

6th Due Diligence Summit for Life Sciences

Cross-functional perspectives and best practices for conducting efficient and effective due diligence on M&A, licensing and strategic alliance targets

Speakers



Ian Hassan, Ph.D.,
*Vice President,
Head of Due Diligence
and Business Intelligence,*
BAYER



Chris Davie,
*Executive Director,
Diligence,*
**MUNDIPHARMA
RESEARCH LIMITED**



Jill Kearney, MBA,
*Director, Licensing and
Acquisitions, BioResearch
Quality and Compliance,*
JOHNSON & JOHNSON



Chris Vlahos,
*Global Head,
Rare Disease External
Innovation,*
IPSEN



Will Tilton, MBA,
*Former Group Vice
President, Due Diligence,
Integration, and
Divestment,*
SHIRE

May 20-21, 2019

Sonesta Philadelphia Downtown Rittenhouse Square
Philadelphia, PA

Conference Chairperson



Mike Myers,
*Senior Director, Lilly Research Labs —
Due Diligence, ELI LILLY AND COMPANY*

Key takeaways

- ✔ Gain valuable insight from cross-functional due diligence team members, as well as leaders in the medical device and biotech industries
- ✔ Understand how to conduct a comprehensive intellectual property due diligence investigation, and how it can alter the strategy for your deal
- ✔ Learn how to evaluate and effectively manage strategic alliances through case studies from industry leaders
- ✔ Explore best practices for companies of all sizes looking to acquire or in-license a product
- ✔ Discover the impact company culture can have on the success of integrating the workforce post-merger or acquisition

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DEAR COLLEAGUE,

With pharma and medtech R&D not providing the ROI companies have been used to in the past and many organizations consolidating their therapeutic focus, companies are often looking at external targets to bolster their product pipelines or find the ideal strategic partner to develop a product with. They have to field partnering requests and evaluate potential targets in a short amount of time to ensure they don't miss the best opportunity. Managing this efficiently, discreetly, and on a global scale requires a robust process, as well as the right talent. Whether it is a licensing deal, a co-development venture, or an outright acquisition, companies need to understand how to develop a tailor-made approach to conducting due diligence for the specific transaction, while ensuring they are taking a 360-degree view of all positive and negative possibilities.

With a limited number of resources and forums dedicated solely to life science due diligence, this Summit has provided cross-functional professionals with a platform for the last five years to explore innovative models and deal structures for collaborating with strategic partners and discuss valuable strategies for conducting efficient and effective due diligence.

The **6th Due Diligence Summit for Life Sciences** is the industry's leading event focused on the needs of cross-functional due diligence professionals with an agenda that continues to evolve year over year. Join our esteemed speaking faculty as they educate due diligence professionals on the different aspects and challenges faced by functional team members, share tactics to improve process management, and provide attendees with the strategies and insight they need to mitigate risks and ensure a profitable investment in a new product, portfolio, company or strategic alliance.

My team and I look forward to meeting you in Philadelphia!

Sincerely,

Zohaib Sheikh

Zohaib Sheikh
Senior Conference Director
ExL Events, a division of Questex, LLC

VENUE INFORMATION

Sonesta Philadelphia
Rittenhouse Square

1800 Market Street
Philadelphia, PA 19103



To make reservations, guests can call 1.800.SONESTA and request the negotiated rate for **ExL's May Meetings**. You may also make reservations online using the following weblink: bit.ly/2EnokbG. The group rate is available until **May 7, 2019**. Please book your room early, as there are a limited number of rooms available at this rate.

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WHO SHOULD ATTEND

This conference is designed for representatives from pharmaceutical and biotechnology companies with responsibilities in the following areas:

- Due Diligence
- Business Development
- Licensing
- Alliance Management
- Mergers and Acquisitions
- Intellectual Property/Patent Counsel
- Search and Evaluation
- Portfolio Management
- Scientific Assessment
- General Counsel/Corporate Counsel
- Legal and Regulatory Compliance
- Regulatory Affairs
- Research and Development
- Commercial Assessment/Strategy
- Business/Strategic Planning

This conference is also of interest to:

- Due Diligence/M&A Advisors
- Accounting/Tax Advisors
- Management/Strategy Consultants
- Law Firms
- Investment Banks
- Private Equity Firms
- Venture Capitalists
- Data Room Providers
- Regulatory Affairs and Compliance Partners

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8:00 Registration and Continental Breakfast

8:45 Chairperson's Opening Remarks
Mike Myers, Senior Director, Lilly Research Labs —
Due Diligence, **ELI LILLY**

9:00 Effective Cross-Functional Communication: The "Bedrock" of the Due Diligence Process

- Gain an overview of the Bayer due diligence process
- Understand how project-based, global teams tasked with conducting high stakes evaluations in a limited time, among other factors, can cause potential communication issues
- Discuss how to breakdown functional silos to create high-functioning teams
- Explore best practices and the use of tools and training to ensure deal risks are effectively communicated across the project team

Ian Hassan, Ph.D., Vice President, Head of Due Diligence and Evaluation, **BAYER**

9:45 Interactive Learning Discussion: Discover How Your Peers Conduct Due Diligence at Their Organizations

- Discuss due diligence challenges and successes in an informal setting
- Share best practices and strategies as a group for problems suggested by your peers
- Explore innovative approaches to due diligence as conducted by industry leaders

Mike Myers, Senior Director, Lilly Research Labs —
Due Diligence, **ELI LILLY**

10:30 Networking Break**11:00 Strategies for Efficient Prediligence Evaluations**

- Triage: Focus on opportunities of value
- Build and engage a rapid assessment team
- Learn how to identify potential pitfalls before committing the resources necessary for a full diligence

Chris J. Vlahos, Ph.D., Global Head, External Innovation for Rare Diseases and Neuroscience, **IPSEN**

11:45 From Diligence to Implementation: The True Impact of Transactional Success

- Completion of due diligence will result in risks and opportunities for translation into deal terms
- Alongside opportunity risks, there are implementation activities requiring consideration for bringing products into the portfolio
- Full diligence should encompass not only the scientific, technical, commercial related considerations but also the internal activities necessary to fully embed the opportunity within the portfolio
- Highlight the criticality of implementation considerations (resource, financial, timelines), and how these might impact diligence outcomes and opportunity valuation

Chris Davie, Executive Director, Diligence,
MUNDIPHARMA

12:30 Luncheon**1:30 Outbound Due Diligence: Finding the Right Partner for the Right Opportunity**

- Explore various partnering models depending on the type of opportunity
- Examine the out-bound diligence process
- Consider the importance of finding strategic alignment
- Hear how to get the partnership moving forward after deal signing

Jane Daun-Tremblay, Ph.D., Director, Due Diligence,
EMD SERONO

2:15 The Coming Tsunami of Digital Therapeutics and Implications for BD&L Strategy

- Understand what digital therapeutics are and where the market is today
- Discuss the potential of digital therapeutics to impact patient experience, adherence, tracking/monitoring, and more
- Examine case studies of how companies are partnering with digital therapeutics companies and review the lessons learned
- Identify the strategic impact of digital therapeutics for biopharma BD&L teams

Brad Payne, MBA, Partner,
ARTISAN HEALTHCARE CONSULTING

3:00 Networking Break**3:30 Identify Negotiation Factors That Can Impact the Purchase Price and Deal Structure of a Transaction**

- Understand the role of commercial assessment and valuation in business development
- Consider different forecasting models that can help realize and communicate the value of a product/portfolio
- Discuss techniques for avoiding common business negotiation pitfalls

If you are interested in leading this session, please contact Charlia Owens, Business Development Manager, at 917-242-3898 or cowens@exlevents.com.

4:15 From Opportunity to Commercial Product in an OTC World

- Hear how OTC opportunities are identified and evaluated
- Due Diligence — process and challenges
- Due Diligence — venturing into new areas

Joe Kiely, Director, Business Development and Licensing, **GSK CONSUMER HEALTHCARE**

5:00 Day One Concludes

8:00 Continental Breakfast

9:00 Chairperson's Recap of Day One
Mike Myers, *Senior Director, Lilly Research Labs* —
Due Diligence, **ELI LILLY**

9:15 Preclinical and Clinical Quality Investigations During Due Diligence

- Determine whether appropriate and adequate in vitro and in vivo preclinical testing for approved/pending products has been conducted by the company or contract laboratories on the company's behalf
- Review all Investigational New Drug (IND) applications and FDA correspondence for products being developed by the company for status and compliance with FDA regulations
- Assess all relevant pharmacological, efficacy, toxicology and metabolism preclinical and clinical information and implement a clinical development plan to rapidly reach a go/no-go decision

Jill Kearney, MBA, *Director, Licensing and Acquisitions, BioResearch Quality and Compliance*,
JOHNSON & JOHNSON

10:00 The Importance of CMC in Due Diligence Investigations

- Ensure CMC alignment with clinical, marketing, quality, and regulatory groups
- Evaluate quality, source, storage, and supply of raw materials, drug substance, and drug product
- Manage expectations around the availability of drug substance, methods, and drug product
- Assess whether CMC is properly aligned with the stage of development

Miriam K. Franchini, Ph.D., *Senior Staff Scientist, CMC (R&D)*, **SMITH & NEPHEW**

10:45 Networking Break**11:15 Successfully Navigate Antitrust Aspects of Future Transactions**

- Gain an overview of recent U.S. and global antitrust enforcement trends
- Discuss key tactics to manage the expectations of your partners
- Develop an efficient process to assess antitrust risks while increasing the speed of clearance reviews

12:00 Key Considerations for the Successful Integration Post-Merger or Acquisition

- Compare a target's development strategy with your core business development plan and create an effective integration plan
- Examine the significance of corporate culture and considerations for tuck-in integrations versus a merger of near equals
- Review considerations for a two-in-the-box approach compared to a tuck-in integration
- Revenue synergies versus cost synergies — how to manage anticipated upside from anticipated commercial efficiencies

Will Tilton, MBA, *Former Group Vice President, Due Diligence, Integration, and Divestment*, **SHIRE**

12:45 Luncheon**1:45 Get the Most Out of Your IP Due Diligence**

- Understand what your IP team needs in order to conduct an efficient diligence
- Consider the types of IP issues that arise in diligence and how they can derail or delay a deal
- Discuss tips for structuring IP terms to reflect issues found in diligence

Forrester Liddle, Ph.D., J.D., *Senior Director of Intellectual Property*, **JOUNCE THERAPEUTICS**

2:30 Common Versus Best Practices in Navigating a Virtual Approach to Informing a Deal Decision

- Review some examples of best practices
- Consider the pros and cons of flying or staying home to conduct a virtual diligence
- Determine whether you're informing a "continue to pursue" or a "sign the contract" decision with your approach to diligence

Mike Myers, *Senior Director, Lilly Research Labs* —
Due Diligence, **ELI LILLY**

3:15 Chairperson's Closing Remarks

Mike Myers, *Senior Director, Lilly Research Labs* —
Due Diligence, **ELI LILLY**

3:30 Conference Concludes

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