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Lessons from the Auto Industry

Executives, investors, advisors and professionals affiliated with the biotechnology industry often forget that many of the struggles they face today have been solved before by other fields and industries. The mid-19th century author, Ambrose Bierce wrote, "There is nothing new under the sun, but there are lots of old things we don't know." The question is where to look for inspiration.

Automobiles in the 1970s

In the 1970s, the global automobile industry faced two significant challenges: a huge push by consumers and regulators to improve quality and safety, and the OPEC-driven increase in gasoline and oil prices. Manufacturing, distribution, and development costs threatened to skyrocket out of control. Automotive companies struggled against a three-dimensional problem: how to improve the fuel efficiency of cars while also improving safety and quality? The challenges faced today by biotech and pharmaceutical companies worldwide are not all that different: how to improve drug, device or biologic efficacy while also improving safety and quality?

The automobile industry approached its complex problem with many strategies such as Total Quality Management (TQM), dramatic cost-cutting, and squeezing suppliers for lower pricing to maintain long-term business relationships. Toyota, however, was the first to discover and then capitalize on a simple, yet effective answer: The sooner in development safety, quality, and fuel efficiency were tackled, the lower the eventual costs and the higher the success rates for getting to market. Toyota executives and engineers reframed the Japanese principle of *kaizen* (continuous improvement). Rather than looking just at manufacturing and distribution, Toyota management followed the processes of automobile creation to their logical beginnings. In fact, its engineers soon discovered that building quality, safety, and efficacy in at the early concept-design stage was most cost-efficient (here I use "efficacy" for the concept of fuel efficiency, plus features, passenger room, and so on). That then freed them to play with and innovate on the remaining elements such as style, handling, and so on, which improved both their time to market and their chance of market success.

Admittedly, the days of the Corona were numbered, but that early work provided Toyota with the funding and marketplace stature to build today's Lexus. Few people could have imagined then that the issues automobile executives were arguing as massive hurdles for their industry — quality, safety, and efficacy — would today be bandied about as competitive qualities. For example, Volvo does not make the most beautiful cars, but surveys of Volvo owners repeatedly point out these top three answers for why they purchased a Volvo over all other options: safety followed by efficacy and quality.

Cutaway view of Toyota Corona
WAYNE STEPHENSON (HTTP://OURWORLD.COMPUSERVE.COM/HOMEPAGES/STEPHO/CORONPRD.HTM)

Applying the Lesson

In my work helping executives at biotechnology, pharmaceutical, and life-science companies, I often hear attempts to rationalize away such a comparison with, "Yes, but we are talking about hundreds of potential compounds in the early preclinical stage, so that's not really applicable." Automakers today routinely develop hundreds of concept cars and frequently go on to build many more prototypes for road testing than any drug company has new treatments in clinical trials. In fact, the cars you and I will be able to buy seven to ten years from now are currently being tested (along with others that won't make it) on raceways and simulated town streets and rainstorms in Michigan, North Carolina, Japan, Germany, and so on.

Applying this lesson from the automotive industry is straightforward. Toyota has already paved the way. Look at your processes and your organization through Toyota's *kaizen* lens. Are there components of compliance and quality that you can build early into your processes to channel rather than slow down your development efforts? Such work can help drive down costs, speed time to market, and improve success ratios in the preclinical stages.

Drawing upon lessons and analogies from other fields and industries can help biotech reframe the compliance challenges it faces and point to ways it can reduce costs, boost innovation, and improve market success. Ultimately, the companies that take the most advantage of such lessons and apply regulatory compliance as a competitive edge will be the ones that dominate their industry 25 years from now. Are you ready?

In case you'd like to read further examples and applications that might be suited to the situation you face, I've made a number of my published articles available as PDF downloads in the Resource Library of our company's website (www.ceruleanllc.com). I welcome your comments, suggestions, and questions.

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