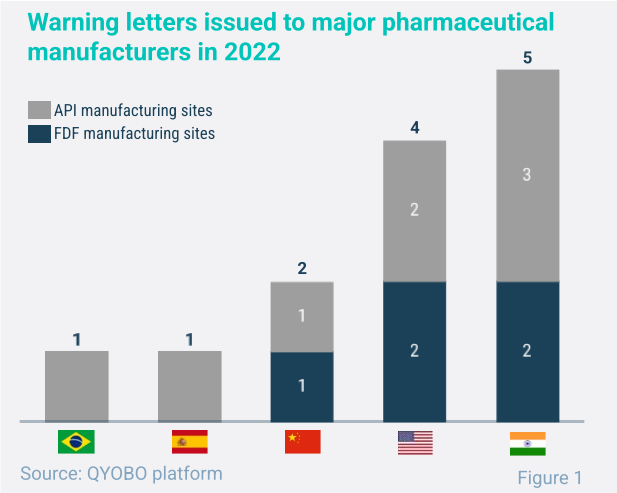
As of March 28, 2023

QYOBO Qualifyze

Identifying warning letters ahead of time with unified insights from QYOBO and Qualifyze



28 March 2023, Munich – Severe violations of Good Manufacturing Practice (GMP) resulting in FDA warning letters put additional strain on pharmaceutical supply chains, with a potentially compounding impact on drug shortages. **In 2022 alone, the U.S. FDA issued 13 warning letters to major pharmaceutical manufacturers** (see Figure 1). 8 of them affected API manufacturing sites, while 5 warning letters were issued to FDF manufacturing sites. Geographically, most of the warning letters were shared with Indian or U.S. companies (5 and 4, respectively). The high share of U.S. companies affected is, however, related to the circumstance that COVID-19 restrictions made foreign inspections much more difficult over the last years compared to domestic inspections in the USA.[1]

To swiftly react or even predict non-compliance events like warning letters, companies need to be able to effectively and quickly analyze suppliers for their products, including their manufacturing sites.

QYOBO and Qualifyze position their clients for success regarding non-compliance preparedness, by providing well-structured, up-to-date, high-quality inspection and audit data.

We'll take a closer look at this by analyzing 3 of the 13 production sites receiving warning letters in 2022 mentioned above. All 3 of these sites have been audited by Qualifyze. Figure 2 illustrates when each of these sites received a warning letter. Two of the sites – Centrient Pharmaceuticals India Pvt. Ltd. (Taunsa - Site 1 and 2) and Sun Pharmaceutical Industries Ltd. (Harol, Baroda Highway) – **were audited by Qualifyze several months before warning letters were issued by the U.S. FDA**. Hence, Qualifyze clients received an early warning on the prevailing quality issues at the site and were given the opportunity to take early action before the warning letters affected their pharmaceutical supply chain. The third site – Aurobindo Pharma Ltd.

(Borpatla - Unit 1) – was audited by Qualifyze in July 2022, half a year after receiving a warning letter. Unlike the previous two sites, the insights from this audit demonstrated to their clients whether the observations during the FDA inspections had been resolved, providing a measure for when a close-out letter, i.e., the lifting of the warning letter, could occur.

Source: QYOBO platform Figure 3

Through their collaboration, QYOBO and Qualifyze provide a unique competitive advantage to their clients by making all quality-relevant information available at their fingertips.

The QYOBO platform provides a combined picture of regulatory inspections (EU, US, Canada, WHO) and Qualifyze audits - the complete audit reports can be easily obtained directly from Qualifyze. **This allows any company to review the full – global – inspection history within seconds** (see figure 3 for Centrient Pharmaceuticals India Pvt. Ltd.) while providing the option to deep-dive into an audit report and thus fully validate the reliability of a supplier of interest or take early action before a non-compliance event occurs.

About QYOBO GmbH

QYOBO's mission is to improve access to essential medication for everyone by contributing to a more transparent, efficient and robust supply of pharmaceutical and chemical raw materials.

For this purpose, we've developed the QYOBO market analytics platform for APIs, intermediates and chemicals. From millions of trade, regulatory and financial datasets scattered around the world, our big data algorithms derive unique, actionable insights on market prices and trends, suggest suitable partners for your business and automate data-heavy workflows in procurement, supply chain and business development.

Founded in June 2019 and based in Munich, our company is pursuing its mission collaboratively with its international clients and has been recognized with numerous awards including the BASF market challenge and the Digital Innovation award 2020 by the German Federal Ministry for Economic Affairs & Energy (BMWi).

About Qualifyze GmbH

Qualifyze supports pharmaceutical companies with consistent, reliable and flexible audits, at scale. They've made it their mission to build the trust layer for global supply chains, using curated data and actionable insights to help their stakeholders make the most of their audits. With over 150+ expert, local auditors, more than 800+ pharma clients worldwide and over 1500+ audit reports available in their database, they're a global leader in 3rd party audit execution.

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[1] Data dashboard FDA