

Case Study

in collaboration with
Dr. Pflieger Arzneimittel & Optimed Pharma



► SITUATION

Shared auditing of active pharmaceutical ingredients (API), excipients or distributors has been an established practice for many years. On the other hand, the large majority of finished dosage formulation (FDF) audits are still performed individually. Globally more than two thirds of pharma companies rely on Contract Manufacturers (CMO). These players are key for the safe operation of the pharmaceutical supply chain and the availability of required medicine for patients. On average, a CMO serves more than 100 customers, meaning that they need to account for roughly 30 customer audits a year in addition to the official authority inspections, certification audits as well as internal audits. The resulting audit fatigue creates an extensive burden for CMOs. FDF audits are more complex than API audits and thus often last at least 2 days. This drives up the audit cost for both customers and CMOs.



► COMPLICATION

The concept of shared audits means that several pharma companies jointly perform a supplier audit at a company, which they all purchase from. Whilst the sharing of audits is well established in other areas, there is an overall reduced awareness of the possibility to design shared customer audits for FDF. Global authorities pressure companies into performing audits by themselves to ensure that companies have a thorough understanding of their suppliers. This has formed an historical "do-it-yourself-mentality" for many customers. At the same time, each FDF has unique characteristics which makes sharing of audits much more complicated.

► KEY QUESTION

Do shared audits also make sense in an FDF environment? If so, how can a shared audit be performed by covering several customers with varying requirements and still produce an authority-compliant audit report and what is the value for the CMO?

► ANSWER

ChemSquare is one of the leading audit service providers in Europe with an innovative approach to performing, scheduling, and sharing audits. The team was approached by Dr. Pflieger Arzneimittel GmbH in Bamberg, well known CMO in Germany. Their challenge was an extensive audit burden resulting from various customers.

Initially, the Dr. Pflieger quality team reached out to various customers which were due for an audit and explained the possibility to join a shared audit, orchestrated by ChemSquare. Despite the novelty of the approach, various customers bought into the idea driven by the benefits of cost savings and sparing of internal resources. After setting the commercial agreements and signing non-disclosure agreements, ChemSquare began to collect the individual audit requirements from the customer and consolidated resulting overlaps. Thereby, an extensive effort was made to ensure that all individual nuances, such as manufactured dosage forms and/or previously identified CAPAs, were properly collected. To ensure that all elements could be covered during the subsequent onsite audit, the team allowed for a longer audit schedule. In addition, a team of two, carefully selected auditors, was allocated to. Documents were reviewed in advance to allow for a well-prepared audit execution. After the audit, the auditor team wrote the report. Thereby, the team focused not only on covering the pure facts discovered during the audit, but also on displaying the situation and atmosphere during the audit. This was made with the intention so that the report readers could get a full grasp of the situation found at Dr. Pflieger's facility. Finally, every customer received an individualized report which only reflected the finding related to their requirements and products. This allowed them to proof the GMP compliance and safe operation of their supply chain. Also, Dr. Pflieger was able to show case their strong production capabilities. Additionally, Dr. Pflieger can offer future customers the availability of an independent audit report to speed up the qualification process. The overall condition was of very high quality and the team acted extremely professional, knowledgeable and experienced during the audit.

During the entire process ChemSquare acted as orchestrator and gate keeper of confidential information. At the same time, the entire project was paid for by the customers so that there was no risk of an independence breach between ChemSquare and Dr. Pflieger. Whilst each party knew that the audit was indeed shared, none knew about the other parties involved or their individual issues.



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ABOUT US

Enabled by new digital technologies, ChemSquare sees great potential in creating one single digital network, in which customers, suppliers, auditors, subcontractors and official authorities are connected and continuously exchange quality data in a secure way. A global pool of independent and accredited auditors, who audit suppliers around the globe on a regular and demand-driven basis, publish their results on our platform. This enables customers to continuously receive qualification-relevant information without having to conduct extensive audits themselves. They have access to a customized supplier monitoring dashboard, and receive the most recent and relevant quality data on their suppliers. Due to higher re-use of quality data, the overall number of supplier audits is reduced. This leads to significant cost reduction for all industry stakeholders,

Dr. Guido Zimmermann, Head of QC / QP OPTIMED Pharma GmbH

“The audit saved us a lot of time. Although our purchase volumes are small, we are still required to audit Dr. Pflieger. Joining the ChemSquare audit was the right decision as the audit orchestration and performance was professional, all requirements were covered and the audit report turnaround time was fast. Joining the shared audit provided several advantages, not only economically. Through the deep experience added by the auditors, we received a very high-quality assessment.”

Dr. Ralf Grulke, Head of Quality Assurance @ Dr. Pflieger

“We were happy to conduct the shared audit for the first time as we were able to save significant time and internal resources by reducing audit fatigue through the pooling of customers in one audit. Covering these customer audits would have resulted in roughly two full audit weeks. Through the shared audit we were able to reduce the overall audit time for those customers by more than two-third. At the same time, we were able to provide our customers with an advanced service, making them feel acknowledged and respected. Going forward the centralized CAPA follow-up through ChemSquare will make this process also much more efficient. The overall audit went very professional and provided a great value-add for us. We would do it again and also recommend ChemSquare as orchestrator of shared FDF audits.”