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# Quality risk in offshore manufacturing: Evidence from the pharmaceutical industry

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## Abstract

Does offshore production pose an added quality risk relative to domestic production? If so, what factors influence the quality risk? Progress addressing these deceptively simple questions has been hindered by the challenges associated with (1) difficulties in controlling for a wide range of factors that may potentially affect quality risk in offshore manufacturing and (2) the lack of available measures that are consistent across geographic regions. This paper contributes to the academic discourse by empirically assessing differences in quality risk across domestic and offshore plants in a setting that naturally controls for many confounding factors. Specifically, we employ a sample of 30 pairs of regulated drug manufacturing plants in the U.S. mainland and Puerto Rico matched both by parent firm and by product standard industrial code (SIC). Using a plant-level measure of quality risk that is measurement invariant, our findings indicate that Puerto Rican plants operate with a significantly higher quality risk than matching plants

operated by the same firm located in the mainland U.S., on average. This finding persists above and beyond potentially important factors, such as geographic distance and the local population's general and industry-specific skills. Thus, challenges related to the transfer and maintenance of the knowledge required to operate with a low quality risk across non-geographic distance are left as the most plausible explanatory factors. Practically, our research highlights the need for manufacturing firms to carefully consider increased quality risk associated with the offshoring of production, particularly with regard to process-sensitive products like drugs. From a policy standpoint, our study highlights the need for the Food and Drug Administration (FDA) to continue to intensify its inspection focus on international manufacturing.



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## Keywords

Delphi/panels; Global operations; Manufacturing and sourcing strategy; Quality risk; Production offshoring; Quality management

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