

Strategic Solutions for Life Sciences



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

Guidehouse has built an international reputation as a preferred expert and trusted partner for life sciences companies seeking to mitigate risk while achieving exceptional growth.

Clients turn to our experts to address an ever-changing, increasingly complex and heavily regulated global market, while striving to deliver innovation to the market in the pursuit of enhanced patient care outcomes.

Our Life Sciences Team

- Provides a foundation of insights to help clients grow and innovate, and develop products, brands, and build franchises.
- Develops solutions that help clients manage strategic, operational, and financial plans, and thrive in the dynamic healthcare environment.
- Implements reimbursement strategies and manage hub Services for complex and innovative products coming to market.
- Evaluates the regulatory environment and support clients with Food and Drug Administration, European Medicines Agency and equivalent body submissions and responses.
- Builds, implement and test healthcare compliance programs.

Solutions & Offerings

We engage in thought partnership with clients to develop insights and solutions to address business challenges. We work closely with **pharmaceutical companies, biotechnology, and medical technology manufacturers** to help deliver measurable and transformative results.

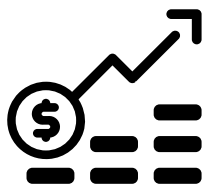
We work with Life Sciences clients to optimize decision-making at the product, business unit, and enterprise level:





Key Contacts

- **Aaron Krause**, Partner
- **Ben Resnick**, Partner
- **Roger Zan**, Partner
- **Jean Chen**, Partner
- **Karla Anderson**, Partner
- **Srikanth (Doc) Rajagopal**, Partner
- **Maya Desai**, Director



Key Contacts

- **Chance Scott**, Partner
- **Jacob Graham**, Partner
- **Youbean Oak**, Director

Guidehouse | Life Sciences

Commercial Strategy and Planning

Our commercial strategy and planning service line provides our life sciences clients with a suite of solutions that integrate science, clinical and commercial strategy providing extensive experience across numerous geographies, indications, and market environments. Our team partners with clients to drive innovative solutions and develop data-powered winning brand and portfolio strategies.

We bring a multidisciplinary, cross-functional view to every engagement, offering services and solutions throughout the product life cycle:

- New Product Planning
- Commercial Launch Strategy & Execution
- Life Cycle Management Strategy & Execution
- Brand Revenue, Profit & Loss Forecasting
- Franchise/Portfolio Strategy & Management Optimization
- Commercial Model & GTM Design, Implementation & Evolution
- Organizational Design & Change Management

Guidehouse's commercial excellence support model provides integrated solutions adapted to the needs of our clients' organizations. Our deeply experienced team of commercial specialists provides flexible support that allows life sciences companies to maximize commercial impact and minimize risk at the product, portfolio, and company level.

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Pricing, Market Access & Reimbursement

Guidehouse's market access services and solutions start with strategy development and extend through tactical execution.

We bring a multidisciplinary, multifunctional view informed by an extensive payer network and industry-leading data resources. A dedicated team of Pricing, Market Access, and Policy experts provides a wide range of services and cross-functional expertise. We are industry-leading when it comes to developing, communicating, and molding the market to capture an asset's value.

We offer market access services and solutions to support all phases of product development and commercialization:

- New Product Planning
- Pricing & Contracting Strategy
- HTA & Evidence Planning Strategy
- Payer Marketing
- Health Economics & Outcomes Research
- Reimbursement Policy
- Coding Strategy
- Hub & Patient Services Strategy
- Access Launch Excellence



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MedTech & Diagnostics

Our MedTech, Diagnostics, and Data Science team of experts helps organizations address unique challenges in the increasingly digital medical technology industry, helping them reach their full potential in the US and around the world.

Our extensive network across the healthcare ecosystem brings a multidisciplinary, cross-functional view to every engagement.

Our experts and network of trusted advisors allow for:

- **Expert opinion** on complex topics pertaining to evolving policy, and clinical and regulatory landscapes.
- **Quick turnaround** on client questions that need expert opinion and advice.
- **Converting** meaningful patterns in customer data through advanced analytics and machine learning, insights, and more effective engagement strategies.
- **Proven market development strategies** to guide meaningful innovation and important decisions at every stage of the product journey.
- Designing tailored customer engagement approaches and resources to **optimize the customer experience** and outcomes.
- **Holistic approach** to understanding the **entire ecosystem** and how to effectively and efficiently impact it.



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Strategic Market Development

Using proven, proprietary methodologies, we offer data-driven critical thinking and analysis to deliver the scientific validation and actionable insights our clients need—before they invest too much or overcommit too early.

Through comprehensive, fact-based research and analysis, we determine the realizable market potential for medical technology and pharmaceutical products as accurately as possible. Our strategic market assessment methodology also informs every stage of product development, spanning clinical trials, fundraising, commercialization, marketing, and market development investments, as well as partnership, acquisition, and exit.

Our Science of Market Development methodology, as pioneered by Dymedex Consulting (now part of Guidehouse), utilizes 14 critical factors to identify, assess, and reduce market risk to help promote the commercial success of ventures. This rigorous process uncovers opportunities, avoids costly pitfalls, increases value, and reduces time and investment.

As a result, we help clients align across the organization, achieve key milestones, successfully secure funding, and develop more powerful go-to-market strategies. Our solutions include:

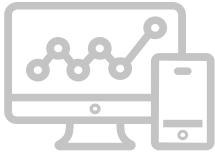
- Strategic Market Assessment.
- Market development, entry, and launch strategy.
- Clinical development strategy.
- Global geographic prioritization.
- Portfolio management/Product planning and development.
- Revenue and growth forecasting.

Key Contacts

- **Marie Cassese**, Partner
- **Mike Fix**, Director
- **Michele Fuller**, Director

Key Contacts

- **David Weiss**, Partner
- **Mike Fix**, Director



Key Contacts

- **David Weiss**, Partner
- **Meredith Moore**, Director
- **William Woywod**, Associate Director

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Digital & Advanced Analytics

We have experience deploying and supporting various technologies across the digital health landscape for our clients. Our teams are expert communities who help organizations transform to realize personalized care via digital health, machine learning, and AI. Our digital and advanced analytics capabilities include:

- Digital transformation.
- Digital health strategy.
- Machine learning-based digital diagnostics and therapeutics.
- Digital approaches to commercial optimization.
- Digital/EMR integration, certification, and application development.

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Key Contacts

- **Elena Stavrakas**, Partner
- **Peter Lang**, Partner
- **John Etchberger**, Partner

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Business Development, Valuation & Transaction Strategy

We understand the sophistication and rigor needed for life sciences companies to successfully navigate business development decisions. From partner and target searches to forecasting, valuation, and transaction advisory, our team has the experience to support the full suite of business development needs. We specifically support our clients with:

- Target search, evaluation, and prioritization analysis.
- Opportunity and Market Assessments.
- Forecasting & Valuation.
- Transaction Advisory.
- Post-merger Integration.



Key Contacts

- **Roger Zan**, Partner
- **Rory Graham**, Director

Guidehouse | Health

Regulatory, Quality & Patient Safety

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

Our portfolio of regulatory services across the life sciences spectrum includes:

- Regulatory Pathway Planning, Analysis & Strategy
 - EU MDD to MDR transition
 - Global Regulatory Development Strategy and pathway development for Pharma/Biotech/Combination/Device products
- Design Controls and Product Realization
 - Software as a Medical Device (SaMD)
 - Artificial Intelligence and Machine Learning (AI/ML)
 - Combination Products

- Regulatory Agency submissions
 - United States NDA, ANDA, PMA, 510(k), BLA submissions
 - EMA: MAA, CTA, ODD, PIP, Scientific Advice
 - PSMF, Pharmacovigilance system and associated Quality System design and implementation
- Quality Management System Implementation
 - ISO 13485, 9001, etc.
 - GAP analysis, Planning, Strategy, Training
- Inspection Readiness Audits
 - Mock FDA, EMA, MHRA and Notified Body audits
- Nonconformance remediation
 - FDA Warning Letters
 - FDA 483
 - Notified body audits
- Software Implementation
 - Design and execution of RIMS (regulatory information management systems) and eQMS (electronic Quality Management System)
- Litigation support for clients and their counsel
- M&A Due Diligence and post-deal integration
- Regulatory compliance with applicable product regulations, guidance, and international standards
- Supplier management for low, medium, and high risk providers



Key Contacts

- **Thomas Hauser**, Director
- **Jenny Pu**, Associate Director
- **Enno Behrendt**, Associate Director

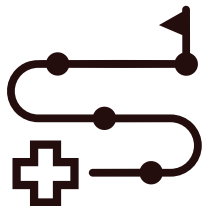
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Risk Management, Compliance & Data Privacy

In the complex regulatory environment of today's pharmaceutical, biotech, medical device and diagnostics industries, companies and their counsel face an increasing number of governance, risk management, and compliance and data privacy issues that have the potential for significant financial, economic, and reputational impact. Guidehouse is the partner of choice when companies and their counsel need a firm 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 governance, risk management and compliance strategy and execution.

Our Governance, Risk Management and Compliance capabilities include:

- Comprehensive compliance program assessment and support.
- Industry code reviews.
- Compliance Assessment and Risk Evaluation development and implementation.
- Compliance auditing and monitoring.
- Discrete issue compliance assessment.
- Due diligence.
- High-effectiveness training and compliance culture-building.
- Contract/vendor compliance.
- Global compliance program development and implementation.
- Comprehensive data privacy and security assessments and program implementation



Key Contacts

- [Liisa Eisenlohr](#), Associate Director
- [Michaela Scheiner](#), Associate Director

support, including Health Insurance Portability and Accountability Act and General Data Protection Regulation compliance.

- Board-level compliance effectiveness certifications.
- Interim compliance officer support services.
- Global transparency assessments and implementation.
- Third-party due diligence.

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Medical Affairs


The Medical Affairs team supports clients across a wide range of medical affairs needs, spanning Europe, the United States, Asia-Pacific, the Middle East, and beyond. Our approach to developing a comprehensive medical affairs strategy is to:

- Understand the client's strategic and operational needs.
- Together define the areas of focus for the collaboration.
- Partner with the client to co-create the medical affairs strategy.
- Conduct a landscape and competitive intelligence evaluation for markets in question.
- Assess patients' medical needs and develop the patient journey.
- Map key stakeholders (nationally and internationally).
- Prepare the company by supporting organizational setup.
- Ready the product.

We offer seamless and integrated specialist services across the Medical Affairs function for diverse therapeutic areas covering prescription, medical device, and over-the-counter products:

- **Medical strategic activities**
Development of an integrated medical strategy for approved/licensed products and new molecular entities
- **Medical communication**
Publication planning and scientific/medical communications (including conference planning)
- **Medical information**
Development of standard response documents, evaluation of processes, and training of internal and external teams
- **Medical education**
Support of healthcare professional (HCP) education and training of internal sales force and medical teams
- **Medical research**
Planning and execution of late-phase and real-world evidence studies
- **KOL/external expert activities**
KOL/external expert mapping nationally and internationally and devising KOL activity trackers
- **Medical field team (MSL) support**
Regional mapping of MSL activities, developing key performance indicators and communication of scientific information through MSLs
- **Digital innovation**
Support the implementation of machine learning and AI to improve HCP interactions via digital platforms



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About Guidehouse

Guidehouse is a leading global provider of consulting services to the public sector and commercial markets, with broad capabilities in management, technology, and risk consulting. By combining our public and private sector expertise, we help clients address their most complex challenges and navigate significant regulatory pressures focusing on transformational change, business resiliency, and technology-driven innovation. Across a range of advisory, consulting, outsourcing, and digital services, we create scalable, innovative solutions that help our clients outwit complexity and position them for future growth and success. The company has more than 12,000 professionals in over 50 locations globally. Guidehouse is a Veritas Capital portfolio company, led by seasoned professionals with proven and diverse expertise in traditional and emerging technologies, markets, and agenda-setting issues driving national and global economies. For more information, please visit www.guidehouse.com.

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