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[Pharmaceutical Competitive Intelligence for the Regulatory Affairs Professional](#) Jul 15 2022 This Brief defines competitive intelligence (CI) as a tool for making investment decisions within the pharmaceutical industry. It provides an overview of processes that the regulatory affairs professional must take into account when evaluating data impacting product-based risk evaluations. These apply particularly to evaluations that focus on outputs such as regulatory approval, or the commercial impact of product labeling on the sales forecast over a limited timeframe. The Brief also provides an overview of intellectual property assessment that can impact a product's lifespan on the market due to patent protection itself (or loss of patent protection) or via regulatory exclusivity. Case examples are discussed to illustrate the importance of keeping up with the ever-changing regulations, and how to interpret them in the context of CI. In addition, there is a section on virtual data rooms (VDRs) which currently function as the cornerstone of due diligence investigations. While aimed primarily at regulatory affairs professionals in the United States, this publication provides a useful adjunct for other pharmaceutical executives, especially those new to product-based investments, and regulatory affairs professionals in other regions. ?

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Simpler Dec 28 2020 Simpler government arrived four years ago. It helped put money in your pocket. It saved hours of your time. It improved your children's diet, lengthened your life span, and benefited businesses large and small. It did so by issuing fewer regulations, by insisting on smarter regulations, and by eliminating or improving old regulations. Cass R. Sunstein, as administrator of the most powerful White House office you've never heard of, oversaw it and explains how it works, why government will never be the same again (thank goodness), and what must happen in the future. Cutting-edge research in behavioral economics has influenced business and politics. Long at the forefront of that research, Sunstein, for three years President Obama's "regulatory czar" heading the White House Office of Information and Regulatory Affairs, oversaw a far-reaching restructuring of America's regulatory state. In this highly anticipated book, Sunstein pulls back the curtain to show what was done, why Americans are better off as a result, and what the future has in store. The evidence is all around you, and more is coming soon. Simplified mortgages and student loan applications. Scorecards for colleges and universities. Improved labeling of food and energy-efficient appliances and cars. Calories printed on chain restaurant menus. Healthier food in public schools. Backed by historic executive orders ensuring transparency and accountability, simpler government can be found in new initiatives that save money and time, improve health, and lengthen lives. Simpler: The Future of Government will transform what you think government can and should accomplish.

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Committee on Government Reform, House of Representatives, One Hundred Eighth Congress, second session, July 7, 2004.

What is the Administration's Record in Relieving Burden on Small Business? Feb 16 2020
Good Manufacturing Practices for Pharmaceuticals, Seventh Edition Nov 07 2021 This book provides insight into the world of pharmaceutical quality systems and the key elements that must be in place to change the business and organizational dynamics from task-oriented procedure-based cultures to truly integrated quality business systems that are self-detecting and correcting. Chapter flow has been changed to adopt a quality systems organization approach, and supporting chapters have been updated based on current hot topics including the impact of the worldwide supply chain complexity and current regulatory trends.

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