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Product pivoting: Compliance issues to consider

By Karen Kroll

Over the past few months, numerous companies have shifted from their regular lines of business. Instead of, for instance, making running shoes[1] or producing artisan liquor,[2] they're crafting face masks or formulating hand sanitizer.

Their efforts have helped safeguard health care workers and others who risk exposure to the coronavirus, which can cause COVID-19. They also can expose the organizations to different risks, as many of the products helping in the fight against COVID-19 are not immune to regulatory oversight, said Simon Jacobson, vice president and analyst with research firm Gartner. For instance, the U.S. Food and Drug Administration (FDA) treats surgical masks as medical devices.[3] "In some cases, the regulatory concerns are underestimated," he added.

The regulatory requirements extend to products that a company doesn't manufacture but imports. The FDA requires foreign establishments that manufacture medical devices for importation into the U.S. to comply with applicable U.S. regulations before, during, and after their importation. The FDA can keep products from entering the country if they don't comply with regulations, said Christina Markus, partner in the FDA and Life Sciences team at King & Spalding.

Mitigating these risks requires understanding all links in an organization's supply chain. For instance, if a product must remain at a certain temperature, the company will need to ensure it's transported in refrigerated cars, said Roy Anderson, chief procurement and digital transformation officer with Tradeshift, a digital business-to-business network. Organizations need to check that any marketing claims comply with applicable regulations and then monitor regulations for any changes.