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White paper

Audit smarter, not harder:

Reducing GMP audit fatigue for pharmaceutical industry

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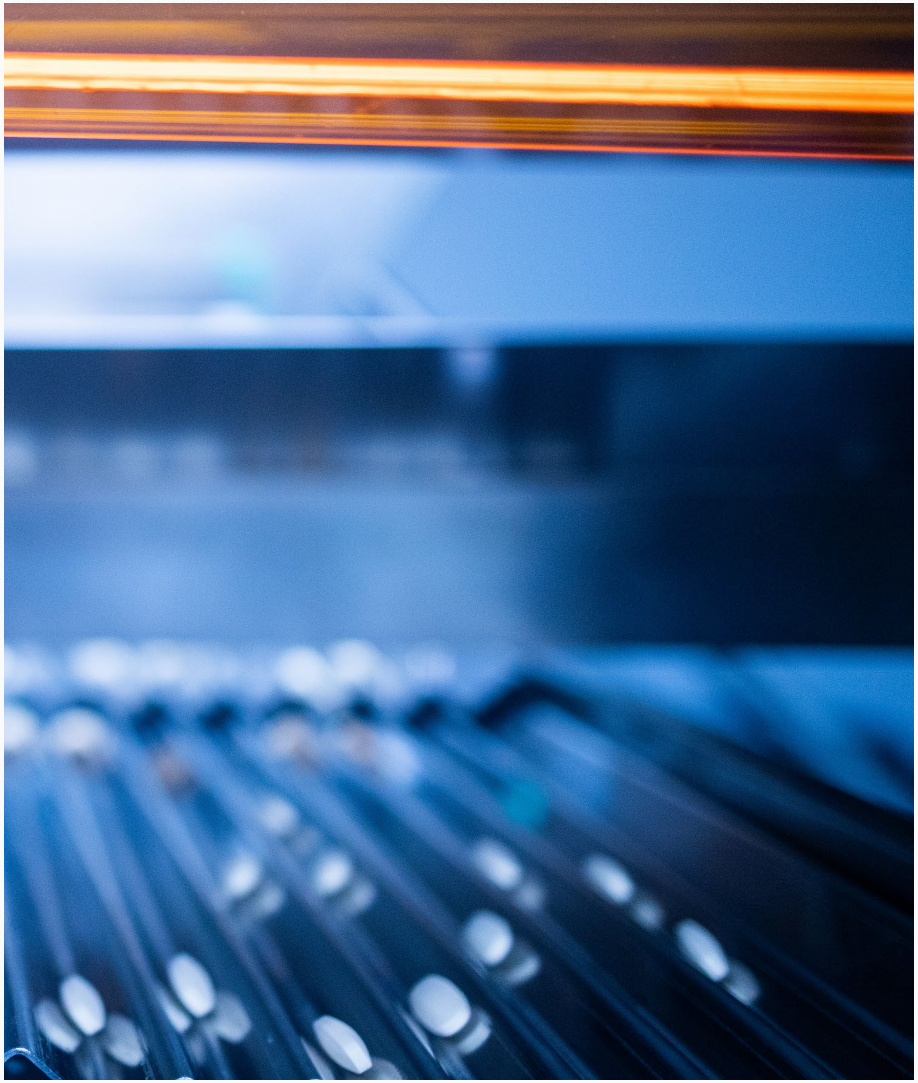
Executive summary



Active Pharmaceutical Ingredient (API) manufacturers are increasingly burdened by multiple Good Manufacturing Practices (GMP) audits from various stakeholders, including regulatory body inspections, customer audits, internal reviews, and second and third-party audit providers. This surge in audits places a significant strain on manufacturing sites and the associated resources, such as quality assurance, compliance, regulatory affairs, and personnel. It results in duplicated efforts in preparation, the audit process itself, and the follow-up on corrective actions post-audit.

The same GMP requirement is expected also for other players in the industry, include suppliers of regulated materials such as excipients and packaging, plus service providers including laboratories, Contract Manufacturing Organization (CMOs), logistics and warehouse vendors.

Although GMP audit reports are crucial for finished drug authorization files submitted to authorities, manufacturers are confronting rising demands for audits from stakeholders. In response, they are seeking to consolidate audit requests by utilizing shared audits that serve multiple customers. Additionally, final drug customers can benefit from existing GMP audit report databases available in the market to access previous audits conducted at their suppliers.

This white paper unveils the hidden costs in audit fatigue and presents a systematic approach to alleviating audit fatigue through shared audits and the resale of prior audit reports while ensuring adherence to quality standards and regulatory compliance. It also highlights the benefits associated with this innovative approach.

Excessively heavy GMP audit burden

To ensure quality and safety of pharmaceutical products, Good Manufacturing Practice (GMP) is a fundamental regulatory requirement of all markets worldwide.

APIs manufacturers, excipients suppliers and services providers undergo multiple GMP audits in a year for different purposes:

- Regulatory inspections from government bodies such as FDA in US, EMA in EU, MHRA in the UK, Health Canada in Canada and ANVISA in Brazil
- Internal audits as part of manufacturers' own quality management systems
- Customer audits from buying pharmaceutical companies
- Third-party certification audits

Unspoken costs of GMP audit fatigue

Repeated audits present very high internal costs to pharmaceutical suppliers as resources are required on audit preparation, execution and follow-up work.

Our experts have estimated that on average, one audit day and one working day cost 1,000 euro and 750 euro respectively**Conducting just one single GMP audit is costing an APIs manufacturer 2,500 euro!**

750€
from 1 working day for preparation

+

1,000€
from 1 audit day

+

750€
from 1 working day for follow-up work

=

2,500€
Real internal cost for 1 GMP audit

Unspoken costs of GMP audit fatigue

Apart from internal cost from financial perspective, such high volume of audit leads to high level of fatigue that create adverse impacts to the companies.

01

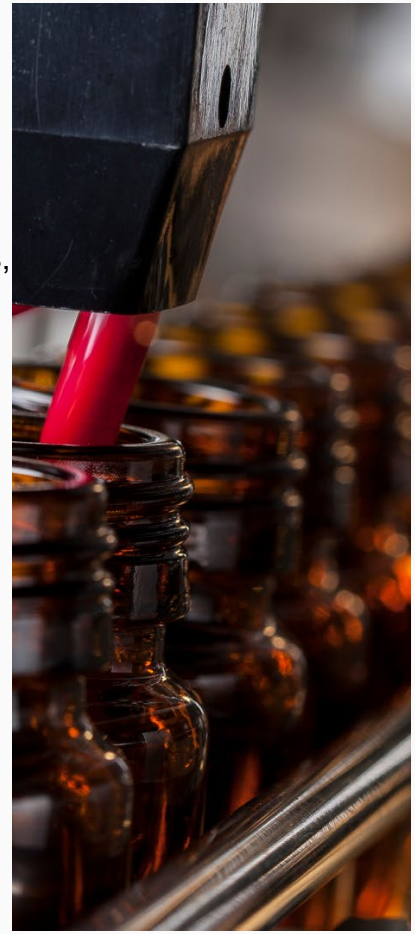
Reduced productivity

Key personnel may spend excessive time and resources preparing for and undergoing audits, detracting from their regular responsibilities and core operations.

02

Resource allocation competition

APIs manufacturers may need to divert resources (both human and financial) to audit preparation and execution rather than investing in innovation, product development, or other strategic initiatives.



03

Decreased employee morale

Frequent and repetitive audits can lead to frustration and burnout among key personnel and employees, reducing job satisfaction and morale.

04

Distortion of business priorities

As companies face resources issues resulting from audit fatigue, potential growth areas such as process enhancement, new markets and new product development are impacted, hindering overall growth.

Audit smarter, not harder

A single globally aligned GMP standard would provide the optimal solution for APIs manufacturers seeking unified compliance; however, stakeholders have been unable to reach a consensus on this matter, despite several attempts.

In the case of excipients manufacturers where the pressure of regulatory compliance is lesser than APIs industry, third party certification standards such as EXciPACt are gaining momentum to alleviate the industry from audit fatigue.

In response to the absence of global standards, the industry introduced a voluntary approach known as **Shared Audit** and **Report Reuse** about a decade ago. While these two models do not address every audit requirement, they effectively accommodate the majority of audits requested by pharmaceutical companies and significantly streamline compliance processes.

Shared Audit

What is Shared Audit?

Shared Audit enables multiple customers to be represented in one single audit with confidentiality well maintained. Customer-specific requirements including particular API molecules, production lines, and individual quality and compliance elements are all addressed properly.

How can Eurofins Assurance support you?

Our GMP audit teams worldwide receive numerous GMP audit requests for pharmaceutical suppliers from global customers every year. Some of them are commissioned audit by a single customer for their own qualification programmes, while some are audit requests for same suppliers from different customers.

Suppliers can certainly coordinate and arrange Shared Audits with their customers directly, but this is a very tedious work that lower suppliers' efficiency. Instead, our GMP audit teams can handle all the communications between suppliers and customers on audit consent, dates, scope and all specifications (scope covering their API, specific quality and compliance elements, specific reporting, data collection), taking away hassle for both sides. During the entire audit coordination and on-site process, confidentiality is observed by our team to protect the interests of every party.

Shared Audit has already become the norm among manufacturing sites in Europe and the USA, while we see this trend growing in India and China. When executed well, the model provides a win-win situation to suppliers and buyers, significantly eliminating the number of audit required without compromising compliance.

Report Resell

What is Report Resell?

Report Resell, as its name has suggested, GMP audit reports are resold to customers upon agreement from suppliers. It works well for APIs sites that do not want to take on more onsite audit, or when a customer misses the audit window of desired sites.

How can Eurofins Assurance support you?

Depending on a number of parameters, GMP audit reports are valid up to three years after issuance. Reports of APIs sites audited by Eurofins Assurance are stored in a standardised manner, allowing the reports to be resold to upcoming interested customers. When requests of buying existing reports arrive at Eurofins Assurance's team, we carefully verify customers' requests (scope and standards) and check if additional information is needed. Formal consent will be obtained from the suppliers before the reports are adapted and released to customers. Throughout the whole process and on the reports, confidentiality is strictly observed. This enables minimum effort of involved parties to fulfill GMP compliance efficiently.

Enormous benefits for pharmaceutical industry

As one of the pioneers in the industry delivering Shared Audit and Report Resell, we have observed substantial benefits to pharmaceutical suppliers and customers. Different positive feedback has been given also from involved parties.

Significant internal cost reduction

As mentioned before, one GMP audit incurs roughly 2,500 euro for preparation, field audit and follow-up work. Let's do a quick math here:

1 shared audit with **5** customers represented

>

4 duplicated audits reduced

>

4 audits x **2,500€** per audit

10k € is saved!

Enormous benefits for pharmaceutical industry

01 Streamlined processes and improved productivity

Fewer audits mean that resources can be allocated more effectively, reducing the time and effort spent on repetitive compliance checks. Key personnel can focus on their core responsibilities for improvement rather than sparing effort on duplicated audit tasks.

02 Improved staff morale and retention

Reducing the pressure of frequent audits can lead to higher morale among staff, as they are relieved from unnecessary audit workload. A focus on business priorities promotes job satisfaction, helping with staff retention and more open-minded collaboration.

03 Stronger relationships with stakeholders

Consistent high performance builds up trust with customers and other partners, fostering better working relationship.

04 Better risk management

Suppliers are able to dedicate proper resources and investment to proactively identifying and addressing risks from holistic approach. Being able to run compliance on more standardised approach facilitates higher consistency in quality standards as well.

The best part of adopting Shared Audit and Report Resell all coordination and communication with buyers is handled our teams, taking away the hassle and headache from you allowing your team to concentrate on the important tasks.

Conclusion

Implementing Shared Audit and Report Resell offers a strategic solution to mitigate audit fatigue while enhancing compliance efficiency for pharmaceutical suppliers.

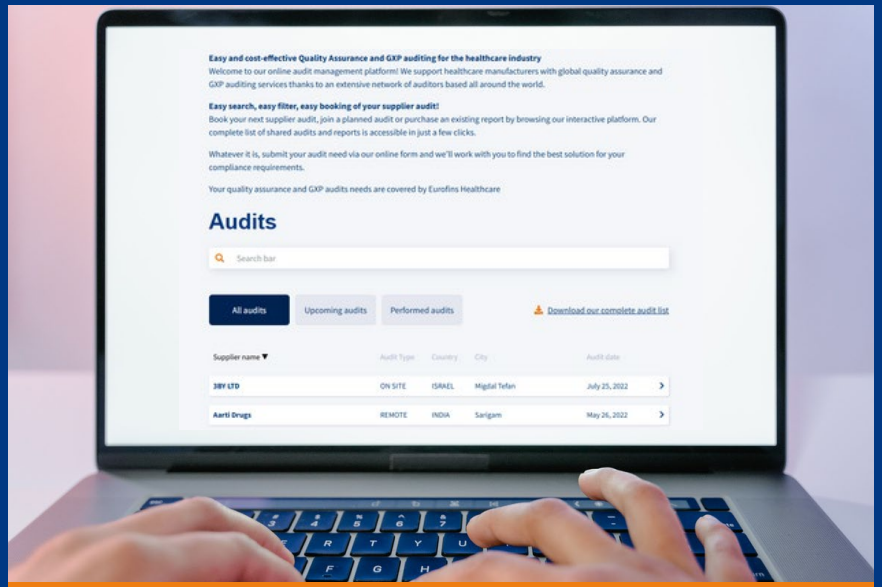
By fostering collaboration among industry stakeholders, businesses can streamline processes, reduce costs, and focus on continuous improvement. This innovative approach not only alleviates the burden of repetitive audits but also promotes effective risk management and quality assurance, ultimately leading to a more resilient and agile supply chain.

About us

Eurofins Assurance companies support customers globally to identify and mitigate risks along their supply chain– with operations, processes, systems, people or capabilities.

For more information about our comprehensive services, please visit:

www.eurofins.com/assurance



Bookmark our GxP audit library
https://h-aol.ai.eurofins.com/audits

Look for upcoming Shared Audit or browse existing reports for Report Resell anytime.

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