

Strategic Solutions For Life Sciences Companies



Take control of your future

For life sciences innovators, today's dynamic healthcare environment offers tremendous opportunities, especially given technological advancements and rapidly improving clinical outcomes.

However, challenges to success are significant in complex and evolving global environments:

- With revolutionary changes in healthcare delivery models, innovators must deal with uncertainty and be ready to adapt quickly;
- The market simply won't accept marginal improvements—instead, life sciences companies are challenged to transform treatment paradigms in ways that demonstrate truly significant clinical and/or economic value;
- Hurdles to successful innovation and commercial success are increasing. They span shifting regulatory requirements, tightening access, increasingly restrictive budgets, and competitive pressures that vary significantly across therapeutic areas and global markets;
- Achieving corporate growth and financial goals demands accelerated commercialization of innovative products and therapies while deriving maximum value from existing assets, leveraging into smart adjacencies, and optimizing the value and return on investment across the entire portfolio.
- Increased enforcement, coupled with massive fines and penalties, can cripple any organization and only those that invest in effective compliance programs reduce the risk of improper behavior allowing the organization to focus on their core values and beliefs; helping treat patients in the highest ethical manner.

Left unresolved, any of these challenges can form roadblocks to success and can meaningfully limit future opportunities. But handled skillfully, they can reveal new pathways to success.





AT GUIDEHOUSE, WE COLLABORATE WITH PHARMACEUTICAL, BIOTECH, AND SPECIALTY PHARMA COMPANIES, AND MEDICAL TECHNOLOGY MANUFACTURERS TO HELP DELIVER MEASURABLE AND TRANSFORMATIVE RESULTS.

Guidehouse clients include 22 of the top 25 global life sciences companies as well as many more of today's most innovative life sciences organizations.

Our seasoned professionals and highly skilled specialists are located in Boston, Chicago, Minneapolis, Dallas, Los Angeles, New York, Princeton, San Francisco, Atlanta, Berlin, India, Shanghai, and London. With deep global relationships, we are uniquely able to augment our in-house expertise with on-the-ground research partners that further expand our perspectives in target markets.

We help life sciences companies build, manage, and protect their businesses by:

- Providing a foundation of insight to help clients grow and innovate, develop products, and **build** franchises;
- Developing solutions that help clients **manage** strategic, operational, and financial plans and thrive in the dynamic healthcare environment; and
- Delivering expert advice and counsel to help **protect** against competitive, market access, and regulatory risks while proactively anticipating and preparing for future challenges.

Guidehouse Life Sciences solutions

We work with clients to optimize decision-making at the product, business unit, and enterprise level.

Product—Planning and development

Market access, pricing, and reimbursement

Product—Commercialization

Franchise and business unit strategy

Corporate strategy

Regulatory and Compliance

Product — Planning And Development

Guidehouse teams work across the product lifecycle from portfolio planning, clinical development, and market development through launch and lifecycle management.

Our Life Sciences Strategy practice maintains a 360° view of the pharmaceutical, biotech, and specialty pharma industries as well as the global healthcare landscape in which life sciences companies operate. We routinely supplement our industry experience with broad provider, payer, and regulatory expertise in collaboration with Guidehouse healthcare practice. We access the perspectives of a wide variety of stakeholders to help our clients understand all the critical aspects of the marketplace.

We provide data-driven market analysis to help medical device and life sciences companies accelerate adoption and maximize growth. Our proprietary Science of Market Development methodology assesses the true barriers to broad market adoption informed by the comprehensive analysis of failed, niche, slow growing and wildly successful medical technologies. As a result, companies can invest and plan accordingly to realize a product's true market potential and improve ROI.

Guidehouse product planning and development solutions

- Customer unmet needs analysis
- TPP optimization and assessment
- Patient journey mapping
- Strategic Market Assessment (SMA)
- Market entry/go-to-market strategy
- Clinical development planning/clinical trial strategy
- Product life cycle planning
- Medical affairs strategy
- Advocacy group strategy
- Advisory board support



UNPARALLELED EXPERIENCE

Guidehouse 220+ life sciences advisors bring decades of experience in market development, new product planning, and the development of innovative life sciences products. They include:

Marie Cassese brings expertise in business innovation, profitability enhancement, evaluation of prospects for new technologies, formulation of strategies for growth, market entry, market development, and tactical implementation. She has published a series of articles on integrating market access into clinical trial design and the development of payer evidence programs in the international biopharma journal *IN VIVO*. In addition, Marie has served as a key senior executive in several multi-hospital health systems. Most recently, she held positions as president of an Atlantic Health System hospital and as a corporate officer of the Atlantic Health System in New Jersey. She also has years of experience as a cardiovascular advanced practice nurse.

Doug Martin, MD, focuses on product, disease, and therapeutic area strategy, new product planning, and due diligence on behalf of senior management, pipeline marketing, and business/corporate development teams. He has expertise in virtually every therapeutic area. Doug began his consulting career at McKinsey & Company. Prior to joining McKinsey, he completed his residency in internal medicine at Brigham and Women's Hospital, served as a teaching fellow at Harvard Medical School, and was elected Chief Resident at the West Roxbury VA Hospital, one of the program's two base hospitals.

Roger Zan joined Guidehouse from Novo Nordisk, where he led a number of commercial functions and developed specialized expertise. He brings extensive background in the pharmaceutical and medical device industries with broad experience in product development, launching new products, lifecycle management, and public affairs. He has worked on a variety of projects within primary and specialty disease areas, such as rare diseases, cardiometabolic, immunology, and CNS.

Powerful results

BREAKING INTO A CROWDED MARKET

The asthma market is crowded with therapeutic options. So, when our client developed a novel biologic therapy for the treatment of severe asthma and other indications, they needed a comprehensive product strategy to overcome the challenges associated with late market entry. Guidehouse drew insights from primary research, cross-functional input, and

Guidehouse asthma experience and expertise to develop a roadmap with clear strategies for medical affairs, market access, and marketing channels. The engagement allowed the client team to establish a roadmap for ongoing product planning, launch, and commercialization and to build broad consensus on future market perspectives and competitor expectations.

STRATEGIC MARKET ASSESSMENT

Applying the proprietary Strategic Market Assessment research and analysis framework, Guidehouse uncovered a multi-billion-dollar opportunity existed for a global medical device company with a new surgical robot technology. Research revealed, to date, most U.S. robotic surgeries targeted complex urology and gynecology procedures with high intraoperative conversion rates.

Guidehouse also identified other appropriate procedures to target, and provided an investment strategy and forecasting model to support the expansion initiative. While this investment would expand the market for all players, it made the competitive dynamics more manageable. With this new insight into the market landscape, the global company reset both its strategy and revenue growth expectations.

ADVOCACY GROUP STRATEGY

A multi-national pharma client hired Guidehouse to help organize its patient advocacy and outreach activities for several of its major brands in development. At that time, the activities had been disparate, one-off engagements with little coordination across the organization or with partners.

The Guidehouse team looked at the current state of activities, while benchmarking competitors, and then facilitated a workshop to help the client team prioritize where dollars are spent. Additionally, we tapped into experts from across Guidehouse healthcare practice, bringing clarity to the value expectations of payers and providers.

Product — Market Access, Pricing And Reimbursement

Securing market access is integral to optimal product development, commercialization, and lifecycle planning.

At Guidehouse, we collaborate with life sciences clients to help develop and integrate market research, analysis, and insights into clinical and commercial decision-making.

With a thorough understanding of country-level reimbursement landscapes and a broad network of key stakeholders, we are able to analyze the key dynamics and levers of market access strategy. We combine economic expertise with deep clinical expertise to identify and substantiate value drivers for products in development.

We help clients incorporate a market access mindset throughout the product development lifecycle from portfolio planning and early development decisions through market development and lifecycle management. Through stakeholder mapping, unmet needs and funding flow analysis, and value proposition optimization, we assist clients in defining and developing differentiated products through a full suite of value substantiation and quantification solutions.

Strategy, Evaluation, and Planning

- Stakeholder mapping/funding flow analysis
- Accurate and quantifiable disease modeling
- Strategic Market Assessment (SMA)
- Value proposition optimization/evidence substantiation planning
- Payer mock negotiations
- Pricing strategy (including qualitative/quantitative price finding studies)
- International price reference modeling

Go to Market and Commercialization

- Launch sequence analysis
- Billing and coding analysis and planning
- Payer policy surveillance
- Reimbursement policy development and legislative analyses
- Health economics and outcomes research (HEOR) studies and real-world evidence (RWE) generation
- Value dossiers and cost-effectiveness, and budget impact models
- Reimbursement hotlines, appeals programs, and other reimbursement support services

UNPARALLELED EXPERIENCE

Guidehouse consultants are experts at gaining access to new markets around the globe. They include:

Dr. Ravi Degun brings more than 10 years of experience in healthcare, life sciences, and R&D with experience in academia, government research, and consulting. Ravi serves major and emerging biological, pharmaceutical, and medical device companies, governments, and the European healthcare sector, focusing on market access/pricing and reimbursement, real world data collection, resource utilization, non-interventional studies, and commercial strategy. His background spans medical research focusing on oncology, virology (HIV), and immunology.

Jacob Graham works with clients to design comprehensive market access strategies with an emphasis on optimizing patient access at a value-based price. With a deep understanding of technology assessment, health economics, coding/payment policy, pricing, and commercial strategy, Jacob has helped many med-tech and biopharmaceutical clients to ensure that R&D, clinical, and market access initiatives align with financial expectations. He has also helped clients achieve meaningful coverage and payment milestones, attain commercial success, and raise capital.

Chance Scott operates as a key member of Guidehouse's Market Access Center of Excellence. Chance has a deep understanding of reimbursement mechanics, including medical policy development, novel coding pathways, and payment policy across settings of care. He leads many of the Firm's engagements for advanced diagnostics, as well as practice areas focusing on payer engagement and pricing strategies. Prior to joining Guidehouse (previously Quorum), Chance worked in a variety of capacities supporting commercial organizations. He spearheaded a number of launch readiness engagements while at Campbell Alliance Consulting Group. Additionally, he held several roles in the commercial organization at Genentech, including sales training and oncology field sales.

Powerful Results

INTERNATIONAL PRICE REFERENCING

Given the interconnectivity of price referencing, rolling out new products across different markets is tricky business for manufacturers. Most established pharmaceutical markets use pricing rules that reference products both across and within country-lines. These rules are known as “international reference pricing” (IRP) and “therapeutic reference pricing” (TRP). Understanding their impact on a global level is challenging, with each market basing pricing decisions on different legislation and mechanisms. Guidehouse set out to better understand the impact

of IRP and TRP on the decay of pharmaceutical drug prices and their effects on launch pricing and sequencing across multiple markets. We developed a model to quantitatively assess the impact of IRP and TRP, as well as parallel trade, on drug prices across major global markets. Outputs of the Guidehouse model include impact to volume, price, and revenue as well as parallel trade. Using a dynamic launch map, the model provides an optimal price and launch sequence of a given pharmaceutical product, helping manufacturers achieve maximum success.

REIMBURSEMENT OPTIMIZATION AND CUSTOMER ENGAGEMENT STRATEGY

Preparing for the launch of a new acute hospital-based treatment, our client engaged Guidehouse to validate their understanding of current reimbursement dynamics, explore new and innovative funding options, augment their team’s deep product knowledge with strategic and tactical expertise in detailed reimbursement processes and up-to-date approaches, and segment hospital and integrated delivery network (IDN) customers for access strategies and tactics. Guidehouse responded with a tailored solution that integrated the expertise of its Global Market Access Center of Excellence, Payer & Provider practice, and Healthcare Analytics team. We provided industry perspective on the policy,

market, and institutional dynamics that would directly and indirectly influence reimbursement; reviewed reimbursement options, identifying the highest probability pathways for securing optimal access and utilization; and developed action plans providing clear direction forward with a business case and an interactive dashboard linking together all supporting research to warrant future investment.

By combining landscape assessment, hospital segmentation, stakeholder mapping, and focus groups, Guidehouse helped the client achieve a successful launch supported by a refined value proposition and a comprehensive customer engagement strategy.

COMPREHENSIVE MARKET ACCESS PLANNING AND EXECUTION INCLUDING PAYER ENGAGEMENT, POLICY DEVELOPMENT, AND REIMBURSEMENT SUPPORT SERVICES

In preparation of launching a new physician administered drug, Guidehouse was engaged to understand the economic value of treatment and whether customer and payer adoption would be affected by different approaches to product pricing.

Guidehouse developed a new pricing strategy and comprehensive payer, customer, and patient-centric programs to drive adoption.

Customer support programs including a reimbursement hotline and appeals program were designed and

launched with market specific requirements in mind. Patient assistance programs and other tools were created to address any market access gaps and ease patient burden. In addition, Guidehouse developed comprehensive billing guides and aids, and facilitated in-person and on-line training programs to ensure adequate field based support.

Guidehouse also lead payer engagement activities related to coverage and pricing, and worked with coding groups to ensure proper coding and payment for physician services and the client’s drug.

Product — Commercialization

Guidehouse product commercialization specialists help our clients achieve the greatest possible market penetration for their new products.

Our consultants analyze market potential and assist clients as they forecast opportunities for new and existing products, optimize product positioning to healthcare providers, payers, and patients, map key decision-making stakeholders, set strategy and roadmap, prepare for launch, and execute tactics.

We employ an evidence-based research approach to provide insights into the patient journey and understand drivers that influence physician decision-making. To help assess the market landscape, our consultants use proprietary tools and methodologies to offer insights through strategic market assessments, geography planning, market landscape analysis, training, and disease reports. Importantly, we reach out to internal and external industry participants to better understand what it will really take for our clients' products to succeed in the real world.

In addition, Guidehouse supports global brand teams by establishing revenue forecasting/modeling and launch metrics/KPIs that our clients will align around and can rely upon..

Guidehouse product commercialization solutions

- Strategic Market Assessment (SMA)
- Stakeholder/key opinion leader mapping
- Competitive planning/war gaming/capability benchmarking
- Product revenue forecasting
- Sales force planning
- Geography planning
- Launch excellence
- Brand plan support
- Project management/resource support
- Loss of exclusivity strategy

UNPARALLELED EXPERIENCE

With 220+ life sciences advisors and 3,000 healthcare specialists, Guidehouse brings decades of diverse industry experiences to help clients plan and launch innovative new products.

Michele Fuller joined Guidehouse from Alcon, the ophthalmic division of Novartis, where she served as country business unit head of surgery in Malaysia and as pharmaceutical franchise head in Asia & Russia, based out of Singapore. Her experience spans nearly 20 years of commercial operations, marketing and sales, management consulting, and market research in the life sciences industry. In addition to those roles, Michele built and led a cross-franchise global marketing sciences function, including market research, analytics, competitive intelligence, and forecasting verticals.

Martin Trautmann partners with clients to execute large and complex pharmaceutical projects such as product launches and post-merger integrations, and he helps clients establish and manage alliances, transfer products, and execute sales force related initiatives. Over the past five years, Martin and his team have successfully supported the launch and commercialization of more than 15 pipeline assets and over 10 inline brands, and he has executed in excess of 50 complex projects. He specializes in developing and supporting highly flexible, adaptable, and innovative biopharmaceutical organizations.



Powerful Results

LAUNCH EXCELLENCE

A start-up medical device company was preparing for the launch of a transformational drug delivery system in a monopolized market to enhance the care of critically ill patients.

Guidehouse provided in-depth qualitative and quantitative primary research on critical launch opportunities and potential hurdles, as well as competitive benchmarking to guide internal infrastructure planning. We helped define roles and core job responsibilities,

guide headcounts and reporting structures, plan the timing of hiring and onboarding, and plan device servicing and support needs. We also developed dynamic revenue forecasting based on a robust, patient-based model, informed by market analysis and access to secondary data sources. The customized readiness and commercialization roadmap guided key activities, milestones, and timing in the 18 months prior to launch.

CUSTOMER EXPERIENCE OPTIMIZATION

Faced with persistent service challenges, a large pharma client engaged Guidehouse to redefine its overall customer experience for a cryopreserved cell therapy, including ordering and billing, supply chain logistics, and on-site storage, handling, and use. Guidehouse highly customer-centric

approach to this project included visits to more than 40 leading centers of care across the globe. The team's findings informed a detailed strategy and set of recommendations that the client will incorporate into future clinical programs and commercial launch plans.

PROJECT MANAGEMENT/BRAND RESOURCE SUPPORT

A specialty pharma client needed implementation support for an asset in the midst of worldwide launches. Guidehouse provided dedicated resources and hands-on project management.

In addition, the Guidehouse team organized logistical support for global launches (taking into account timing, supply, and regulatory considerations) and international reference pricing. We were then entrenched in brand

strategy and commercial readiness activities, working with several of the client's country teams to develop launch plans, define and build the set of materials they would need to support a successful launch, and develop key account plans. Guidehouse guidance led the client to become more organized through a critical transition period, and we trained and onboarded new client team members as they were hired.

Franchise, Business Unit, And Corporate Strategy

We use objective and fact-based assessments and prioritization of company portfolios, geographic opportunities, white space analyses and acquisition candidates. As a result, the organization shares a common language, common measures, and a systematic approach. Cross-functional teams move forward collaboratively with a mutual understanding of what success looks like and how to achieve it.

Guidehouse collaborates with clients to develop winning growth strategies at all levels of their organizations.

We help clients identify the therapeutic areas that are best suited for their investment. Supporting business unit leadership, we uncover promising opportunities for growth, balance risk and return, prioritize pipeline investments that support strategic goals, and help squeeze maximum value from de-prioritized projects.

At the corporate level, we help our clients envision and position for sustained success. Working closely with corporate leadership, we help identify platforms best aligned to three, five, and 10-year growth planning, down to the specific allocation of resources and investment, to position organizations for success.

Guidehouse franchise, business unit, and corporate strategy solutions

- Portfolio Management
- Strategic Market Assessment (SMA)
- Business development & licensing
 - Target search & prioritization
 - Due diligence/revenue forecasting (external asset assessment)
 - Asset valuation & transaction support
- Franchise/BU strategy development
 - Disease area landscaping
 - Franchise/BU strategy
 - Portfolio planning & management
- Franchise/BU commercial model
- Enterprise strategy development
 - Corporate strategy & board support
 - Alliance/partnership management
 - Organizational excellence strategy & execution
 - Digital technology strategy
 - Geographic strategy
 - Innovation planning

UNPARALLELED EXPERIENCE

Guidehouse experts help clients plan long-term strategies for accelerating business unit and corporate growth.

They include:

Ashwin Singhania has 12 years of consulting experience and an extensive practice with product launch and commercialization strategies, market access strategies, portfolio planning and optimization, and life cycle management. Ashwin has led teams across a variety of global client stakeholders, including brand marketing, market access, new product planning, business development, and medical affairs.

Eduardo Schur is the leader of Guidehouse Life Sciences practice and brings more than 25 years of experience in the pharmaceutical and biotech industries. Previously, Eduardo was vice president of marketing for Plavix, a blockbuster brand for Bristol-Myers Squibb. He also held multiple pharmaceutical marketing and sales management positions with Johnson & Johnson in the U.S. and abroad. Eduardo excels at strategic planning, commercial assessments, and new product launch readiness; his therapeutic areas of expertise include neurology, cardiology, infectious diseases, gastroenterology, and women's healthcare. Most recently, his work has been focused on oncology and immunology.

Powerful Results

FRANCHISE STRATEGY

A global pharmaceutical company engaged Guidehouse to help define their U.S. ophthalmology franchise strategy. Our team then screened more than 200 assets based on key criteria such as deal accessibility, mechanism of action, market potential, probability of technical success (PTRS), and development timeline. Through interactive working sessions with key client leaders, Guidehouse helped prioritize a short list

of high-potential targets. Guidehouse also produced a PTS-adjusted profit and loss model demonstrating the level of investment required and the timing of potential return on investment. The client team successfully aligned with senior leadership, and they will be moving forward with the implementation of the recommendations developed in partnership with Guidehouse.

STRATEGIC CORPORATE GROWTH

Guidehouse was engaged by a top healthcare company challenged to identify a new platform for promising opportunities that would not only deliver returns as a stand-alone investment but that would have a synergistic effect across its existing product lines. Guidehouse scanned the industry for investment opportunities and identified more than 300 potential technologies. We overlaid a rigorous set of criteria, including

asset availability, category economics, financial track record, likelihood of technical success, competitive differentiation, and strategic fit with the client's current assets and capabilities. Ultimately, Guidehouse identified six investment opportunities that, when combined with existing assets, would result in multibillion dollars in projected revenue by 2020 and grow five-fold by 2025.

FLEXIBLE CAPABILITIES, STRATEGIC SUPPLIER RELATIONSHIPS

A large traditionally structured pharmaceutical company struggled to adjust to changing market dynamics and client needs. Seeking to propel commercial growth, it engaged Guidehouse commercial excellence team to work across a wide range of strategic,

operational, regulatory, and portfolio management challenges and develop an integrated insight generation platform that was faster, cheaper, and more effective than the company's previous methodology.

Therapeutic Area And Industry Expertise

With more than 150 life sciences experts and over 3,000 healthcare specialists globally, Guidehouse brings unparalleled experience and expertise to the life sciences industry.

Our team includes leading experts — including many MDs and PhDs — with deep experience in:

- Cardiology
- Critical care
- Chronic disease
- Diagnostics and Monitoring
- CNS/Neurology
- Immunology
- Infectious disease
- Oncology
- Ophthalmology
- Orthopedics
- Pulmonology
- Rare/orphan diseases
- Urology
- Vaccines
- Women's healthcare

Our clients include the world's leading pharmaceutical, biotech and specialty pharma companies.

Our medical device and diagnostic clients span the life sciences industry, including traditional global device manufacturers, innovative device and diagnostic newcomers, and companies pioneering digital devices and sensors, software, and apps for data and analytics and technology-enabled services.



UNPARALLELED EXPERIENCE

Guidehouse consultants draw expertise from decades of hands-on industry experience. Our team includes:

Douglas Martin, MD has more than 20 years of life sciences consulting experience. His primary focus is product, disease, and therapeutic area strategy, commercial excellence, and due diligence on behalf of senior management and pipeline marketing and business/corporate development teams. He has worked in virtually every therapeutic area and primarily serves biopharmaceutical clients and their investors.

Peter Lang leads the Guidehouse oncology group and brings more than 20 years of consulting and industry experience working with pharmaceutical and medical device clients. He has deep expertise in strategy development and strategic brand planning, product launch, marketing, business development, new product evaluation, and post-merger integration. Peter has extensive knowledge across various areas including oncology, ophthalmology, cardiovascular health, and women's health, as well as various medical device markets and technologies.

John Etchberger has more than 6 years of experience in consulting specializing in commercial strategy and marketing, including launch strategy and value proposition development, for pharmaceutical and biotech companies. John works with clients in the pharmaceutical and biotech industries to address critical portfolio and product strategy issues.

Catherine Ellis works with clients from a variety of all sizes — from global corporations to smaller, single-technology companies. With expertise in both acute and post-acute settings, she collaborates with clients to assess growth opportunities, develop business and market access strategies, and provider commercial support, including due diligence, market assessment and development, forecasting, portfolio analysis, and competitive intelligence.

Life Sciences Regulatory and Compliance

MANAGING COMPLEX RISKS

In the complex regulatory environment of today's pharmaceutical, biotech, medical device, and diagnostics industries, companies and their counsel face an increasing number of dispute, regulatory, compliance, and investigation issues that have the potential for significant financial, economic, and reputational impact.

Guidehouse is the firm of choice when companies and their counsel need a resource that can successfully and efficiently integrate the skills of complex data management and analysis with the synthesis of highly-complex healthcare transactions, rules, regulations, data, documents and business practices to bring meaningful value to the co-development of a dispute, regulatory, compliance, or investigation strategy and execution.

Saul Helman, MD provides support in investigations, litigation, and compliance integration matters involving healthcare and life sciences companies. Applying his knowledge, secured through working in international marketing and clinical development for two decades, Saul has led projects involving expert witness testimony, litigation support, compliance implementation and assessment, and investigation support.

J. Mark Farrar, CPA, CFE, CFF advises clients in Europe, South America, Africa, Asia, and the U.S. on complex compliance issues including anti-bribery and anti-corruption program development, sales and marketing compliance, economic damages, global transparency, privacy and GDPR issues, conducting risk assessments, assessing patient support programs, and various auditing and monitoring assessments. Mark has served as the Independent Review Organization for a number of life sciences organizations and advises Boards on the creation and development of compliance programs.

David Berger advises on global regulatory strategy, labelling, regulatory submissions (IND, NDA, ANDA, 505(b)(2), BLA, 510(k) and Rx to OTC switch), quality management systems, and product lifecycle strategies. David's experience includes: developing strategies for regulatory affairs and quality assurance teams in connection with FDA matters and proceedings (including Type A, B and C meetings and appeals); leading multi-disciplinary teams in response to Warning Letters and 483s and conducting mock audits; establishing promotional review committees, policies, procedures, as well as databases for collateral; advising on pharmacovigilance matters; reviewing advertising and promotional collateral for compliance with OPDP/FDA rules, regulations and guidance; and managing and overseeing clinical trial agreements (including informed consent forms, study protocols and IRB proceedings).

Ann Beasley, JD has extensive experience in building, managing, and optimizing corporate compliance programs in life sciences companies. With a deep understanding of anti-bribery and anti-corruption, conflicts of interest, and regulatory matters, Beasley has worked with executive management teams to ensure that governance and oversight obligations are fulfilled and outstanding issues are identified and addressed.



COMPLEX FDA REGULATORY COMPLIANCE

A major diagnostics company required assistance with ongoing recalls and interactions with the FDA, responses to FDA 483 and Warning Letter findings, identifying and remediating quality system gaps and FDA inspection preparedness. Guidehouse was engaged to assist and deployed multiple consultants at each site to perform a variety of functions including: quality system gap analyses; mapping existing processes and skill sets to determine best course of action for addressing gaps/redundancies based on business strategy, needs, and

risks; participation on corporate quality improvement teams; assistance with FDA readiness including identification of front and back rooms; training of employees and subject matter experts; mock inspections and the creation of tools to assist with an inspection; and project management for remediation activities. The company was able to successfully navigate their regulatory compliance challenges with the FDA and achieve good standing and maintain access to their diagnostics supporting patient care.

DEPARTMENT OF JUSTICE LAUNCHES ANTI-KICKBACK INVESTIGATION

A global medical device company received a subpoena related to their contractual arrangements with healthcare professionals. Outside counsel turned to Guidehouse to investigate the company's arrangements and determine risk, support settlement activity and recommend actions to address risks. The Guidehouse team established a statistically relevant sample, analyzed extensive data sets and quantified the

potential risk and related exposure. Working with outside counsel, our recommendations provided a road map to ensuring healthcare professional arrangements were established with the appropriate controls to manage risks associated with the Anti-Kickback Statute, while maintaining healthcare professional relationships that continued to support product development and product use.



GLOBAL CAPABILITIES

Guidehouse's global capabilities help clients achieve success across borders:

- Our expanding global network covers over 40 markets, including the EU, Central & Eastern Europe, U.S., Canada, Latin America, the Middle East, & North Africa. We serve the Asia-Pacific region with offices in China, India, Singapore, and South Korea.
- Our global network allows us to connect with the most relevant stakeholders to help solve your strategic market challenges.
- We personally manage our global network of payers, key opinion leaders, policy makers, and leading academics.
- We speak 15 major languages fluently in-house, enabling us to conduct stakeholder interviews in key established and emerging markets.
- All of our staff are fully trained in best practice interview methods, ensuring the highest quality insights are gained.

Integrated Solutions

With broad ranging expertise, including healthcare, transaction advisory, and risk and compliance management services, Guidehouse's is prepared to help life sciences clients with specialized solutions that are beyond the expertise of most consulting firms. Here are a few samples of our specialized solutions.

HEALTHCARE

Guidehouse's life sciences professionals work closely with experts from our healthcare practice, which serves the full landscape of payer, provider, pharmacy, and other channel customer segments. Our clients include hospitals and other provider institutions, accountable care organizations, academic medical centers, physician group practices, commercial payers, public payers (CMS, Medicaid), health plans, government agencies, pharmacies and pharmacy benefit managers.

Guidehouse healthcare clients span more than 300 health systems, including 11 of the 15 "Honor Roll Hospitals" as rated by U.S. News & World Report and 80% of the largest health systems in the United States as listed by Definitive Healthcare. This expertise allows us to bring our clients a deep understanding of important market trends and dynamics in the payer/provider universe.

VALUATIONS

We are experts in analyzing and valuing businesses, ownership interests, and intangible assets. Our professionals also specialize in real, personal, fee-for-service, and intellectual property valuation studies as well as fixed asset inventory and asset management services. Clients rely on our valuation studies and fairness opinions to help raise capital, support mergers and acquisitions, conduct due diligence, and support tax positions.

REGULATORY AFFAIRS, QUALITY, AND PATIENT SAFETY

Guidehouse's extensive industry experience provides U.S. and international clients comprehensive solutions for regulatory, quality, and patient safety issues. Our team delivers expert advisory services to a wide array of companies in the life sciences sector — from pharmaceutical and biologic businesses to those involved with manufacture and distribution of medical devices, in-vitro diagnostics, companion diagnostics, and digital/connected health technologies. Partnering with clients to manage risks and create optimal solutions during all phases of a product's life cycle — from product concept and early planning to registration with FDA, EMA and related international agencies to post-approval compliance — we regularly manage challenging projects to help maintain compliance with the stringent and evolving regulatory requirements worldwide.

GOVERNANCE, RISK MANAGEMENT, AND COMPLIANCE SERVICES

The core operations of global life sciences companies are inherently exposed to increased risk. This industry is among the most heavily regulated in the world. We help U.S. and international companies navigate these unparalleled challenges by providing a full range of global compliance solutions. Our team includes a diverse mix of individuals ranging from former chief compliance officers from industry to veterans from government agencies (FDA, EMA, OIG, CMS, DOJ, FBI, SEC, CIA, SFO) who have been at the forefront of the industry for decades. Our unique, firsthand expertise gives clients the competitive edge they need to manage and protect their businesses. Our team provides a wide range of proactive and reactive services that include:

- Serving as the Independent Review Organization or Board Advisor pursuant to Corporate Integrity Agreements
- Performing 3rd party due diligence as a part of establishing a comprehensive anti-bribery anti-corruption program
- Assessing patient assistance and support programs
- Establishing global transparency programs
- Conducting various auditing and monitoring assessments
- Performing internal investigations
- Creating and operationalizing compliance risk assessments
- Establishing compliance programs for new and emerging companies

The services listed above only scratch the surface on the compliance advisory services our team can provide. We are often called upon to help solve problems that are emerging in the industry as our experts offer out of the box problem solving and are tailored to each organization.

INVESTIGATIONS AND LITIGATION SUPPORT

Guidehouse's investigators help clients with matters involving allegations or suspicions of potential fraud, misconduct, or violations of regulatory requirements. Our team includes former law enforcement professionals such as special agents from the FBI and the criminal investigation unit of the IRS, former federal and state prosecutors, certified public accountants, individuals with advanced business and law degrees, certified forensic and e-discovery professionals, and technologists with data analytics and systems expertise. These experts also support litigation matters with expert advisory and testimony, including both industry insights and economic analysis.



DATA ANALYTICS, INFORMATION SECURITY, AND DATA PRIVACY

The data life sciences companies collect can be a powerful tool to assess and manage risk. The challenge is that this data is often spread across many disparate systems, both in-house and in the cloud, which can be difficult to manage, aggregate and analyze to insight. This same data may also increase the potential for risk in any organization for privacy and cybersecurity, and life sciences companies need to make sure their data is properly governed and utilized. As a result, organizations must develop policies, procedures, and documentation demonstrating global compliance that can also be operationalized by employees — all the while continuing to move business forward.

Guidehouse supports our clients through our collaborative expertise in compliance, data management and security from both a governance and technical level. We can help life sciences companies develop processes to address their needs through effective data mapping, data blending, data analytics, dashboarding, and reporting. Our technical capabilities are a differentiator, complementing our life sciences subject matter experts who understand the risks and business problems facing today's life sciences companies and advise across the product life cycle, including product planning, commercialization, compliance and risk monitoring, regulatory requirements, transparency and reporting, and complex litigation or investigations.

- Data Privacy and Security - Assessment and risk management; Policies and procedures; Privacy program governance (HIPAA security requirements and workforce training; Breach response process; Patient rights issues); General data protection regulation (GDPR)
- Data Analytics, Management, and Visualization — Risk and business evaluation; Data Mapping, Analytics and Quantum Analyses; Centralizing disparate systems into a single platform to perform predictive analysis and present findings that are easy to understand



Contact

To learn more about Guidehouse life sciences capabilities, visit [Guidehouse.com](https://www.guidehouse.com) or contact lifesciences@guidehouse.com.

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