

7

ROUTES TO NAVIGATE

CHALLENGES OF COMPLIANCE

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Pharmaceutical companies are heavily regulated.

These regulations impact all parts of the organization - not just the delivery of new drugs to market, but in terms of public safety, financing, mergers and acquisitions, and software development. These regulations are further complicated by geographical influences. Non-compliance to these regulations can result in million-dollar fines, bruised reputations, and in some cases - jail time. Hence, compliance needs to be managed closely across the entire organization to avoid the associated risks.

Here are 7 routes that Blueprint suggests are key to manage compliance in pharma.

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3. Involve regulators in your innovation process

There needs to be a tight alignment between your development teams and your compliance stakeholders. Make sure the two groups are able to collaborate, in real-time, and understand the impact of regulatory change on transformation initiatives.



4. Don't lose sight of the criticality of innovation and software development

Every company today is a software company, and if there isn't a digital transformation underway at your company, you are in jeopardy. Leverage compliance best practices that can streamline delivery and improve quality of all of your development initiatives.



5. Maintain an integrated, enterprise-wide compliance view

You need to be considering regulatory impact across all business units and stakeholder interests.



6. Focus on local compliance resources to mitigate risk

A broad view is not sufficient. Make sure you trickle down the policies, practices and controls so that local teams have the supports they need to comply.



7. Develop skills to achieve the right compliance talent mix

Compliance needs to be part of your DNA given its importance. Make sure you have resources in place to support this growing priority.

2. At all times, be ready for regulatory audits

No organization is truly compliant until the moment that the auditor signs off. Treat your compliance mandate as an ongoing initiative, and not a point-in-time state. Regulations change frequently, and you need to be able to demonstrate compliance to the auditors on-demand.

1. Support your teams to achieve and maintain compliance

Without regulatory context and ongoing support, your teams will lose sight of how their work aligns with the broader corporate compliance mandate. Make sure you are providing that context, along with the resources your teams need to achieve compliance.



HOW BLUEPRINT'S RCM SUPPORTS COMPLIANCE

Overwhelmed by demanding new and ever-changing regulations, organizations today are leveraging technology to help provide regulators and auditors with the information they need - better, faster, cheaper and more reliably than ever before.

Regain control of global regulatory change with Blueprint RCM:

- Swiftly and automatically identify regulatory changes and measure their impact
- Reduce costs by eliminating redundancies and automating change management
- Collaborate with stakeholders across the organization in real-time
- Demonstrate compliance with automatically generated audit trails and reports
- Provide a centralized view of enterprise-wide compliance programs

Blueprint Regulatory Change Manager resolves the complex compliance challenges that plague the world's biggest organizations. Blueprint is trusted by the Fortune 500 to ensure regulatory compliance and safeguard the business value of products from definition to delivery.

To learn more about Blueprint Regulatory Change Manager, visit www.blueprintsys.com or contact us at info@blueprintsys.com.

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