audit sponsors can rely on us for the whole audit organisation.

	Auditing starting material and intermediate suppliers of API manufacturers	**Auditing raw material and intermediate suppliers for excipients manufacturers**
Gap analysis	to prepare National Health Agencies inspections (Brazil, EU, US, UK, Japan, Australia…)	with IPEC GMP/GDP to prepare external audits
Audit of your Contract Manufacturers	●	●
Independent assessment with IPEC GMP/ GDP to help you to export products	●	Eurofins Healthcare Assurance delivers Statement on compliance with IPEC GMP/GDP
Audit of your supply chain	Our auditors have a long experience in starting material and intermediates audits and can adapt to customer needs	Our auditors have a long experience in raw material audits, with the competency to adapt the ISO 9001 and pharma requirement to the right level
Mapping of your supply chain to increase your control on it and mitigate associated risks	●	●
Building of your risk analysis to prioritise your auditing programme	●	●
Optimise your budget thanks to a shared audit proposition	●	●
Optimise your budget thanks to a network of qualified auditors, located in the main manufacturing countries to reduce travel fees and increase reactivity	●	●
Training of your employees to applicable GMPs. On-site and remote training	EU GMP part 2, ICHQ7, EU GDP for API , US FDA, ANVISA guidelines, etc.	IPEC GMP, IPEC GDP…

**IPEC: International Pharmaceutical Excipients Council*

CONTACT US

healthcareassurance@cpt.eurofinseu.com

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

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