

Generics overview

Improving the performance of
business models while fueling
transformation and growth



Not unlike the broader Pharmaceutical market, Generics companies are being shaped by a number of powerful dynamics, such as regulatory reforms, the Affordable Care Act, globalization, and the convergence of the health care and life sciences industries. The industry is also experiencing strong growth fueled by patent expirations and the demand for less expensive drugs.

In this highly competitive market, companies must master a broad range of skills—from the legal sophistication to acquire new products through creative contract negotiation, to quickly bringing safe products to market. This requires effective regulatory, approval, and manufacturing processes, as well as strong distribution and channel management strategies. Business infrastructure rationalization is also essential to capture synergies and efficiencies, given the redundancies that are often created through acquisitions.

Insights spanning the entire payer, provider, and manufacturer ecosystem

The complexity of these changing market dynamics—for both Generic subsidiaries of more traditional Pharmaceutical corporations and companies that are primarily focused on Generics—means that business strategy development and problem solving requires a new level of rigor. That is why at Deloitte, there is no substitute for industry-wide insight. Our practitioners bring an informed perspective, spanning the pharmaceutical and health care market, from manufacturer and provider, to payer and governmental agencies to consumers. We also offer organizations a cross-functional approach to problem solving, strategy development, and implementation.

One important way we bring this insight is through innovation centers like client Greenhouses and other lab environments that cultivate and nurture new ideas and solutions. In addition, the Deloitte Center for Health Solutions produces research and other thought leadership that is objective, data-driven, and embraces a diversity of viewpoints on trends and issues affecting the U.S. Health Care system.

This informed perspective enables Deloitte to help organizations scan the horizon to anticipate future business opportunities, while increasing the value of their existing programs and investments.

Implementing solutions to critical business needs

Equally important is our ability to apply deep implementation experience to help clients turn powerful ideas into reality. With Deloitte, your organization's strategic and operational goals are core to our engagement process right from the start. This means that we pull together a team of practitioners to analyze and propose innovative solutions that meet your specific requirements and deliver enterprise value. When it comes time to execute, we bring a highly collaborative, hands-on approach and a depth of technical skill to each engagement.

We also know that a Generics company's complex challenges aren't typically solved by a single service offering, but rather through a multidisciplinary solution. At Deloitte, we offer a broad array of executable solutions that address our client's business challenges and opportunities. Unlike other professional services firms, this includes solutions spanning the business areas of audit, finance, tax, and consulting.



Improving business models and fueling growth

Evolution in the customer landscape, combined with portfolio diversification, rapid growth, and geographic expansion pressures, are presenting a range of new strategic and operational challenges for Generics companies.

Deloitte's Business Model and Growth Solutions focus on helping companies evaluate their business models to position themselves for continued long-term growth by capitalizing on the value of the pharmaceutical products being delivered to customers. This may include helping clients identify new opportunities, such as improving asset identification, business development, market expansion, and M&A success rates, while improving their existing portfolios to include higher-margin therapies. For companies who operate both branded and generic pharmaceutical businesses, our practitioners are skilled at helping increase efficiencies by realigning and consolidating organizational structures under a single leadership team.

Effective product launch planning and execution

Whether launching a branded or a generic product, it is essential for a Generics company's profitability to bring the drug to market as quickly as possible. As a product comes off of patent, speed and quality of contracting and supply are essential—whereas branded product launches require more communication and promotional capabilities to drive awareness and brand. Either way, the effectiveness of the product launch will likely greatly determine the new drug's success.

That's why Deloitte offers Product Launch Solutions. Not only can our experienced practitioners help guide you through a detailed launch readiness assessment, but they can also assist you with planning and executing your launch and post-launch strategy. This includes ANDA/NDA preparation and filing support, OPDP submission strategies, R&D, supply chain, manufacturing operations strategies, and even market entry strategies.

Improving supply chain efficiency and quality

Generics companies must consistently deliver the right combination of products, at the right time, and at the right cost while diligently monitoring product safety. This leaves little or no room for inefficiency. At the same time, the Generics industry is going through unprecedented change, putting new pressures on supply chain and manufacturing operations to develop agility and speed to compete in the changing marketplace.

Deloitte's Product Supply and Operations Solutions assist clients in meeting the overall goal of delivering quality products to their customers within their business constraints. Our offerings include a broad array of solutions, from supply chain strategy and integrity; strategic sourcing and procurement; and manufacturing network and operational excellence—to demand, supply and inventory planning, and distribution that includes access to emerging markets.

Enhancing commercial success through creative contracting and pricing excellence

Capturing and securing new markets requires effective marketing and sales strategies, as well as creative contract negotiation delivered through a broad legal discipline. It also means that companies must effectively position themselves as good partners that provide value to payers and, increasingly, larger provider organizations across the market.

When a Generics company wants to improve its commercial practices, Deloitte's practitioners offer a range of solutions that can help retool their commercial and portfolio management strategies. Our practitioners have a depth of experience in areas such as account and contract management, customer service, as well as areas like sales forecasting, pricing and analytics, inventory management, and marketing.

Managing risk, regulatory, and compliance issues

In a global environment, the risk and regulatory landscape is constantly changing. What is considered acceptable by the regulators and society today, can be out of sync tomorrow resulting in significant losses in reputation and shareholder value for the unprepared.

Against this backdrop, Generics companies need an effective, efficient, and ultimately frugal way to address regulatory requirements that impact their business activities and strategic objectives. Done correctly, effective management of risk, regulatory, and compliance issues is a competitive advantage.

With deep industry and regulatory experience, Deloitte's Risk, Regulatory, and Compliance Solutions have the capability to address the wide array of compliance and regulatory requirements facing our Generics clients. These capabilities include designing and implementing corporate compliance programs, addressing safety challenges, and remediating regulatory breaches. Our practitioners have helped clients develop and promote compliance standards, educate the workforce, and address potential violations. We also have assisted clients by responding to and interacting with regulatory authorities. But in each case, our approach to helping clients is custom-tailored to their different situation and needs.

Rationalizing infrastructure and building functional synergies

After experiencing rapid growth, often through M&A activity, today's Generics companies need help addressing redundant infrastructure issues and identifying ways to improve organizational performance.

Deloitte's Infrastructure Solutions help clients first improve the performance of their business models, then rationalize, transform, and build synergies across a range of functional areas, including IT, Finance, HR, and other back office functions. Once a sound infrastructure strategy has been developed, Deloitte's experienced consultants and technology practitioners work with clients to implement organizational structures and systems that can help support and sustain a company's long-term growth.



Deloitte's Solutions to Generics Market Issues

Market Issue	Sample Solutions	
Business model and growth Improving business models and fueling growth by identifying new acquisition targets, improving M&A success rates, and entering emerging markets	<ul style="list-style-type: none"> • Business model performance assessment • Branded and generic commercial business integration strategies • New growth opportunity identification • Commercial assessment and transformation • Corporate brand strategy • Contract adherence • IP review 	<ul style="list-style-type: none"> • Legal strategy • Government relations • Business development and pricing negotiation • Portfolio management • M&A strategies • Emerging markets and globalization solutions
Product launch Product launch preparation	<ul style="list-style-type: none"> • Launch readiness assessment • Product launch planning and execution • ANDA/NDA preparation and filing support • OPDP submission strategies 	<ul style="list-style-type: none"> • R&D project management • Medical affairs strategy and planning • Market entry strategies
Supply chain Enhancing supply chain efficiency and product supply and quality	<ul style="list-style-type: none"> • Supply chain strategy • Network rationalization and performance enhancement • Supply chain planning—demand planning, supply planning, inventory planning • Sales and operations planning • Sourcing and procurement • Supplier rationalization, stratification, and relationship management • Manufacturing scale-up, and Lean Six Sigma • GMP/QA/validation compliance 	<ul style="list-style-type: none"> • Manufacturing excellence, Lean Six Sigma • Contract manufacturing strategies and assessment • Logistics and distribution strategy and management • Supply chain integrity and secure value chain • Supply chain competency, career path, talent, and organizational design • Consent decree mitigation and compliance improvement offering
Commercialization Focusing on pricing excellence and creative contracting, while engaging new markets	<ul style="list-style-type: none"> • Account management strategies • Contract management strategies • Customer service enhancement • Sales forecasting and tracking solutions • Multi-channel engagement strategy and execution • Promotional effectiveness assessment 	<ul style="list-style-type: none"> • Inventory management solutions • Pricing strategies • Advanced analytics tools and techniques • Therapy area assessments and strategy • Revenue and economic value enhancement services • Marketing and resource planning services
Risk/regulatory/compliance Managing safety and reducing risk	<ul style="list-style-type: none"> • Compliance program review and assessments • Enhance labeling and promotional materials strategy and approval process Board risk oversight/governance education • Risk and compliance policy and procedure creation • Strategic risk assessment with a health reform lens 	<ul style="list-style-type: none"> • Incremental and transformational risk framework/procedures remediation • Quality and risk management review and enhancement • Regulatory inspection response and remediation • Pharmacovigilance system review and assessment
Infrastructure Rationalizing and building synergies across IT, finance, HR, and back office functions	<ul style="list-style-type: none"> • Business model performance improvement planning • Finance function transformation • IT services transformation • Sales force automation and eDetailing solutions • Digital marketing platforms and integrated solutions • HR transformation 	<ul style="list-style-type: none"> • CIO services • IT strategy • IT workforce assessment • ERP management • Information management and business analytics • Application management services

Globally positioned to be responsive

Our Life Sciences and Health Care practice leverages the extensive knowledge, skills, and experience of approximately 7,600 professionals in 76 countries around the world—with more than 3,900 professionals in the United States focused on meeting the complex and interconnected needs of Health Plans, Health Providers, and Pharmaceutical and Medical Device organizations. We recognize that this is an important factor to consider when selecting an organization, because as you expand into new markets, you'll need confidence that you will have the in-country support you need to achieve your goals.

“Deloitte provides one of the widest ranges of capability in the industry and the relationship models to support large program initiatives. The breadth of these capabilities and the organizational ability to integrate these skills together allow Deloitte to focus on a variety of strategic issues such as pricing and profitability, strategic commercial models and collaboration models for R&D.”

Source: Thomson Reuters. *MarketLine Industry Profiles Global Pharmaceuticals (2013)*.

World's #1 ranked Life Sciences professional services organization

Today, increasingly, clients need advisors who have the experience to understand the complexities of the Generics business in the context of the broader life sciences environment—while maintaining the skills, knowledge, and personal commitment to help their organization effectively navigate these extraordinary times.

The proof of our achievements is our track record. We have helped leading Life Sciences and Health Care companies effectively develop and implement customized services and solutions for more than 70 years. This has allowed Deloitte to claim its position as the world's #1 ranked Life Sciences professional services organization.¹

As the organization widely recognized as the industry leader—**serving nearly 90 percent of the 15 largest Pharmaceutical companies and 8 of the 10 largest Generics companies**—Deloitte will help you solve your toughest challenges, anticipate your next big opportunity and achieve lasting results.

We invite you to begin a conversation with Deloitte Life Sciences today.



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For additional information, please contact:

Faith Glazier, Deloitte Consulting LLP

Generics Segment Leader

fglazier@deloitte.com

+1 203 708 4224



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