

MARKET UPDATE

The Life Sciences Legal & Regulatory Landscape





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Introduction

The life sciences industry has experienced significant growth and innovation over the past few decades, resulting in an increasing need for legal and regulatory professionals to advise on clinical trials, authorisations, market access, and much more.

Lab space alone, according to the CBRE, is expected to increase 22% in the next two years, while a boom in data technology transformations has fundamentally changed the way in which medical data is stored.

Given the importance of pharmaceuticals, biotechnology, health tech, and life sciences

overall to public health and safety, our mini report provides a quick overview of 5 key trends across the life sciences legal & regulatory landscape, exploring some of the challenges and opportunities facing both life sciences companies and the legal profession.

Informative for both those hiring and those considering making a move, we hope you gain a better understanding of the legal and regulatory space in life sciences and the impact it has on this critical industry.







The Art of Leveling:

How Bigger Firms and Start-Up Companies Differ

In the world of law firms, titles are almost entirely uniform across the board. An attorney with 2 years of experience is a 2nd year, an attorney with 3 years of experience, a 3rd year, and so forth. But titles and leveling in the world of in-house life sciences & healthcare teams are not nearly as homogenous and are assigned more arbitrarily at the discretion of each individual organization.

Oftentimes, especially with more mature organizations, leveling is assigned with two anchor titles, "Director" and "Vice President." Some companies have different sub-leveling stemming from each anchor title, those typically being "Associate," "Senior," and "Executive." There also exists titling in terms of the Legal title – ex, Associate Counsel, Counsel, Senior Counsel, Assistant General Counsel, Associate General Counsel, Deputy General Counsel, General Counsel, Chief Legal Officer, Head of Legal, and so forth.

It may seem to professionals that becoming a Director, Senior Counsel, could be step down from Vice President, Deputy General Counsel. If title is the metric being used to assess an upwards vs downwards vs lateral move, then perhaps it may in fact be. However – since there is no consistent leveling system as with firms, each company determines titles

differently based on their chosen years of experience, compensation bands, reporting structure, etc., to assign to it. For example, the Director, Senior Counsel role in question might be offering a \$50,000 compensation increase with the ability to manage a team and report directly into the Chief Legal Officer. There are select larger organizations where an individual does not become a Director until they are managing a sizable team, whereas at certain smaller organizations a Director is looked at as a more junior attorney within the legal department.

"Titling alone also seldom puts one's candidacy in a more positive or negative light. When hiring, companies will also use quantity and quality of experience to determine fit rather than titling, given that is an uncontrolled metric often unable to consistently reveal much about years of experience. While title is absolutely something to be paid attention to, it is important to pay attention to it in the context of the organization, and what the title entails for the specific team the role would be part of."

Lauren Robinson

Head of Life Sciences & Healthcare Legal, Vice President, US



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Building Out a Legal Department:

When to Start & When to Hire

For an organization to survive in the highly regulated life sciences industry, **the question of Legal support is not an "if," but rather a "how."** The two options include utilizing a law firm as outside counsel, or hiring an inhouse attorney wholly dedicated to that sole company.

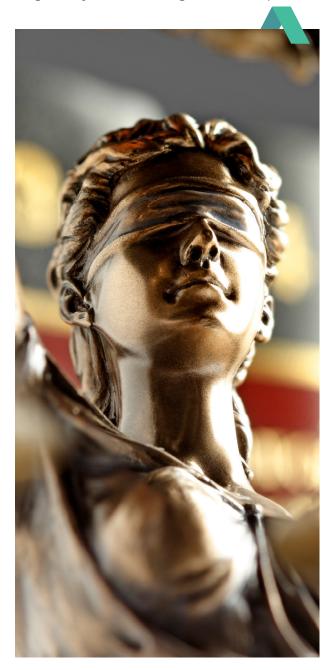
When an organization's legal needs grow to a certain point, having an in-house legal function can be more cost effective than the hourly rates charged by an external law firm. Additionally, law firms have large books of business with multiple clients whose needs they rotate through.

Every organization has different needs, priorities, and goals. Perhaps a business has no existing Legal team and needs an all-encompassing Legal partner to assist in high-level strategy. Or maybe an organization can outsource 90% of its Legal needs but requires a subject matter expert for the 10%. For some organizations, their needs lay in the middle.

For privately held life sciences companies, we find a Commercial Contracts profile to be quite common. This can take form in either a JD optional Paralegal/Contracts Manager to assist in pure volume of contracts, or with a more senior attorney specialized in agreements. For public life sciences companies making their 1st Legal hire, the profile commonly being targeted is a Corporate/Securities attorney.

With healthcare companies, Contracts & Regulatory/Compliance tend to be the most popular skillsets for a 1st Legal hire. Especially

with younger, more innovative healthcare companies, both skillsets are important to assist in both high-volume agreements and to ensure Compliance with nuanced Regulatory laws as an organization expands.







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Going In-House:

Why, Who, and When

In-house employers typically look for a strong background of law-firm training.

Once a lawyer moves in-house, the mentoring opportunities may not be as structured as in law firms and while the work-life balance may be better, it is often a more fast-pace environment where one likely needs to wear many hats and be able to hit the ground running. Therefore, employers typically prefer that an employee receive more formal training, with strong time management skills, skilled drafting and negotiating, and have direct experience with clients. Law firm experience also allows the candidate to cultivate strong research skills and a certain level of maturity.

An attorney looking to make the transition should ideally have at least 3-5 years of law firm experience. Having these years of experience allows the candidate to cultivate their skills and become an effective contributor.

On the flip side, waiting too long to go inhouse makes the transition more difficult

in the sense that one may have a gap in a necessary skill set and companies may not be able to match the law firm salary. In the life sciences industry specifically, we often see a majority on senior opportunities requiring previous in-house experience.



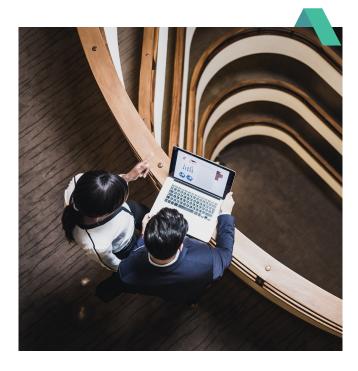


Hybrid vs Remote:

The Pros and Cons of Both

Within the life sciences industry, the majority of companies are adopting a hybrid model, with workers being expected to come into the office around 2-3 days per week. The mix of face-to-face in-person time and flexibility of working remote is key for employers but the more flexibility that is offered, the more attractive the role is to candidates. We have been seeing the most remote flexibility on the West Coast with California-based companies.

The life sciences space is a mission-driven industry, so overall these companies tend to see culture as a cornerstone for success. Life sciences companies are made up of multi-disciplinary teams, with in-house lawyers often needing to work cross-functionally among departments. Developing relationships across the different business units to work together towards a common goal is key for driving the mission forward. Another cornerstone of a life sciences company is creativity. Creativity thrives in spontaneous environments, so being in office face-to-face helps to spur new ideas. Therefore, offering a hybrid model provides the best of both worlds for both candidates and companies and will allow both employees and employers to feel more connected to each other and the missions of the company.





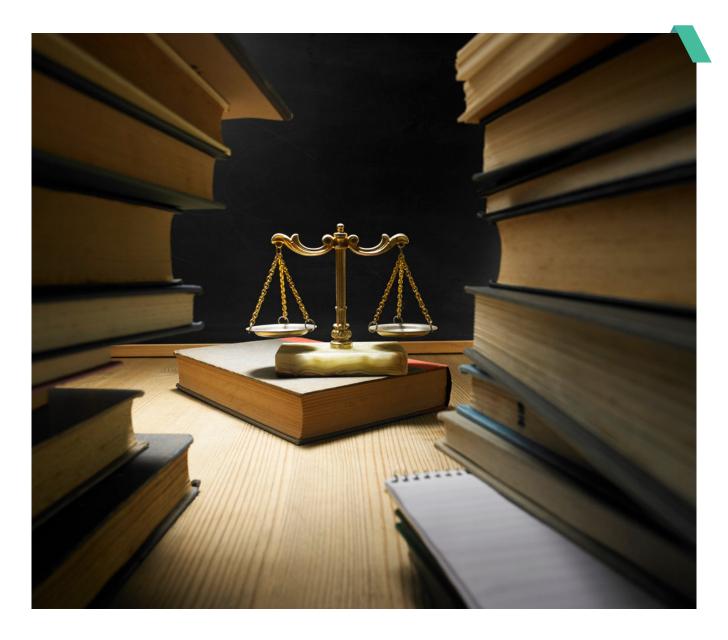
Hot New Skillsets:

Intellectual Property, Data Privacy, and Technology Transactions

As markets are changing and artificial intelligence (AI) is becoming extremely centralized across the board, skillsets such as Intellectual Property, Data Privacy and Tech Transactions will become higher in demand. It is clear that **life sciences organizations** have become, and will continue to become, increasingly digitalized. Due to this, various executives are reinventing and modernizing their solution stacks and implementing the latest technology to achieve maximum innovation and effectiveness.

This includes the addition of decentralized clinical trials, 3D printing to manufacturer cell & tissue products, Al companies developing their own drug development pipelines, and pharmaceutical companies increasing their own Al expertise – which in turn increases the need for attorneys specifically focusing on this area.





Summary

From when to build out legal teams in-house, to the always relevant debate of hybrid working, there are certain themes in the life sciences regulatory space that are ever present.

The legal world has also changed due to hot new topics, such as the evolution of artificial intelligence and fresh digital health laws passed since the pandemic. In addition, there have been recent approvals and recalls of medical devices impacting consumer trust, making the life sciences legal and regulatory environment complex and advancing. All these developments come with a critical need for the right talent to be in place to keep up with the pace of change.

Whether you are an organization looking to hire legal talent to support with your latest innovation, or an individual considering career opportunities, the life sciences industry, and in turn its regulatory and legal landscape, is poised for growth.



About Larson Maddox

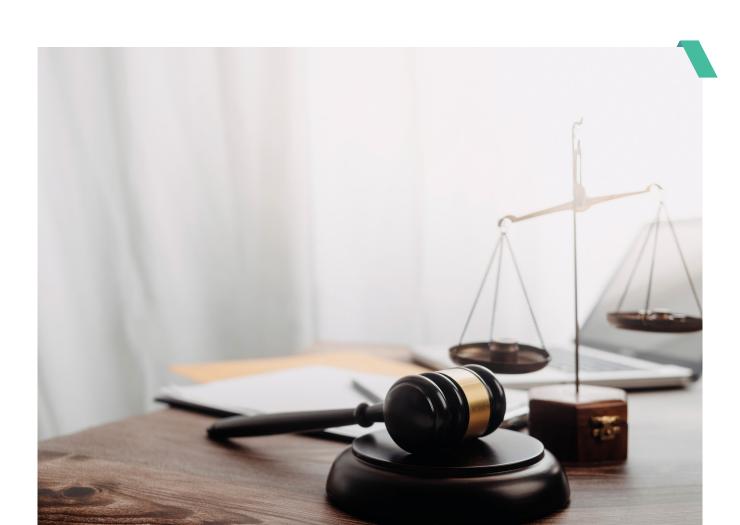
At Larson Maddox, we give essential guidance to leading firms by connecting them with the best in-house counsel talent for their regulatory & legal needs.

From data privacy and formalizing financial resilience, to ensuring umbrella companies are compliant and approving innovative technologies for use, an ever complex regulatory landscape is emerging. Through an increasing amount of laws and governance comes the need to secure the right talent to scale for growth, but also to protect your organization best.

With Larson Maddox as your leading talent partner, you can rest assured that you have the expertise needed to succeed in a regulated market.

Our Specialisms

- · In-House Counsel
- · Legal Operations
- · Contract Management
- · Compliance
- · Regulatory Reporting
- · Government Affairs
- · Regulatory Operations
- · Data & Privacy





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