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Accelerate your Biotech success
- A legal guide to launching your product candidate on the European market.

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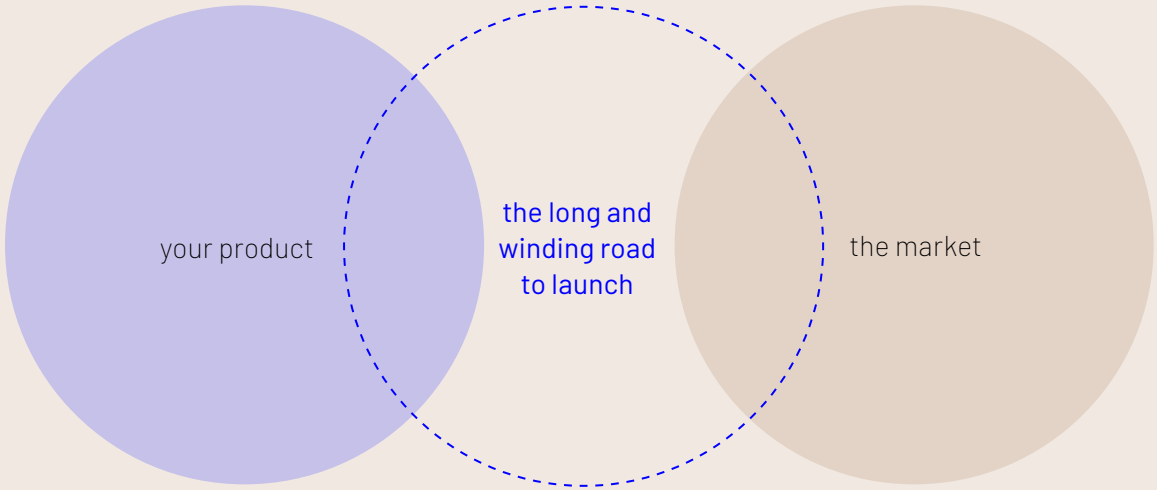
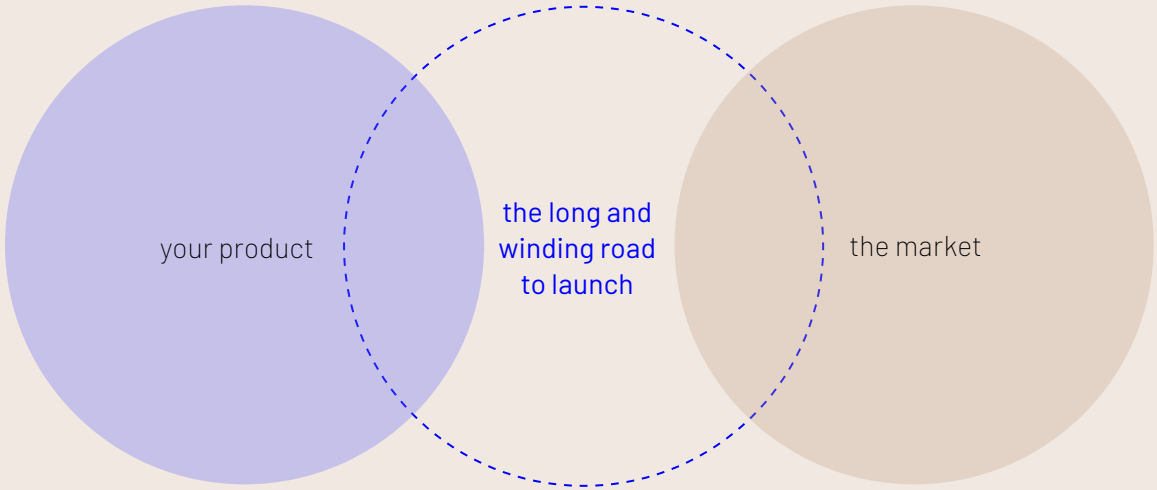
How to ensure that you are (sufficiently) ready and compliant to commercially launch your (first) drug candidate or health technology on the European market?



Biotech companies that have a promising (first) clinical drug candidate or health technology in their portfolio often find the various legal and ethical requirements for bringing their product candidate to market in Europe a major obstacle to success. While such legal and ethical obstacles can indeed be extremely time-consuming and may seem insignificant or of low priority at first glance, the market has proven that companies that incrementally address each obstacle at the right time will actually accelerate and improve the successful launch of their product candidate. This will also increase their attractiveness to potential investors, acquirors and licensees. Denying their existence, on the other hand, has rarely proven to be a successful recipe for a smooth product launch...



In our view, the 10 most important legal and ethical obstacles your company might encounter on the way to a successful launch of its (first) drug candidate or technology are the following:

R&D

COMPLIANCE

GDPR

CLINICAL

SUPPLY CHAIN

CORPORATE AND EMPLOYMENT

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REGULATORY

MISCELLANEOUS PROCUREMENT WORK

IP OPTIMIZATION AND BD

Who are we?

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R&D readiness

Developing your product candidate cannot only be done in-house. Typically, you will need to outsource critical R&D steps to external R&D service providers *(e.g., formulation development, development manufacturing)*, in-license valuable technologies *(e.g., cell lines, assays, polymers)*, or enter into strategic collaborations for joint development. You may also want to raise external funding *(e.g., by joining national or international funding programs or consortia)*. Often you have little negotiating power in this process, but it is imperative that you protect your confidential know-how and preserve (and not dilute) your IP portfolio and freedom to operate. Not only to ensure a profitable launch of your product, but also to remain attractive to investors, acquirors and licensees.

We assist you in selecting and negotiating your strategic R&D outsourcing, in-licensing, co-development and financing projects. In particular, we focus on understanding your technology and science, protecting your confidential know-how, and preserving your IP position and freedom to operate (see also IP optimization and BD below).

I need more details. →

Who are we? →

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Compliance readiness

You must progressively design and implement compliance policies, review/approval procedures, and standard operating procedures (SOPs) to meet (and demonstrate your readiness to meet) the increasingly demanding requirements of today's mandatory healthcare compliance standards. These standards have a firm grip on a wide range of activities you will undoubtedly undertake in light of your product candidate's development and launch: whether and how you may share information about your product (including its clinical progress) with healthcare professionals, investors, or the public (including via social media); whether you may engage/pay your key opinion leaders to provide valuable services; under what conditions you may sponsor scientific events and make grants to healthcare organizations; etc. These standards also include local and international anti-bribery and corruption requirements, which are increasingly scrutinized by relevant authorities.

We conduct compliance audits, identify compliance priority areas, and draft global/EU compliance policies. We also design review procedures tailored to the risk profile of our clients (including on grants and sponsorships, scientific publications, social media communications, communications with HCPs and the general public about a product candidate, transactions with HCPs and hospitals during the approval process for a product candidate).

In addition, we review marketing communications across Europe on a daily basis, provide ad hoc assistance with specific (often multi-country) compliance queries, and support our clients in drafting and negotiating compliance-related contracts (speaker agreements, sponsorship agreements, advisory board agreements, etc.).

I need more details. →

Who are we? →

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GDPR readiness

You need to set up general policies for data protection and document retention. Your readiness to ensure and document adequate GDPR compliance will be increasingly scrutinized as you begin to implement clinical programs for your product candidate and manage healthcare data of patients.

We perform GDPR gap analyzes, implement privacy policies, and can act as a DPO. We also provide day-to-day GDPR support (ad hoc advisory issues, DPIA implementation, drafting and negotiating of GDPR clauses/DPAs).

I need more details. →

Who are we? →

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Clinical readiness

Managing and monitoring your multicenter clinical trials is hardly possible without the external help of a so-called "CRO". In addition to establishing and monitoring your contractual relationship with said CRO, you will be required to review and oversee the execution of a variety of clinical trial agreements with the investigational sites involved in your clinical trials. You will also be expected to make decisions about your clinical strategy/design and may be faced with a number of ad hoc (regulatory) challenges related to your clinical trials.

I need more details. →

Who are we? →

We assist our clients in selecting and monitoring their contractual relationships with their CRO. We also draft, negotiate and/or review for our clients the various site agreements (and ancillary documents) required to conduct their clinical trials (typically in collaboration with the client's chosen CRO). In addition, we also provide ad hoc consultation on a variety of clinical issues.

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Supply chain readiness

Most likely, you will need to outsource (part of) the manufacturing of your product candidate to external manufacturers. At a time when manufacturing capabilities are considered the "new gold," this is a challenge. Once your product candidate is close to launch, you will also need to develop a solid distribution strategy and establish contractual agreements with a variety of distributors, logistic service providers, and other trade or promotional representatives.

We assist our clients on a daily basis in drafting and negotiating contracts that cover their (clinical and commercial) manufacturing activities.

This support includes drafting and negotiating contractual agreements with a variety of distributors, logistic service providers and other trade/ promotional agents.

I need more details. →

Who are we? →

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Corporate and employment

As you approach launch and need to deploy your operations across Europe, you will be expected to establish subsidiaries or branches in strategic locations in Europe or appoint physical representatives through a variety of local agents and/or medical-scientific liaisons (MSLs) and ensure their compliance with local labor laws.

I need more details. →

Who are we? →

We assist our clients in selecting, establishing and incorporating the appropriate local corporate structure in accordance with industry best practices (through subsidiaries, branches or otherwise) and ensure appropriate governance rules for their organization in full compliance with local law. In addition, we assist our clients in appointing and managing local representatives across Europe (and integrating these decision makers into their chosen governance model) to ensure streamlined decision making in accordance with their existing policies. Finally, we help our clients manage the various local labor and social requirements associated with hiring local staff and consultants, and provide further support on local employment issues (including drafting local employment contract templates and ensuring that our clients' existing policies are in line with local jurisdictions).

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Early access readiness

You need a platform that facilitates early access to your product candidate by HCPs and patients until the approval process is complete. This platform can take various forms (open-label extension, compassionate use, named-patient delivery, free samples, etc.) depending on the applicable legislation in the patient's country of residence and your preferred early access strategy. Not only do you need to engage an external logistic service provider to organize your early access deliveries, but you also need to oversee a variety of local early access requirements.

I need more details. →

Who are we? →

We support our clients in setting up compliant early access programs for their pre-commercial product candidates across Europe (open-label extension, compassionate use, named-patient delivery, etc.). We also support the management of our clients' external logistic service providers in organizing early access deliveries.

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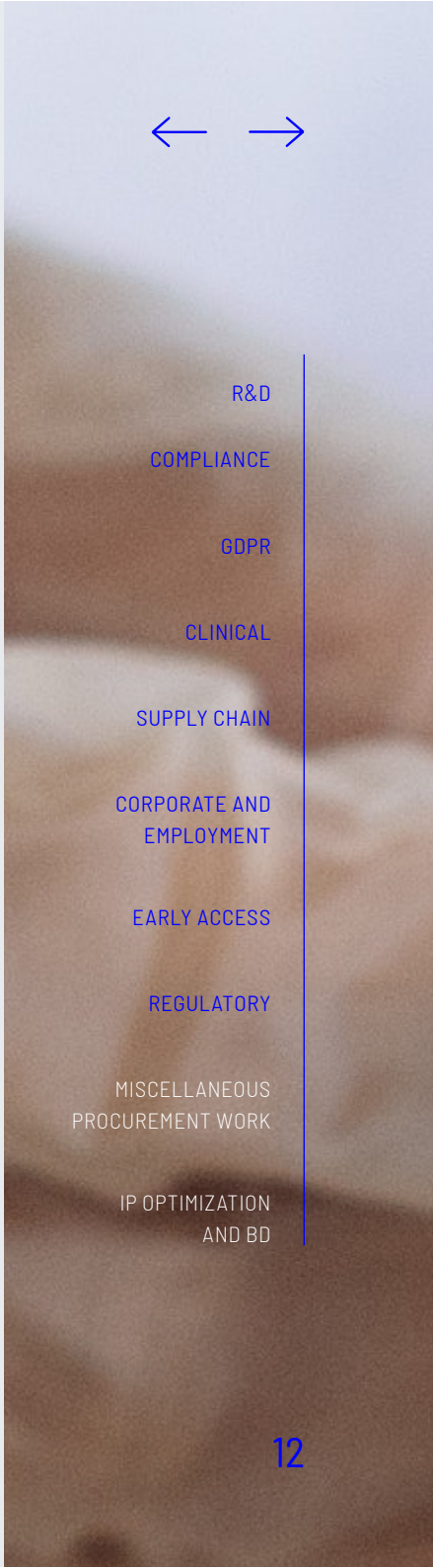
Regulatory readiness

In general, you will likely encounter several local regulatory challenges on your path to commercialization. These include legislation governing your clinical trials, your early access programs, your marketing authorization applications, your local dossiers for pricing and reimbursement, etc. Having a good network of local attorneys to assist you in these matters on an ad hoc basis will prove very useful.

I need more details. →

Who are we? →

Together with our network of local law firms, we assist our clients on an ad hoc basis with a wide range of day-to-day regulatory issues (e.g., clinical trials, early access programs, regulatory submissions, local pricing and reimbursement dossiers).



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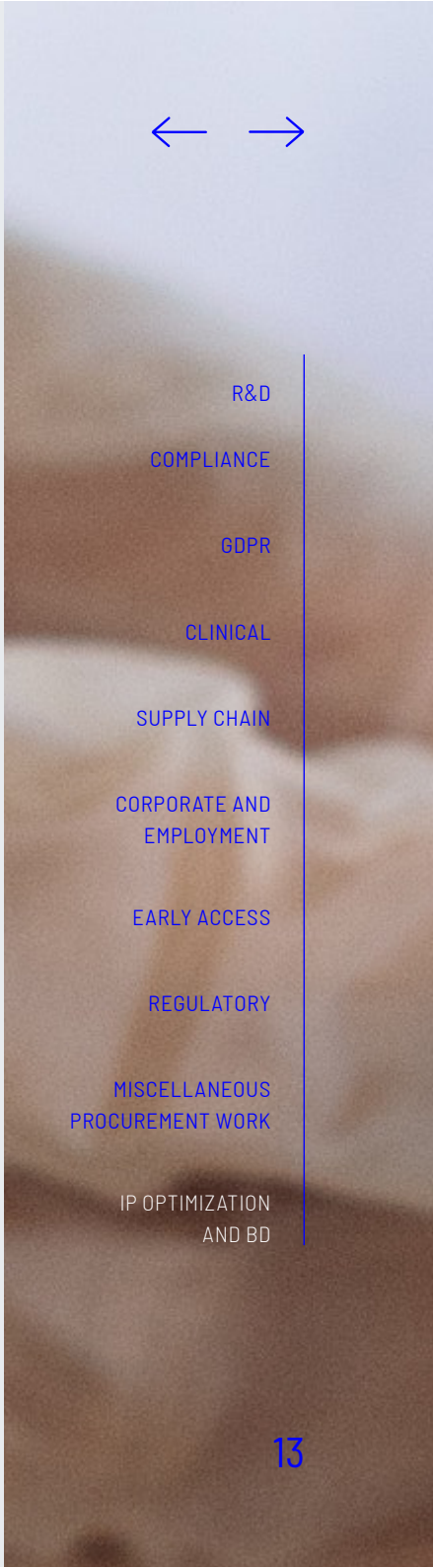
Miscellaneous procurement work

The closer you get to launching your product candidate, the more procurement-related contracts (support services contracts, consulting contracts, IT software development or licensing agreements, etc.) and compliance-related contracts (speaker agreements, sponsorship agreements, advisory board agreements, etc.) will come your way and require (ongoing) legal support.

We support our clients in managing their extensive procurement-related and compliance-related contracts.

I need more details. →

Who are we? →



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IP optimization & BD

I need more details.

Who are we?

The (golden) thread that runs through your entire readiness journey remains the preservation, optimization and valorisation of your technology and IP portfolio. You will need to manage and strengthen the lifecycle of your patent(s). You may need to share your confidential know-how with third parties, ask third parties to improve your technology, in-license technologies from third parties, enter into joint development projects with third parties, attract external funding (private or commercial) with demanding funding requirements. You may wish to valorise your IP, attract revenues and mitigate the risks of a largescale launch by out-licensing your IP regionally (e.g. to a region of lesser interest) or for a specific field (e.g. a therapeutic indication outside your primary focus area). In all these steps, you should prioritize protecting your confidential know-how, preserving your freedom to operate, and optimizing/valorising your IP portfolio (without diluting it). This will ensure the viability of your product candidate once it is on the market and maintain your attractiveness to external investors, acquirors and licensees (also if you decide to exit before commercial launch)

First and foremost, we make sure we understand the science behind your product candidate. Throughout our support on your strategic IP collaborations, our focus is on protecting and enhancing your IP portfolio and freedom to operate. This reflex is crucial when you share confidential know-how with third parties, ask R&D service providers to improve your technology, in-license add-in technologies from third parties, enter into joint development projects with strategic partners, negotiate ancillary out-licencing agreements to generate revenue or mitigate the risks of a largescale launch. Our primary goal is to ensure the viability of your product candidate and maintain your attractiveness to investors, acquirors and licensees. If you decide to exit before launch, we have a dedicated licensing and M&A team to assist you with these exit strategies.

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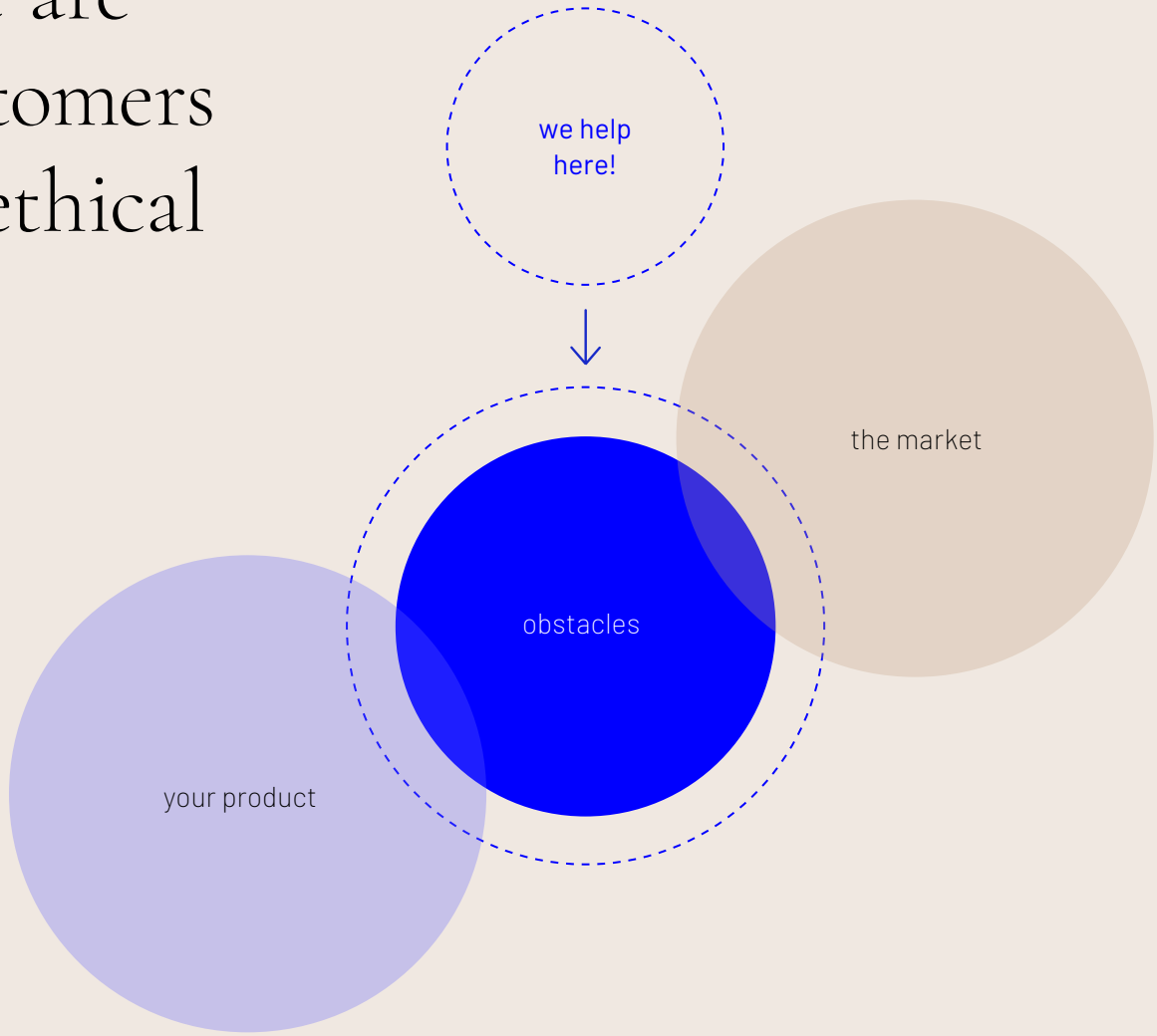
There are many ways we are helping our biotech customers address these legal and ethical challenges.



type of support

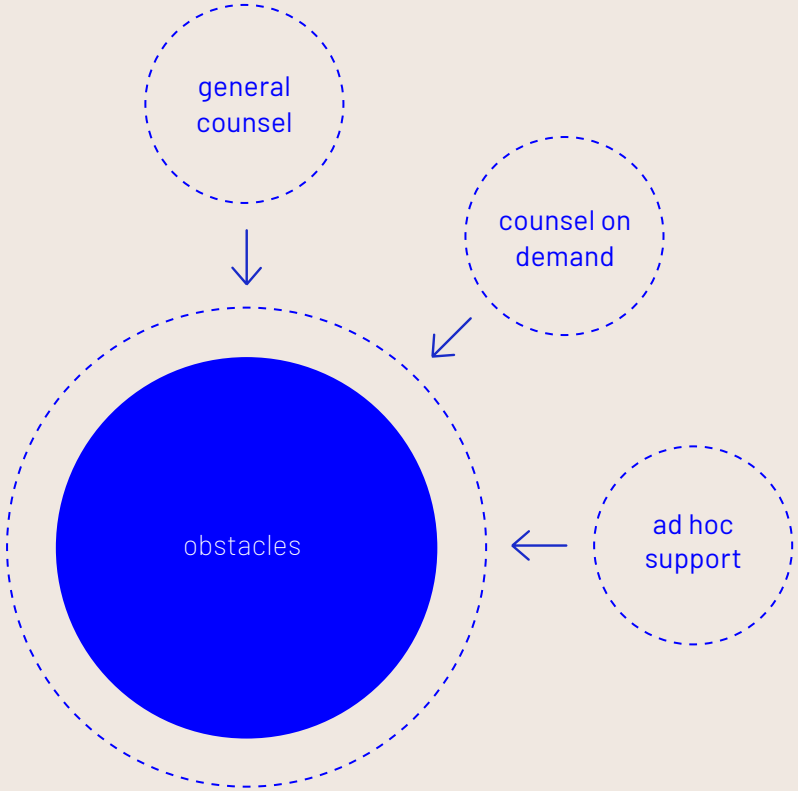
Some clients do not have legal counsel on board (yet) and ask us to manage their entire readiness package in close cooperation with their management. Other clients have a (sole) general counsel on board, with whom we work hand-in-hand on a number of selected readiness projects (e.g., compliance reviews of product communications and drafting and negotiating supply chain agreements). Other clients already have an established in-house legal team that outsources ad hoc requests or labor-intensive (recurring) projects to us.

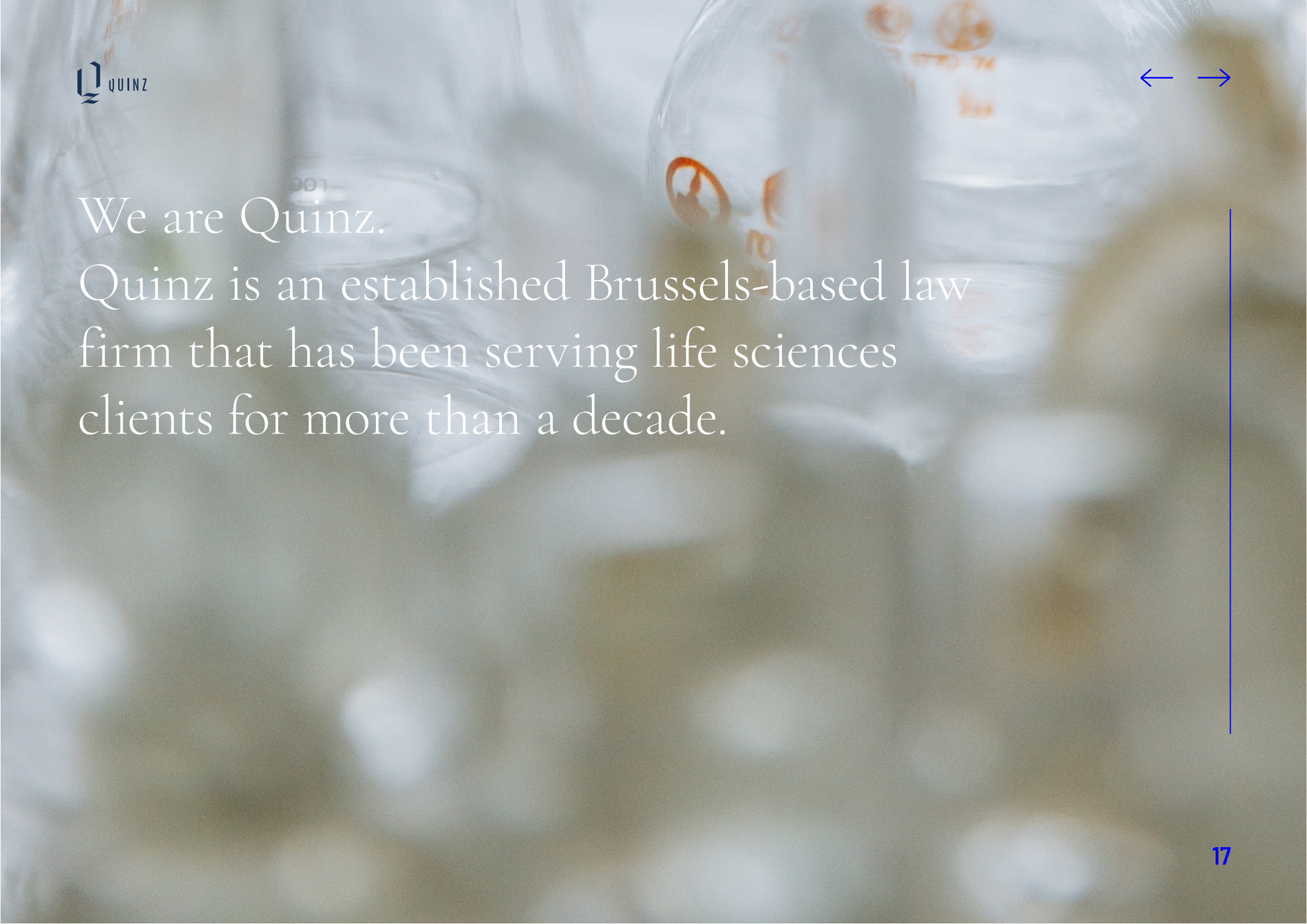
timing of support

Our market readiness support may begin as early as ten years before the anticipated launch date and generally begins about one year before a candidate is first used in humans. Sometimes we may become involved at a (much) later stage (e.g., regulatory and compliance support after completion of a successful phase 3b trial).

who we support

Part of our customers have their global headquarters in Europe. The other part has its global headquarters outside Europe, usually in the United States, and has (or is considering establishing) regional headquarters in Europe (often in Switzerland). We support both categories in their readiness projects in Europe.





We are Quinz.
Quinz is an established Brussels-based law firm that has been serving life sciences clients for more than a decade.

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Together, we have more than 30 attorneys and consultants at your service, most of whom have extensive in-house experience in life sciences companies.

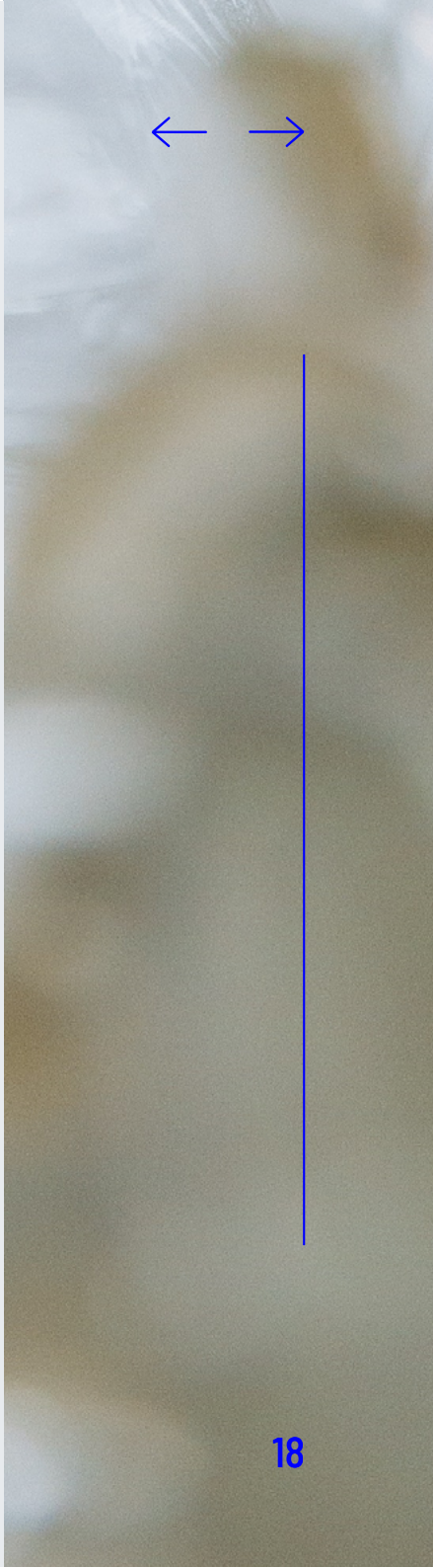
We have an intimate understanding of the unique characteristics and challenges of the life sciences sector (and its need for prompt, pragmatic and diligent legal and compliance support).

We also support multinational pharmaceutical companies, but our heart clearly beats for biotech innovators. Our market readiness expertise is unmatched on the European continent, and we have become a household name in Europe for helping biotech companies bring their first (or subsequent) product candidate to the European market.

We do not work alone. We closely work with Ask Q. Ask Q is Quinz' sister company and was recently established by Quinz as a legal services company to help its life sciences clients manage their ever-increasing workload of contracts on a day-to-day basis. For local regulatory issues or local corporate and employment matters, we work hand-in-hand with our carefully built, dedicated network of friendly local partner firms. We also work with clinical and supply chain consultants to help you develop clinical and supply chain strategies and select suppliers.

Hungry for more detailed info? In the following, we have explained the legal and ethical obstacles mentioned above in more detail and given some practical examples of our support in this regard.

contact us visit quinz.be visit askq.com



For added value seekers: some additional details and case highlights on our expert areas.

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R&D readiness

How is this a challenge?

Developing your product candidate can only be done in-house. You will usually need to outsource critical R&D steps to external R&D service providers (e.g., formulation development, development manufacturing), in-license valuable technologies (e.g., cell lines, assays, polymers), or enter into strategic collaborations for joint development. You may also want to attract external (private or government) funding (e.g., by participating in national or international funding programs or consortia such as Horizon Europe), which regularly impose stringent requirements that may affect your future freedom to operate.

In doing so, you often have little bargaining power: valuable R&D capacity is scarce, patented technologies you want to in-license are too important to your development for you to negotiate at the drop of a hat, important funding opportunities often come with onerous requirements, and - more generally - your development timelines are too tight for you to get lost in endless negotiations. Despite this difficult negotiating position, you should ensure that your R&D projects do not slow down your development timelines and - more importantly - that you protect your confidential know-how and do not dilute your IP portfolio and freedom of action.

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How can we help?

We support you in the selection and negotiation of your strategic R&D outsourcing, in-licensing, co-development and financing projects. In particular, we focus on understanding your technology and science, protecting your confidential know-how, and preserving your IP position and freedom to operate (see also IP readiness below). We also assist you in drafting contractual mechanisms to ensure the timely execution of your development projects.

For a Netherlands-based biotech company focusing on oncology:

more cases ↓

We assisted the company in drafting and negotiating its global R&D outsourcing projects (including in-licensing and co-development). These R&D projects involve formulation development, domestic and international consortia, clinical trial development, etc. The company's manufacturing projects include API and drug product development (including filling and finishing), as well as primary and secondary packaging services.

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For a Switzeland-based biotech company focusing on degenerative diseases:

We helped the company outsource formulation development and in-license a variety of solutions to improve the stability of its candidate. We are now helping the company through the scale-up manufacturing of its compound in anticipation of its first clinical program.

For 4 out of the "Top 10 Global Pharma Companies 2022":

For more than 10 years, we have supported (worldwide) the R&D functions (including international consortia) of 4 of the top ten global pharmaceutical companies.

For 7 out of the "Top 10 Global Pharma Companies 2022":

For many years, we have become the preferred partner of most multinational pharmaceutical companies for Horizon Europe (formerly Horizon 2020) funding projects and consortia.

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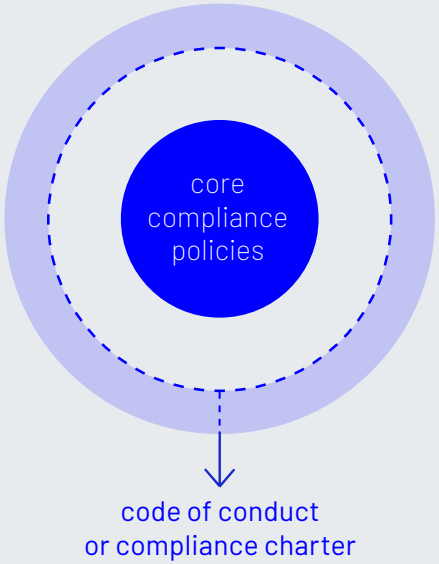
contact us

Compliance readiness

How is this a challenge?

Healthcare compliance may not always be your first priority. As you prepare to launch your first product candidate, you often face an underdeveloped compliance framework in your organization and a lack of time and resources to develop and implement the necessary organizational structure.



- *interactions with HCP's & HCO's (ToVs)*
- *anti-corruption & anti-bribery*
- *GDPR*
- *social media*
- *pipeline communications*

- *relationships with suppliers*
- *promotional materials*
- *data retention*
- *transparency*
- *adverse event reporting*
- *interactions with patients/PAO's*
- *fair market value determination*
- *early access*
- *anti-trust*
- *whistleblower protection*

- *Environmental impact & sustainability*
- *animal welfare*
- *diversity*
- *employee health & wellbeing*

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A lack of understanding of healthcare compliance in your organization can be detrimental to your business. Violations of compliance standards can result in large fines, ammunition for competitors, increased scrutiny from payers and regulators, and bad press within the scientific community and toward patients. It could also cause potential investors and collaborators to reevaluate their relationship with your company. Reputational damage is much more difficult to repair than it is to prevent. That's why a solid compliance framework is essential for any biotech company looking to bring a first product to market.

How can we help?

We can help your company establish the necessary compliance framework for your business in a timely manner. In addition, we can support you in introducing a compliance culture throughout your company:

case

(i) We can help you identify the priority areas for your business and create a risk profile tailored to your company's needs and sensitivities and, in particular, your company's risk tolerance. Based on this, we can help you define the essential compliance standards in clear, written policies that your company will want to adhere to. In doing so, we follow a clear, step-by-step roadmap to address the priority areas first and improve the level of compliance with each step.

(ii) Healthcare compliance is an ongoing task that requires clear and structured operating procedures for your organization's employees and leaders to enable and monitor concrete compliance with these standards. We can help you embed robust (new) SOPs and processes into your existing organization and identify and address gaps where appropriate.

(iii) In addition, we may assist in kick-starting the roll-out of the updated compliance framework by providing customized training for employees or management and/or providing permanent training materials for internal training. We can furthermore help prepare internal guidance and reference materials and have a wide network of highly capable befriended partner firms for any country-specific matter.

case

(iv) We have a broad expertise in healthcare compliance sensitive contracts, including the drafting/updating of template agreements for interactions with healthcare professionals, especially where a transfer of value is considered.

(v) We can provide necessary resources and expert advice on a wide range of other compliance-related matters, including review of communications materials, issues related to transparency requirements, and other ad hoc matters.

For a US-based biotech company focusing on rare genetic (muscular) diseases:

contact us

We helped the company build its European compliance organization from the ground up. This included designing and drafting internal policies and SOPs, conducting compliance training for relevant staff, reviewing company communications materials, and creating standard templates for the company's core European market for interactions with healthcare professionals.

For an Australia-based biotech specialized in obstetrics:

We supported the company in the mapping of relevant local compliance standards in several European countries. In doing so, we coordinated all requirements and consolidated them into one overarching master reference document. We also provided several compliance training sessions for the company's regional sales team and regularly advise the company's European operations on compliance issues.

For a US-based biotech company focusing on rare genetic (respiratory) diseases:

We helped the company ensure that its communications materials complied with applicable standards. As part of the client's internal communications review committee, we review international and local materials about the company, its products, areas of interest, and activities to be disseminated through a variety of channels (social media, newspapers, congresses, websites, brochures, etc.).

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GDPR readiness

How is this a challenge?

Any company active on the European market must have a basic level of compliance with the General Data Protection Regulation (GDPR). Once your company begins the long road to commercializing its product candidate in the European market, the processing of personal data is inevitable. You will be faced with personal data of employees, patients, doctors, etc. that will force you to comply with GDPR requirements.

Even if these GDPR requirements are nothing new for your company when it comes to your general business activities, you will soon find that clinical research opens up a whole new dimension of GDPR requirements. Being at the forefront of cutting-edge research brings with it the responsibility of handling sensitive personal data. To gain and maintain the trust of ethics committees, study sites, and patients alike, you should audit your entire facility for GDPR compliance and ensure it is robust and ready for clinical trials.

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At first glance, this may seem like a daunting task, as compliance with the GDPR requires many different steps and very specific expertise (partly legal, partly IT). Furthermore, as you start your studies at sites in different European countries, you will be confronted with different data protection regulations and views on a local level.

How can we help?

GDPR compliance is all about accountability and being able to demonstrate that you have considered data protection in the design of your research. Our team of experts can help with this:

PRE-CLINICAL

We prepare your business and your team to become GDPR-proof during early R&D and help you get ready for the whirlwind of compliance requirements once clinical studies commence.

case

- Drafting of internal data protection SOPs;
- Internal trainings on data protection awareness for all business activities;
- Conducting Data Protection Impact Assessments (DPIAs) prior to any activities with a high impact on the rights of individuals (e.g. clinical trials);
- General privacy notice and cookie notice for your online presence.

CLINICAL

We guide your team through all GDPR demands of clinical studies from your first ICF until your final study report.

- Drafting and review of ICFs with adequate GDPR consent;
- Data processing agreements/terms with CROs, sites and subcontractors;
- Contractual terms and other measures for transfers outside the EEA (SCCs and transfer impact assessments);
- Data breach response plan.

POST-CLINICAL

We help you in managing retention of your clinical datasets and prepare your for what is next.

- Policies regarding further use of research data;
- Reviewing and drafting of Early Access ICFs;
- Drafting of data protection compliant documents for interactions with HCPs and patients (e.g. direct marketing tools, adverse event privacy policies, agreements with HCPs, data subject access request policies...).

case

Do you need more support? If you feel more comfortable having our GDPR team on your side for ongoing data protection support (e.g., ad hoc advice, handling data breaches, etc.) and long-term updates to your GDPR procedures, you should make us:
- your EU Representative (if your company is not already located in the EU) or
- your Data Protection Officer (which is a mandatory function if you are running clinical trials, for example).

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For a France-based biotech company focusing on hematological malignancies:

We advised the company on GDPR compliance in its international clinical trials. After providing the sponsor's study team with accessible SOPs and multiple interactive trainings, we guided the company in preparing a DPIA and GDPR-compliant ICF for ethics committee review, drafted and negotiated data processing agreements with the study sites, coordinated GDPR requirements with CRO, and conducted risk assessments as appropriate. In the end, the company was able to begin the clinical trial with confidence and address any concerns raised by ethics committees during the review.

For a Switzerland-based biotech company focusing on epilepsy:

We conducted a GDPR risk assessment and gradually implemented all relevant GDPR policies and security measures. We initially acted as DPO (prior to the appointment of the company's internal DPO) and then provided ad hoc support on a variety of GDPR issues.

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Clinical readiness

How is this a challenge?

Conducting clinical research projects means a significant increase in workload for your organization, even more so if it is your first clinical candidate. Not only do you have to make a variety of strategic decisions related to these projects and ensure regulatory compliance and security of the data generated, but you also have to manage and monitor the (often simultaneous) execution of your studies by multiple clinical sites. These management and oversight requirements are typically outsourced to a CRO, but selecting, engaging and managing your CRO remain challenging and very time consuming.

case

How can we help?

We provide all-round legal support throughout the entire lifecycle of your clinical trials, ranging from transactional support, i.e. drafting, reviewing, negotiating agreements and other legal documents, to advisory support, i.e. providing legal advice on various regulatory and compliance questions that may arise during the conduct of the clinical trial. We also provide vendor-selection support of your CRO.

For an Ireland-based biotech company focusing on oncology treatments:

We developed the company's RFP for the selection and appointment of its CRO in view of the conduct of the clinical studies of its first product candidate. We assisted in the selection of the CRO and negotiated the main services agreement with said CRO. We currently support that CRO on a daily basis with the drafting and negotiation of all clinical trial agreements for the company's relevant studies.

For a Belgium-based biotech company focusing on immunology:

We drafted and negotiated all contracts for a global multicenter phase III clinical trial, including clinical trial agreements, ICFs, indemnification agreements, DPAs, and logistic services agreements.

Supply chain readiness

How is this a challenge?

Typically, you will outsource the manufacturing of your product candidate to a contract manufacturing organization. This likely applies to development, scale-up, clinical manufacturing, and commercial manufacturing. This is a difficult task, made even more difficult at a time when manufacturing capabilities are considered the "new gold." Small biotech companies today face risk-averse and inflexible CDMOs that take full advantage of the scarcity of capacity in the market. This leaves smaller biotech companies with fewer options to negotiate a commercially sound contractual agreement for the manufacture and delivery of their product candidate, and to obtain the necessary delivery guarantees for both clinical requirements and scale-up projects towards a market launch.

Second, once your product candidate is "close to launch," you will also need a comprehensive sales strategy. Various contractual arrangements will need to be made with a variety of distributors, logistics service providers and other commercial agents to ensure a smooth and successful launch of your product candidate once it has received the appropriate regulatory approvals.

How can we help?

Based on our long experience in drafting and negotiating so-called technical operations contracts for several multinational life sciences companies, we have all the requirements and expertise to be your dedicated partner in drafting your external manufacturing strategy and contracts to ensure clinical readiness and timely scale-up towards the launch of your product candidate. In addition, we can assist you in the development of your logistics and distribution strategy and make all necessary arrangements for its implementation. In terms of clinical readiness, we work with a variety of consultants to develop both the upstream and downstream strategy for bringing a product candidate to market. So we not only support you from a purely legal perspective, but can also help you with the actual design of your network of external development, manufacturing and distribution/logistics services.

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(i) clinical manufacturing and scale-up

Clinical development often requires entering into clinical manufacturing agreements to ensure the timely and continued delivery of your clinical product candidate. Once the clinical phase is complete, our biotech clients delve into establishing a commercial supply network with one or ideally multiple CDMOs. On a day-to-day basis, we assist our biotech clients in developing technology transfer agreements that protect the client's data and know-how and, more generally, maintain the client's competitiveness and the appropriate performance and capacity of the CDMOs concerned.

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(ii) current market conditions

Especially in the current market, clients sometimes struggle to find sufficient capacity to support their clinical projects and go-to-market plans. Unfortunately, the capacity and availability of raw materials is so tight right now that biotech and pharmaceutical companies may be left empty-handed in their go-to-market plans if plans were not made early to secure that capacity and raw materials. We understand the hectic nature of current market conditions and pride ourselves on not only recognizing and understanding the issues they bring, but also entrusting our clients with the contractual tools and related strategic advice.

(iii) supply chain strategy and contracting

Once the product is on the market, we understand the need and support our customer to ensure continuity of product supply to maximize the customer's ability to market their products. We believe that this is a continuation of the efforts made during the scale-up phase, and that it is a task that remains relevant for the entire lifecycle of a product. It is one thing to ensure sufficient capacity and have qualified CDMOs to manufacture your product. At the other end of the scale, there is the question of how to get your product to market. We can add value for customers looking to navigate the various structures of (pre)wholesale, distribution and logistics service contracts by providing the necessary strategic, compliance and transactional perspective.

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For a Switzerland-based biotech company focusing on obstetrics:

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We drafted and negotiated the entirety of the company's upstream external manufacturing agreements with selected CDMOs to cover its late (large-scale) clinical needs and ensure a timely scale-up for commercial launch. We also closely worked together with the company to establish its distribution strategy (through warehousing, third party logistic service providers and distributors) and drafted company templates to support these activities.

For 4 out of the "Top 10 Global Pharma Companies 2022":

For more than 10 years, we have supported (worldwide) the supply chain functions of 4 of the top ten global pharmaceutical companies. This ongoing exposure to the global manufacturing landscape has provided us with invaluable insights into the benefits and pitfalls of working with key CDMOs. This experience also means we are frequently engaged by our clients in the CDMO selection process.

For a Switzerland-based biotech company focusing on oncology:

We negotiated the entirety of the company's external manufacturing arrangements in view of the impending European commercialization of its product candidate. We also assisted the company in setting up its distribution network throughout the European continent.

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Corporate and employment readiness

How is this a challenge?

Biotech companies face a number of hurdles when expanding outside their headquarters to take advantage of new markets and local opportunities. A key hurdle is establishing local satellites within an overarching corporate structure that meets their specific needs and governance requirements and ensures compliance with local and transnational regulations.

While tax issues are often at the forefront of establishing local satellites (whether through local branches, subsidiaries, or otherwise), it is critical that such a corporate structure effectively manages the various EU and local sector-specific regulatory requirements (e.g., compliance with local agency rules related to pharmacovigilance, drug promotion, etc.) while being consistent with overall local regulatory requirements (e.g., related to local labor and corporate law).

Moreover, setting up such a corporate structure is a daunting task in itself, but special care should be taken to ensure an overarching governance structure and its local implementation, so that the right people in the right places can effectively act

on behalf of the company and have the appropriate authority, within the limits set by a delegation of authority policy tailored to your company.

Hiring local staff and consultants carries a number of specific risks that can only be managed by a specialized local consultant. You need to ensure that local employees are sufficiently integrated into the overall structure of the company and are subject to the company's HR policies, while maintaining local regulatory compliance and consistency across the organization. In addition, provide appropriate guidance to your central HR services to ensure they can effectively manage these employees in full compliance with local laws.

How can we help?

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We can help you navigate your business through the complexities of these various requirements. You can rely on us to coordinate a smooth rollout across the various countries of the EEA. By using specialized local consultants through our dedicated network of friendly local partner firms, we can ensure fast response times and close coordination with local industry experts, while ensuring a single point of contact and consistent implementation for you.

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For a Switzerland-based biotech company focusing on epilepsy:

We helped the company build its local corporate structure across the European Economic Area (including the UK, Nordics, DACH, France, Belgium and other major markets) through a combination of local subsidiaries and branches, ensuring compliance with applicable corporate policies and regulations. This included the overall corporate structuring (in close cooperation with the company's tax department), the establishment and development of these local subsidiaries (including the appointment and integration of local representatives into the corporate structure), and the establishment of appropriate governance measures to ensure efficient decision-making on local company matters. We were able to assist the company in hiring local employees and consultants by providing uniform templates for employment and consulting agreements in accordance with the company's HR policies and adjusting the company's HR policies as needed to ensure compliance with all covered jurisdictions and to ensure consistent application throughout the company. We were also able to provide additional guidance (e.g., on compensation packages, layoffs, jurisdiction-specific policies) to further support the local operations of these subsidiaries/branches.

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Early access readiness

How is this a challenge?

To ensure timely patient access to your product candidate while the regulatory application is ongoing but outside the scope of your clinical trials, you need to build a platform that facilitates early access to your product candidate through a variety of different forms (open-label extensions, compassionate-use programs, named-patient deliveries, etc.). The availability of early access opportunities, as well as their terms, sometimes vary drastically depending on the applicable legislation in the country where your patient resides. This can slow down your clinical efforts to develop a global early access strategy across the EU. In addition, managing your early access programs requires you to engage external logistics services providers to organize your early access deliveries, which is often found to be a challenging task.

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How can we help?

We can help you either directly or through our dedicated network of friendly local partner law firms with all your early access issues in any relevant European jurisdiction and assess the feasibility of your global early access strategies. We can also assist you in your negotiations with your European early access logistics provider,

which often require highly tailored contractual and financial arrangements and ongoing monitoring/change management.

For a Switzerland-based biotech company focusing on immunology:

We helped the company establish its early access programs across the EU. Such programs often varied widely from country to country and required tailored arrangements and logistics.

For a US-based multinational focusing on rare diseases:

For many years, we were the law firm of choice for all early access issues throughout Europe. This gave us invaluable insight into the complex patchwork of early access in the EU.

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Regulatory readiness

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How is this a challenge?

As a growing clinical-stage biotech company, you are faced with a seemingly endless number of EU and local regulatory issues that often require specific expertise that you cannot easily and satisfactorily find in a single (even global) law firm. These issues involve a wide variety of topics (e.g., use of human biological samples, GCP compliance, provision of free samples, marketing authorization applications, local pricing and reimbursement procedures, local pharmacovigilance obligations, validity of patient support programs, etc.) that may attract the attention of regulators and should therefore be approached with caution.

How can we help?

Through our dedicated network of befriended local partner firms, we often act as a point of contact for biotech companies when dealing with specific local regulatory issues or coordinating cross-country surveys on a particular topic.

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Miscellaneous procurement readiness

How is this a challenge?

Biotech companies moving toward commercialization face an increasing number of contractual interactions that are often viewed as less strategic but place a large burden on their legal team. These contractual interactions are many and varied (NDAs, research services contracts, consulting agreements, IT procurement contracts, day-to-day supply contracts, compliance-related contracts such as speaker agreements and healthcare organization sponsorships, etc.) and can be complex and time-consuming.

This increase in the so-called "contractual backlog" has become a bottleneck for most life science companies, but is particularly burdensome for clinical-stage biotech companies, which typically operate with a small and lean legal team that lacks the human resources to manage this workload in a timely manner and must keep a constant eye on strategic matters.

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How can we help?

To address this increasing contractual workload of life science companies, and clinical-stage biotech companies in particular, we provide dedicated and tailored legal support on an ongoing basis through a team of contract experts to reduce the contractual workload of biotech company legal teams. By acting as an extension of the legal teams, we enable these teams to focus on strategic matters without giving priority (or hiring additional staff) to the growing contractual demands of their business.ongoing monitoring/change management.

This is a type of support that we provide by default to the majority of our clients on a day-to-day basis to alleviate their workload and allow them to focus on more strategic legal matters.

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IP optimization & BD

How is this a challenge?

The (golden) thread that runs through your entire readiness journey remains the preservation, optimization and valorisation of your technology and IP portfolio. You will need to manage and strengthen the lifecycle of your patent(s). You may need to share your confidential know-how with third parties, ask third parties to improve your technology, in-license technologies from third parties, enter into joint development projects with third parties, attract external funding (private or commercial) with demanding funding requirements. You may wish to valorise your IP, attract revenues and mitigate the risks of a largescale launch by out-licensing your IP regionally (e.g. to a region of lesser interest) or for a specific field (e.g. a therapeutic indication outside your primary focus area). In all these steps, you should prioritize protecting your confidential know-how, preserving your freedom to operate, and optimizing/valorising your IP portfolio (without diluting it). This will ensure the viability of your product candidate once it is on the market and maintain your attractiveness to external investors, acquirors and licensees (also if you decide to exit before commercial launch)

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How can we help?

The (golden) thread that runs through every step of our support is that we make sure we understand the science behind your product candidate. Throughout our support on your path to market, and especially in your strategic IP collaborations, we will always make sure that we (in close cooperation with your IP counsel) protect and enhance your IP portfolio and freedom to operate. This reflex is crucial when you share confidential know-how with third parties, ask R&D service providers to improve your technology, in-license add-in technologies from third parties, enter into joint development projects with strategic partners, raise external funding, negotiate (regional and/or field-specific) out-licencing agreements to generate revenue or mitigate the risks of a largescale launch. Our primary goal at every step of our support through your readiness journey is to ensure the viability of your product candidate once it is on the market and to maintain your attractiveness to external investors, acquirors and licensees, also if you decide to exit before commercial launch. Of course, we also have a dedicated licensing and M&A team to assist you with these exit strategies. Our consistent support throughout your readiness journey, will enable our team to provide perfectly tailored support throughout your exit story.

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For a Belgium-based biotech company focusing on virology:

We have been assisting the company since its inception and the in-licensing of its core intellectual property portfolio as it continues to develop its activities, ensuring that this intellectual property portfolio remains protected (and not diluted) throughout these activities. We are currently preparing the company for a due diligence project to sell its shares or assets to a major pharma multinational.

For a Belgium-based biotech company focusing on the development of vaccines:

We have supported the company during several investment series and ensured that its core (unpatented) in-licensed intellectual property remained protected from disclosure. We recently assisted the company in out-licensing one of its technologies to a major biopharma company and are currently negotiating the transfer of the company's more mature assets to an institutional investor.

For a Switzerland-based biotech company focusing on obstetrics:

We have assisted the company as of its stage I clinical projects throughout its entire readiness journey. We are currently supporting the company (in late clinical stage) in the exclusive out-licensing of its entire IP portfolio to a major multinational pharmaceutical company.

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