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# Toward a Conceptual Framework of Regulatory Strategy: The Bio/Pharm Industry Case

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## EXECUTIVE SUMMARY

*This paper aimed to elaborate a conceptual framework for regulatory function strategy identification in industries heavily exposed to regulations, such as the biotechnology/pharmaceutical industry. The scope was to synthesize applicable prior existing fundamental theories and concepts, to apply them to the regulatory field and develop a taxonomy for use by academic research and industry. The TCE (Williamson, 1981), bargaining power of customers (Porter, 1980), organizational adaptation (Hrebiniak & Joyce, 1985), and institutional theory were employed as primary tools for the framework development. The paper introduced four types of regulatory environment that may exist in the biotechnology/pharmaceutical industry. Relevant strategies, research and managerial practice implications are presented.*

**Keywords:** Regulatory compliance, Strategy, Biotechnology, Pharmaceutical industry