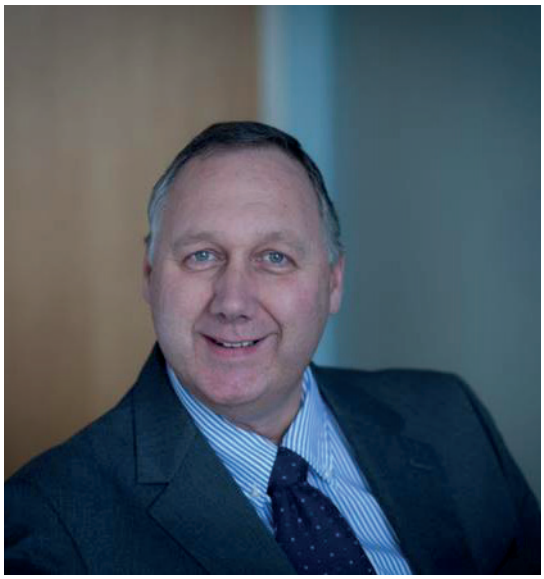
PHARMALEX
CONFIDENCE BEYOND COMPLIANCE

WHITEPAPER

HOW CAN YOU EFFECTIVELY MANAGE YOUR MERGER AND ACQUISITION ACTIVITIES?

Dr. Adam King
Senior Director, Regulatory Affairs
adam.king@pharmalex.com



"I have almost 30 years experience working in the Pharmaceutical industry of which the last 18 years+ has been in Regulatory Affairs, both in a global R&D environment and Regulatory Consultancy. Excellent experience in the oversight and delivery of large scale Regulatory CMC Compliance projects."

Companies engaging in Merger and Acquisition (M&A) activities aim to gain momentum by undertaking one or a combination of the following to:

- Increase market share by consolidating their product portfolio into specific therapeutic areas
- Replenish their previously dwindling product pipeline
- Enter into emerging markets with existing and new products
- Reduce costs through the consolidation of manufacturing sites

In many cases, the decisions are made to satisfy shareholder's and investor stakeholder's expectations, who are eager to see more immediate business results. However, it is crucial to reflect on the various divisions that must be integrated in this process and be aware that M&A activities bring along tasks that lie outside the scope of the usual everyday business. Additionally many fail to see some of the pitfalls that come with these decisions and to what degree this affects the regulatory affairs department.

PharmaLex recognizes the significant and often pivotal role that the regulatory affairs function plays in the consideration of the regulatory implications and subsequent execution of M&A related activities (Figure 1). Senior management may consider many of the regulatory activities involved as merely administrative, but fail to understand that every detail can have an impact on the timeliness and compliance of the M&A project. For example, country-specific nuances especially in emerging markets can result in an overly extended approval time and subsequently hinder the entire M&A implementation process.

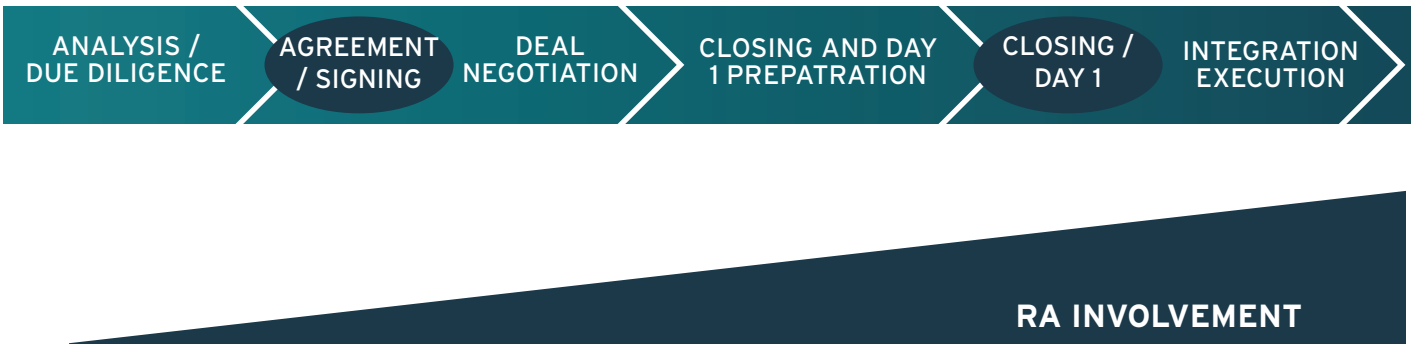


Figure 1: Level of Regulatory Affairs Involvement with M&A Programs

PharmaLex is able to leverage their extensive experience working on M&A related RA activities on both a European and worldwide level across multiple client programs (Figure 2) to tackle these hurdles and allow current or prospective clients to achieve their corporate goals in a compliant and timely manner.
Since M&A programs come with an additional set of tasks it is imperative to define the individuals that are able to project manage and take oversight of all the regulatory activities affected by the M&A process. PharmaLex has the breadth and depth of regulatory knowledge, experience and expertise to lead and run such M&A programs on behalf of the client.

Figure 2: PharmaLex expertise in supporting execution of M&A RA activities

Our experts ensure the success of your M&A project through provision of the following specialist skillset:

- Project management oversight
- Experience working directly with health agencies
- Local market regulatory intelligence
- Experience working with local RA affiliate teams
- Invaluable personal experience insights from many years of exposure to the regulatory processes / procedures
- Practical tools and checklists
- Experience working in close collaboration with key business functions within the client organization (Regulatory Affairs, QA, Manufacturing / Supply Chain and Commercial) during the "end-to-end" regulatory procedures to ensure that the senior leadership team and therefore key stakeholder needs and requirements are met.

In conclusion, it is important to highlight the following key facts that exist for any M&A program:

- M&A activities will have an impact on the global RA function within a company
- The RA function is crucial for the success of the M&A project since this role oversees all regulatory activities related to M&A and has the insights on potential challenges at an RA level such as local submission / approval timelines and local requirements
- Companies often underestimate the serious risks that surround the execution of M&A activities such as reduced performance, loss of compliance and loss of key employees. Therefore, it is imperative to assess these issues well ahead of undertaking the M&A activities
- PharmaLex can support your company with all RA related tasks during the M&A process and ensure compliance, effectiveness and timeliness

DELIVERING SUCCESS WITH CONFIDENCE

PharmaLex can quickly supply the widest range of **highly-skilled market leading experts** to our clients. We work with you to identify and overcome any challenges, but remain sufficiently flexible to respond and adapt to your evolving needs. Our **experienced team** spans all geographies, helping you to **accelerate your products or accelerate access to much needed resources,** and to stay one step ahead of essential requirements needed by health agencies worldwide. Our **knowledge accelerates** your business success.

Put simply, our approach transcends all of our work, providing you with our expertise and ability to achieve quicker timelines, or...

Knowledge. Accelerated.

KNOWLEDGE.
ACCELERATED.
confidence *beyond* compliance

PharmaLex is one of the largest providers for Development Consulting, Regulatory Affairs, Quality Management & Compliance and Pharmacovigilance, Pharmacopimediology, & Risk Management worldwide. Our global teams of experts can take you through early strategic planning activities and nonclinical requirements to clinical development, through regulatory submission processes and finally guide you to market approval and product maintenance post-launch activities.

PHARMALEX IN NUMBERS

700+
SUBJECT MATTER EXPERTS WITH A UNIQUE BLEND OF EXPERTISE

25+ YEARS
OF INDUSTRY EXPERIENCE

9/10
TOP PHARMACEUTICAL COMPANIES ARE OUR SATISFIED CLIENTS

40+ NATIONALITIES
ON STAFF, INCLUDING FORMER FDA AND EMA EXPERTS

50%
OR OUR PROJECTS ARE GLOBAL

contact@pharmalex.com
www.pharmalex.com