It’s Time to Change the Game on Regulatory Management

by Colin Speakman and Mackenzie Hales

Conversations about regulatory management in the CPG industry drive anxiety and a vision of dollar signs. Some even view regulation management as an anchor that prevents innovation by slowing down speed to market and increasing overhead costs. Instead of accepting this mindset, flip the script on regulatory management through the application of advanced analytics to enable innovation and growth.

Understanding the Challenge

Through regulations passed in the U.S. (FSMA) and in the European Union (OCR), regulatory bodies have been empowered with new authority and can proactively investigate and ask for proof of compliance. In turn, regulatory complexity is growing. Current operations become more difficult as more regulations are implemented and/or changed where brands currently operate. The European Union is cracking down, and during 2016 and 2017 they inspected over 50,000 sites and seized 230 million euros of goods. On top of this, companies expanding distribution to new geographies must consider the regulatory impact, potentially affecting how the product is made, what it contains, how it is packaged, and what claims can be used.

So what happens? Innovation – including new products and launches to new regulatory jurisdictions – slows down. Organizations are trying to increase regulatory reviews while managing resources in an era of cost cutting and zero-based budgeting, so they rarely have the necessary resources or capacity to get everything done as desired.

The result is that products are launched without a full internal regulatory review, are mistakenly launched with incorrect labeling, or are launched later than expected due to the time needed for review. This isn’t happening due to malicious intent, but the result of countless team members doing everything they can to seek out growth as quickly as possible, as prescribed by their situations.

Using Data & Analytics to Mitigate Regulatory Compliance Challenges

How can this increased regulation management be anything other than a cost and a challenge to an organization? Simple: through data.

Data can help mitigate regulatory compliance challenges. In fact, companies in the life sciences and pharmaceutical industries already use regulatory intelligence (the application of advanced analytics to regulatory data to drive actionable insights and recommendations) to enable informed product development and lifecycle management. Once a drug is released to the market, pharmaceutical companies use regulatory intelligence to inform regulatory strategy by mining publicly available data from government regulatory authorities, regulatory journals, and conferences. Medical device companies mine the same data for insights around which products in the pipeline are more advantageous to develop given future regulatory regimes, and they can monitor risks to current products in real-time.

CPG companies can also leverage data and advanced analytics to collect the necessary information on current regulations, and to build awareness of what regulations might apply if they want to sell the brand in a different geography. There are solutions out there that allow organizations to quickly understand the basics around what regulations need to be managed. Suddenly, what now takes days or weeks for regulatory functions to research and analyze can be answered within minutes.

But the real benefit comes from the next step of applying analytics to regulatory data. By layering on active monitoring through configured machine learning, organizations can quickly create a center of excellence that monitors trends and informs the business of new opportunities and new challenges as they arise. Regulatory groups can even do predictive modeling or mine data to listen for future regulatory events.

An “always on” monitoring capability combines regulatory management data mining with machine learning algorithms, enabling CPG companies to stay ahead of changes and predict internal and supplier regulatory issues. It leverages machine learning algorithms to predict business risks, and uses regression models to identify correlations between data sets and regulatory events.

Many organizations are starting to realize the potential this can unlock, and are starting to explore. Ultimately, leveraging regulatory data as an asset and applying advanced analytics enables growth and innovation by better informing the entire organization throughout the process.

At Kalypso, we are helping companies understand how to leverage digital across the innovation value chain. Thinking about regulatory management as an opportunity, and not an annoying government-driven cost, can reduce the costs of compliance, labor, and regulatory risk. Utilizing new technologies can help you turn this thinking into growth and performance.

To learn more about this, or how you can use this right now, reach out to Colin Speakman or Mackenzie Hales.
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About the Authors

Colin Speakman
colin.speakman@kalypso.com
Colin has been advising leaders on the power of innovation for 15 years. Colin enjoys golf, cheering on his University of Virginia alma mater, and is a Cleveland Browns season ticket holder.

Mackenzie Hales
mackenzie.hales@kalypso.com
Mackenzie Hales specializes in product development and innovation strategy in the Consumer Goods and Medical Technology and Devices industries. An avid adrenaline junkie, she broke her first bone at three while attempting to fly, and now leaves that to professional pilots.