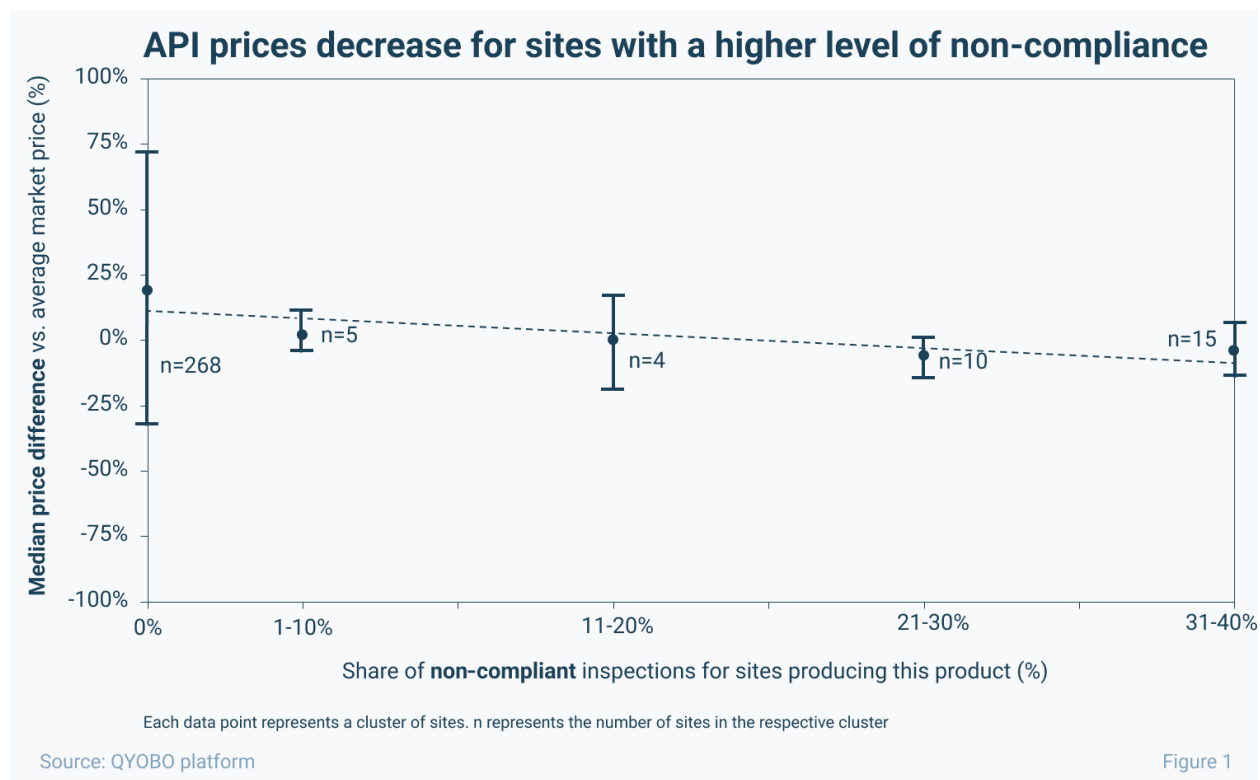


The impact of compliance on API pricing

18 July 2023, Munich – Our [recent analysis](#) of 2023 API prices highlighted that APIs exported from Europe became more expensive while the average API prices decreased on a global level. In general, a higher price level of European APIs is not a major surprise because the continent is generally associated with higher production costs and stringent quality standards. In this analysis, we examine whether the two aspects - higher prices and compliance (reflecting higher quality standards) - have a quantifiable correlation not only for Europe but also on a global level.

For that purpose, we focused on 61 of 300 APIs in the QYOBO API index - those with a substantial manufacturing footprint in Europe, India, and China. For the analysis, we used a two-step approach, combining intelligence available in different modules of the QYOBO platform.



In the first step, we analyzed API prices by country from January 2020 through May 2023 for these molecules. In the second step, we identified the exact manufacturing site producing each of these APIs around the globe via the locations feature. The GMP inspection data for each manufacturing site was then used as a measure of compliance. For a timely perspective, the analysis was limited to GMP inspections conducted in the last 10 years. In total, more than 300 sites and 4,000 GMP inspections were part of this analysis.

The results are shown in Figure 1. It compares the deviation from the global average price (y-axis) for sites with varying levels of non-compliance (x-axis). Each bar represents a cluster of sites with a similar degree of non-compliance: e.g., 0% of non-compliance are all sites that had exclusively had compliant GMP inspections in the last 10 years. In contrast, the 20-30% cluster indicates that at least 1 out of 5 inspections was found non-GMP-compliant for these sites.

The general falling trend supports the hypothesis that higher quality - measured via GMP compliance - comes at a higher cost. The data shows that API buyers expecting full compliance (0% non-compliant inspections) should expect a markup of 19% on average against the market average price. The bars in the chart show the standard deviation for each data point. Hence several exceptions exist where prices are substantially higher (up to 72%) than the average market price. However, also the opposite situation exists when sites with a better compliance record offer prices up to 30% below the average market price - one example is Amoxicillin trihydrate.

For this molecule, our [last article highlighted price differences between Europe and the rest of the world](#). While European exports are currently roughly 30% above the average market price, prices from European manufacturers outperformed Indian and Chinese competitors for much of the last year. This is even more surprising considering that energy costs spiked in Europe as a result of the Russian invasion into Ukraine.

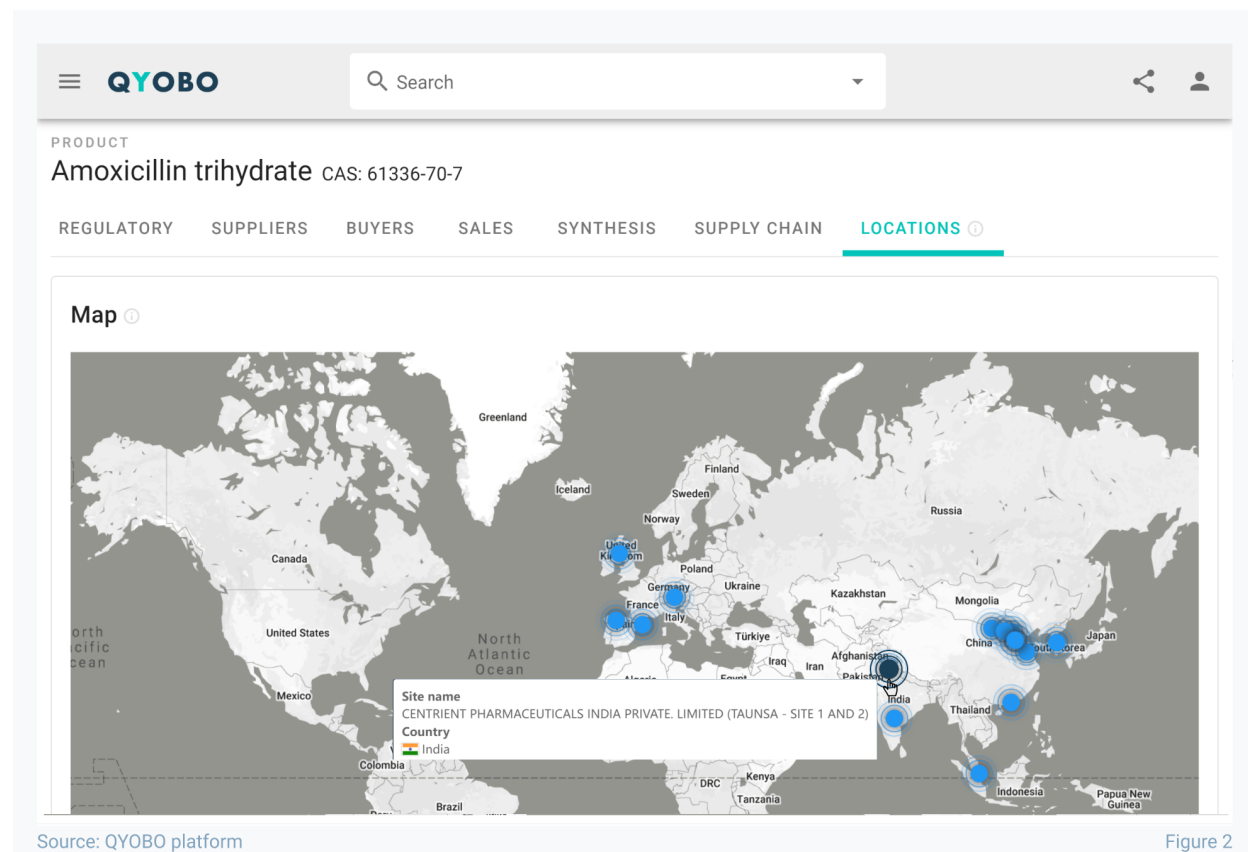
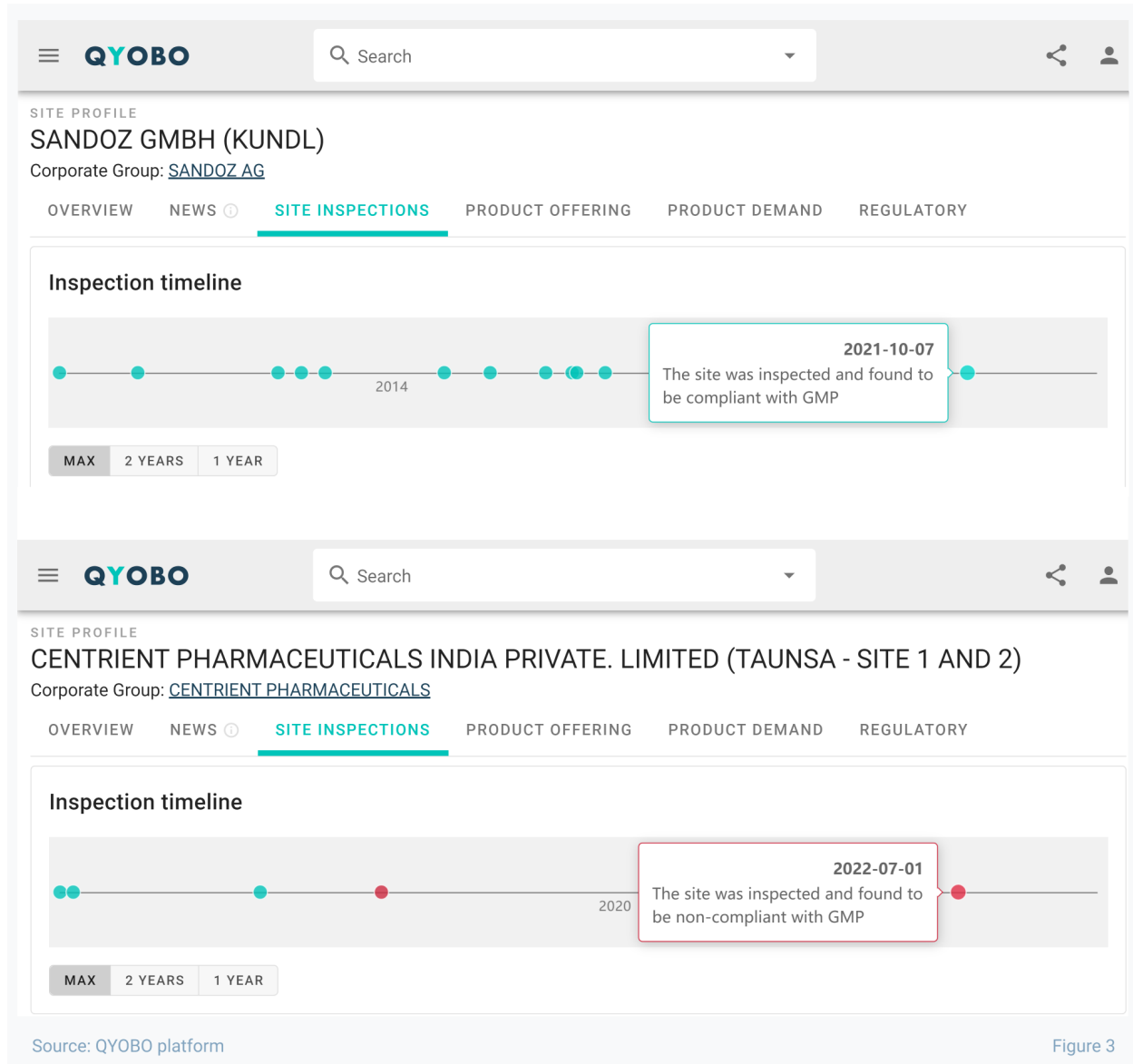


Figure 2

Figure 2 in this article highlights a screenshot from the QYOBO platform with API manufacturing locations for Amoxicillin trihydrate. Figure 3 shows the GMP inspection timeline of two manufacturing sites – SANDOZ GMBH (KUNDL) and CENTRIENT PHARMACEUTICALS INDIA PVT. LTD. (TAUNSA - SITE 1 AND 2). While the Austrian site has an unstained compliance history, the latter site in India, unfortunately, does not. Considering that export prices from Europe (particularly Austria) for Amoxicillin trihydrate were cheaper than exports from India and China for much of 2022, this means that several companies have, in fact, paid more for their API while also having a higher risk exposure due to the Indian site’s GMP situation.



Source: QYOBO platform

Figure 3

In summary, as shown in Figure 1, manufacturing sites with a better compliance record will generally charge higher prices for their products. But as Amoxicillin trihydrate shows, exceptions to this rule exist. Hence API category managers are strongly advised to take a close look at their

supply base by analyzing the latest industry price benchmarks alongside the compliance history. For details on how to do that, feel free to reach out to our marketing and sales contacts below.

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).

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