

PERSPECTIVE

The Future of Pharma: Challenges and Opportunities of R&D, Safety, Regulatory, and Compliance Functions

Trends Affecting the Pharmaceutical Industry



Industry overview

The pharmaceutical industry is going through a difficult yet interesting phase. The current drug-funding model is under pressure with exploding costs putting pressure on pricing and creating demand for value-based healthcare (outcomes focused).

The challenges in the R&D, Safety, Regulatory, and Compliance (RDSR)

functions in the value chain are also immense. The R&D function is becoming complex in terms of portfolio and operations; and is under constant pressure to improve productivity. On the other hand, Safety, Regulatory, and Compliance functions have to increasingly support varied market needs (product and price) across geographies and navigate through

complex regulatory environment asking for more information and transparency.

In order to take these challenges head on and exploit new opportunities, it has become imperative for the pharmaceutical industry to keep pace with emerging technologies and adopt efficient and agile operating models.

Key takeaways

- In the current scenario, there is increased pressure on price, which has been further impacted by a declining product pipeline. To drive growth, pharmaceutical industry will require a comprehensive shift in its business model and operations that can help in providing a better experience to customers, improving the clinical trial process, and reducing costs overall.
- In addition, patients have a vast amount of information available at their fingertips, which allows them to proactively get involved in evaluating different healthcare products and services with respect to their cost and the value derived from them. This creates a necessity for pharmaceutical companies to create and demonstrate value-based healthcare and develop a channel where they can engage patients as they make decisions.
- Mobile engagement with patients can lead to easier exchange of information and recruitment for clinical trials. This allows for collection of big data, which can be used to improve the process related to how clinical trials are planned and executed. In addition, clinical trials enabled through mobility, will improve patient-adherence and engagement.
- Advanced data analytics, predictive analytics, and automation of processes can help the pharmaceutical industry in improving the operational efficiency, quality, and responsiveness of business processes.
- Perceptions across different geographies and regulators vary regarding benefits vis-à-vis risks:
 - The US is seeing a shift in focus from a simple 'safety versus efficiency' parameter to a more patient-centric 'benefit versus risk' parameter
 - In the EU, regulators' focus is moving towards 'benefit' and 'cost-effectiveness' of a product as opposed to the present benchmark of 'care'.
- Moreover, requirements of emerging markets have become more intricate and complex:
 - Different governments are responding differently to the financial crises, their responses varying from higher reliance on Health Technology Assessment (HTA) appraisals and health economic data to mandated reductions in price.
 - Approval requirements are often found to be unpredictable and lacking consistency. For instance, Russia demands locally based clinical trials, while other countries such as Brazil require a bioequivalence testing.



Top three lessons

Building a patient-centric model

Dynamics of just involving prescribers and payers is not going to work in a connected world where increasingly, patients are getting involved about their treatment paths. A patient-centric approach to deliver better outcomes at same or lower costs is a must-have strategy for pharmaceutical companies to succeed.

Create an efficient and agile operating model

Given the forces of change that the industry is witnessing; such as pricing pressures, increasing costs, productivity issues, R&D complexity, and continuously rising regulatory / compliance demands, there is a need to build an efficient and agile operating model that fully embraces new technologies (Internet of things, cloud, mobile, big data and analytics, and social media).

Unlock the potential of big data across the value chain

Big data offers transformative potential for the pharmaceutical companies across the value chain; search for new drugs, segmenting patients for trials / treatments, supply chain efficiencies, personalized treatments, risk-based monitoring of trials, all utilize real-world data for design, prediction, etc.



Summary

The pharmaceutical industry today is witnessing a transition that impacts the approach towards healthcare. As organizations implement a patient-centric model, there is an urgent and growing need to innovate and find more effective healthcare solutions. Companies will have to harness the power of new technologies such as IoT, cloud, mobile, big data and analytics, and social media, to seek greater value and succeed in this altering landscape.

The thoughts in this document have been derived from the perspectives shared by some of the key opinion leaders of the life sciences industry, at the Roundtable Event held by Infosys at Basel, on September 30th, 2015.

Event Speakers

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