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Whitepaper

How to Successfully Apply for Orphan Designation in the EU and How to Maintain It

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Summary

Abstract

Successfully applying for and maintaining orphan designation (OD) in the European Union (EU) is a critical pathway for sponsors developing treatments for rare diseases. The process involves navigating regulatory frameworks set by the European Medicines Agency (EMA) under Regulation (EC) No 141/2000.

To obtain an OD, the applicant must demonstrate that:

- the condition affects no more than 5 in 10,000 individuals in the EU,
- the product offers significant therapeutic benefit over existing treatments, or
- no satisfactory method of diagnosis, prevention, or treatment exists.

Once granted, maintaining this status requires ongoing compliance with regulatory obligations, including regular reporting on the development status, marketing exclusivity updates, and adherence to timelines.

In this whitepaper we provide key reflections for navigating potential challenges in the preparation of an OD application, such as classification of the orphan condition, prevalence estimation, evidence of significant benefit, and medical plausibility. We emphasise the importance of a pre-submission meeting for obtaining an OD, and about generating evidence during the marketing authorisation (MA) process to maintain the designation. We also review the benefits and incentives of ODs such as protocol assistance, market exclusivity, access to EU grants, and fee reductions, which are vital for the commercial viability of orphan drugs in the EU. Finally, we highlight how the new EU pharmaceutical reforms are going to impact ODs.

Introduction

The orphan designation (OD) in the European Union (EU) is an important regulatory milestone for companies developing therapies for rare diseases. Successfully navigating this process involves understanding the regulatory frameworks and compliance with current regulations established by the European Medicines Agency (EMA). Our whitepaper outlines the essential considerations for preparing and submitting successful OD applications, as well as maintaining OD status. It covers eligibility criteria, application dossier preparations, application prerequisites, OD incentives for both small and medium-sized enterprises (SMEs) and non-SMEs, post-designation obligations, and OD maintenance activities. Additionally, the whitepaper discusses the impact of upcoming EU pharmaceutical legislation on the OD, including changes proposed to eligibility criteria and incentives, to keep sponsors well-informed about current developments.

The legislation on orphan medicinal products, Regulation (EC) No 141/2000, was adopted on 16 December 1999 and published in the Official Journal of the European Communities on 22 January 2000. This regulation outlines the process for designating medicinal products as orphan medicinal products and offers incentives for the development and marketing of these designated products.

Assess eligibility criteria: To qualify for orphan designation, a medicinal product must meet eligibility criteria according to the sponsor's guide to an orphan designation (europa.eu).

The current Regulation also establishes the Committee for Orphan Medicinal Products (COMP) within the European Medicines Agency (EMA), which is responsible for determining whether the applicant has established that the designation criteria are met.

As part of the OD application in the EU, the applicant is expected to submit a comprehensive scientific document. The success of the application hinges on the following key aspects in the scientific document, such as justification of the eligibility criteria, a high level of detail in defining the conditions, evidence of low prevalence, severity of the condition, demonstration of significant benefit, medical plausibility, and a clear distinction from related conditions.

In this Whitepaper we provide key considerations that need to be taken into account for successfully applying and obtaining an OD with the EMA as well as the key points of OD throughout development of the medicinal product including the incentives provided by OD. We also outline some of the changes to OD expected with the proposed new pharmaceutical legislation.

Key aspects for a successful application

Defining the orphan condition

To determine the OD eligibility of a medicinal product, it is crucial to grasp the differences between a condition, an orphan condition, and an intended orphan indication. A condition refers to any deviation from the normal structure or function of the body, as manifested by a characteristic set of signs and symptoms (typically a recognised distinct disease or a syndrome). An orphan condition specifies a rare condition that affects a small percentage of the population in the EU. Specifically, in the EU, a condition qualifies as "orphan" if it affects no more than 5 in 10,000 people. The intended orphan indication attributes the specific use of medicinal product in relation to the orphan condition and it indicates the therapeutic scope of the medicinal product; whether it is intended for the treatment, prevention or diagnosis of the orphan condition. It should be noted that the eventual indication sought for a MA application does not have to exactly match the orphan condition but should be covered by it in order to receive the incentives of the OD.

Tools for defining a distinct medical condition & expectations for level for condition.

When applying for an OD in the EU, defining a distinct medical condition requires the use of well-established scientific tools such as classifications, clinical descriptions, and epidemiological data. The COMP often expects the proposed orphan condition to be referenced according to internationally recognised classifications such as International Classification of Diseases (ICD) from the World Health Organisation (WHO) and Orphanet. These commonly used classification tools provide standardised criteria for naming and distinguishing rare diseases.

What are orphan subsets?

When a condition is not qualified as rare, but certain patient groups do, the applicant can still apply for an OD if their condition qualifies as an orphan subset.
Orphan subsets refer to subgroups of broader medical conditions that are not rare on their own but can have a subset of patients with specific characteristics making them eligible for OD. The subsets are defined based on distinct features such as a particular genetic mutation or a specific clinical manifestation that differs from the general population affected by the broader condition. However, it should be noted that as per the orphan regulation, subsets are only acceptable where solid scientific evidence is given that the activity of the product is not shown in the larger population. As such, "salami slicing" where non-orphan conditions are split into 'artificial' subsets, commonly seen in oncology indications, are not accepted.
An example of an acceptable sub-set would be the treatment of rhodopsin-linked retinitis pigmentosa, where patients have a mutation for the gene and therefore products aiming at providing a normal copy of the rhodopsin gene would not be effective for non-rhodopsin-linked retinitis pigmentosa.

Is it possible obtain an orphan designation in the EU for a previously not defined/new condition?

Yes, this is possible, but it requires defining a new condition based on changes in medical understanding. The process can be challenging as it involves a structured and scientifically rigorous process. The applicant must clarify the basis for the condition, define its pathophysiology, demonstrate its distinct clinical presentation, establish diagnostic criteria, provide epidemiological data, explain the unmet medical need, justify its distinctness from other conditions, utilise emerging classifications and expert guidelines, provide supporting evidence from the literature, consult with experts in the field and patient advocacy groups, and most importantly, consider interactions with the COMP for guidance and assistance early in the application process, including a pre-submission meeting as outlined below.

Medical plausibility

It is essential to provide preclinical and clinical evidence supporting the *potential* efficacy of the medicinal product when applying for OD. Applications for OD can be submitted at any time before an MA application but are generally submitted during the early stages of drug development. If no human trials have been performed for the drug intended to treat the rare disease or condition, the COMP will assess in vitro or animal study results that convincingly demonstrate the drug's potential effectiveness in treating the rare disease or condition. However, it is crucial that the species used in animal studies is recognised as an appropriate model for the corresponding rare disease or condition in humans, and relevant documentation should be provided to substantiate the appropriateness of the animal model. In cases where a suitable animal model is not available, creative approaches may be necessary to justify the use of a non-human model and clarify the drug's mechanism of action.

How to tackle prevalence calculations

The assertion that the condition impacts fewer than 5 in 10,000 individuals within the EU is based on careful prevalence estimates associated with an OD request. These estimates can be derived from published sources and databases (incl, epidemiological studies published in peer-reviewed journals, data from patient registries and national health databases, data from national and international health authorities such as WHO, Eurostat, or national health ministries, information from Orphanet Report Series, COMP Minutes, etc). It is important to note that the Orphanet or prevalence calculations from other approved ODs as per the European Commission's (EC) community register of orphan medicinal products must not be the primary source of information for the proposed prevalence

calculation. However, it can be used to support and validate the estimates calculated through other sources mentioned above.

COMP prevalence guideline: Points to consider on the estimation and reporting on the prevalence of a condition for the purpose of orphan designation

When encountering a range of prevalence estimates, the highest figure is considered the most conservative. Ultimately, the precedence search should be aimed to reflect the most conservative figures, indicating that the condition affects no more than 5 in 10,000 people. It is essential to differentiate between prevalence and incidence, with incidence referring to the number of new cases and prevalence representing the total number of individuals affected by the condition within the EU. While many prevalence estimates are based on data from previous years, it is crucial that the supporting sources pertain specifically to the EU population in the context of an OD request. Given the scarcity of data on the prevalence of rare diseases, applicants may need to employ innovative approaches to ensure a sufficient prevalence estimate.

In cases where no prevalence data is available, to manually estimate prevalence for diseases with acute versus chronic durations it is important to understand the impact of disease duration on prevalence. For acute conditions, the prevalence is often lower because patients either recover or die quickly, so the cases at a given point in time are fewer. On the other hand, chronic diseases tend to have higher prevalence, despite lower incidence, because individuals live with the disease for extended periods.

When estimating incidence from a larger population, careful attention must be given to population size and demographics, as well as the period over which new cases are tracked. Incidence rates are often derived from epidemiological studies, registries or screening programs, particularly in chronic conditions such as cancers or cardiovascular diseases. Screening allows detection of cases in asymptomatic stages, which can lead to higher incidence estimates. Therefore, estimating prevalence from larger populations or screenings requires some accounting for misclassification and misdiagnosis to ensure robustness of these estimates.

While addressing extreme situations where a disease's prevalence is approaching 5 in 10,000 threshold or when dealing with an ultra-rare condition, then focus on the most accurate, relevant and recent data along with justification of assumptions. If the prevalence is approaching the 5 in 10,000 mark, consider focusing on target population i.e., on subtypes, specific disease stages, or genetically defined group of patients that are smaller than the disease population or emphasise on the most recent and reliable data as long as the subset is justified as discussed earlier. On the other hand, if the prevalence data for an ultra-rare condition is incomplete or hard to find, the applicant may make transparent assumptions and justify them by explaining the methodology, particularly, if extrapolating from available prevalence given for a higher disease classification or using data from non-EU populations to adjust for differences, ensuring to account for any biases or limitations. However, in such situations, anticipate and prepare for a request for information from the COMP if not discussed before the submission.

Potential for significant benefit

In accordance with the orphan Regulation, the applicant must demonstrate that there are no satisfactory method of diagnosis, prevention or treatment of the condition in existence, or if such method exists that the medicinal product will be of significant benefit to those affected by that condition.

It is generally considered by the COMP that any therapy which is authorised under the same orphan condition in the EU is considered to be a satisfactory method. In these instances, there must be preliminary evidence demonstrating that the new medication has the potential to provide considerable advantages compared to existing therapies. The term "significant benefit" refers to a clinically relevant advantage or a major contribution to patient care which covers the new drug's ability to present a notable improvement over the approved drug. This may include enhanced efficacy, improved safety for a considerable segment of the target

population—indicating that it results in fewer or less severe adverse effects—or a substantial enhancement in patient care, which is more challenging to achieve. The vast majority of approved ODs are expected to improve efficacy (77% of approved ODs as of 2015; Fregonese et al. 2018).

Applicants should also be wary of other treatments that may be considered to be satisfactory, including non-pharmacological interventions such as surgery in the treatment of the orphan condition when considering the need to demonstrate significant benefit. While such instances are rare, a pre-submission meeting can be used to avoid any surprises at validation where the COMP may deem additional significant benefit arguments justified.

Applicants need to have a good understanding of the proposed positioning of the new treatment in the existing treatment landscape before authoring this section of the OD application. It's important for the applicant to discuss each and all available treatments to identify the different benefits per existing treatment, or class of treatments, if necessary.

When an applicant seeks OD for a new formulation of a previously approved drug—where the active ingredient remains unchanged—for the same rare disease or condition, it is essential to articulate the reasons why this new formulation may offer significant benefits to the patient population over the original.

Other points to consider

Additional prerequisites for an OD application which need to be considered include:

- Sponsor establishment in territory. The sponsors are required to submit a proof of establishment in European Economic Area (EEA). DLRC has EU legal entity, we can act as your EU representative and hold your OD should your company not be established in the EU.
- Translations. A document with product name and proposed orphan indication translated into all official languages of the EU plus Icelandic and Norwegian should be provided, unless the applicant is a registered as a SME.
- Registration of the applicant and product on the IRIS portal (Incorporated Regulatory Information System). This can be a lengthy process if your company has not used IRIS before. Full information for setting up on IRIS can be found here: IRIS guide to registration and RPIs v2.16 (europa.eu), but the main points to consider are the below:
    - Registering the company via EMA's Organisation Management System (OMS) and users via an EMA account management.
    - Requesting a research product identifier (RPI) for the product via IRIS. This requires your active substance to be registered in the EMA SPOR/SMS database. If it is not, additional time should be given for this activity. To note, the active substance name for the product will then be made public on the community register of designated orphan medicinal products if the OD is approved.

Is a pre-submission meeting with the EMA really needed?

Pre-submission meetings before the application are optional and requires draft version of the document for this. The EMA therefore advises applicants to arrange a pre-submission meeting through the IRIS portal by submitting a request at least two months before their intended submission date. This allows the COMP to review the draft application and to comment and answer any questions regarding the application and for the application to be updated before submission. Typically, these pre-submission meetings are conducted via teleconference.

While such meetings do mean additional time needed before submission of the OD application, the DLRC Group's experience of pre-submission meetings are that these meetings significantly enhance the likelihood of successful application(s) by minimising the risk of validation questions and review questions, leading to a faster approval time, or identifying major risks to the application that should be considered before submission. For example, potential issues regarding the acceptability of the proposed orphan condition, the prevalence calculation and any significant benefit considerations can be discussed. The evaluation process of the OD is strictly limited to a duration of 90 days and cannot be extended to address any deficiencies or missing information in the application. Therefore, having the ability to identify any potential issue before submission can really give applicants the best chance for a successful outcome.

IRIS portal: All OD-related submissions (pre-submission meeting request and initial OD applications) are submitted through the EMA's online portal, IRIS (Incorporated Regulatory Information System) following the submission deadlines.

Being prepared for the COMP evaluation

The Committee for Orphan Medicinal Products (COMP) evaluates OD applications. The process typically includes:

- Validation check: Ensuring the application is complete and meets basic requirements.
- Scientific review: Detailed assessment of the data provided.
- Questions and clarification: The COMP may ask for additional information or clarification during the evaluation.

The initial OD application process has a maximum duration of 90 days from the start of procedure assuming successful validation, without clock stops.
The timelines for the submission and procedure are preset by the EMA. However, it is possible to receive a positive outcome after the first COMP meeting at Day 40 if no questions are issued.

In case of any pending issues from the COMP's first discussion, a list of questions is sent to the applicant. The COMP usually invites the applicant to attend an oral explanation (OE) at Day 90 before a final decision is made on the application.

The OE usually takes place as a virtual meeting between the applicant and involves a presentation by the applicant and a question-and-answer session based on the list of issues raised by the COMP. After the OE, the COMP privately votes on the outcome of the procedure based on the arguments made by the applicant. This is the last opportunity for the applicant to address remaining issues form the COMP and is therefore important and a lot of preparation is required in both the preparation of the slides to contain convincing justifications and also to decide who from the applicant should attend the meeting and the roles and responsibilities are for each attendee. It is also possible for OEs to be cancelled during the COMP meeting if the COMP feels that the written responses to the list of questions issued are adequate to address the outstanding points. Therefore, there is a high importance for the responses to be of high quality with appropriate justification.

The opinion and decision

As discussed earlier, the COMP will adopt an opinion on the application within 90 days of submission, Opinions may be reached earlier than day 90 if no questions are raised by COMP.

If the COMP's opinion is negative after an OE, the applicant can appeal. However, the scientific coordinator for the procedure is able to inform the applicant if the vote is trending towards a negative opinion which allows the applicant the chance to

withdraw the application before the procedure is completed. This is good mechanism that can be used by applicants to prevent the negative decision from being made public.

The EC issues a decision on a COMP opinion within 30 days of receipt. Following the EC's decision, EMA makes information on the OD publicly available on the IRIS platform and the EC enters the OD into the community register of designated orphan medicinal products.

Don't forget about post-designation obligations!

Once the OD has successfully been granted, the sponsor of the OD must submit an annual report with updates on the status of product development each year until a Marketing Authorisation Application (MAA) has been approved. No other activities are required to retain the OD until MAA submission. However, the OD holder has an obligation to ensure that the criteria for OD are still met throughout the drug development and should be communicated to the COMP if the criteria is no longer met. As with all OD related submissions, annual reports are completed in IRIS.

Preparing for eventual MAA submission

Once OD has been granted, the OD Sponsor can approach the EMA for Protocol Assistance for development for any indication covered by the approved condition. Protocol assistance has the same benefits as scientific advice in the EU, but with the added benefit of including questions related to significant benefit, such as how significant benefit can be demonstrated against other approved therapies through clinical trial design elements, approaches for indirect comparison if required and refinement of the scope of treatments that require comparative data and planned evidence to maintain designation at the time of the MAA. This is one of the incentives of having OD in the EU and is an important opportunity that many developers can miss, which can often give them a great advantage for the maintenance activities during the MAA review as below. It is valuable to keep a close eye on the existing treatments as agreed during the initial OD application as drug development continues as this can influence data gathering efforts during this period to ensure relevant comparative data at maintenance review as discussed below.

Maintenance activities during MAA review

During the MAA procedure, to retain the OD and benefit from OD incentives for the MAA and nationally (see below for more information), an orphan maintenance report is required which is sent to the COMP as a separate procedure to the MAA. This procedure is a more in-depth review of the designation compared to that for the initial OD submission, including a review of the prevalence, nature of the condition and significant benefit.

The orphan maintenance report will also need to consider any new approved medicines in the EU covered by the orphan condition in addition to any included as part of the initial OD application. The requirement to show significant benefit over these approved medicines is higher than that needed for the initial designation as comparative data will be required to demonstrate the justifications. Ideally the data should be presented as a head-to-head comparison, but where this is not possible, an indirect comparison of the data may be needed.

MAA applicants need to carefully consider the maintenance report and significant benefits well in advance of the submission. The chances of the COMP issuing questions and the need for an OE during the procedure can therefore be quite high, which can be a challenge while also trying to manage an MAA procedure and review questions! The timing of questions from the COMP also differs depending on if the MAA procedure is for a standard timeline or for Accelerated Assessment procedure and for the latter the exact timing of first COMP meeting can be unpredictable. The

COMP can leave the review of the maintenance report until the end of an MAA procedure to be sure of the indication of the MAA, whereas for an accelerated assessment, the COMP may review the application earlier. The MA applicant must therefore be prepared to answer questions raised by the COMP on the maintenance report and prepare for an OE while also potentially dealing with MA review questions, especially the case of an accelerated assessment procedure which can be quite intensive for the applicant's functional team.

In order to derisk the maintenance report review, protocol assistance as below, is available to OD holders to discuss significant benefit justifications and should be utilised where possible.

After the MAA has been approved and OD hopefully retained, maintenance activities may also be required if an extension of indication application is submitted and therefore it's important for MA holders to plan any such regulatory activities carefully.

By following these steps and ensuring that all criteria are met and properly documented can improve Sponsor's chances of successfully obtaining and maintaining an OD in the EU.

Benefits and incentives of orphan designation

A successful designation EU provides several incentives to the sponsors, additional fee reductions are available for sponsors with SME status.

- Protocol assistance: A type of scientific advice specifically designated orphan medicines. This allows sponsors to get answers to their questions on the types of studies needed to demonstrate the medicine's quality, benefits and risks, and information on the significant benefit of the medicine.
- Market exclusivity: 10 years post-authorisation market exclusivity period, this is further extended by two years for medicines that also have compiled with an agreed Paediatric investigation Plan granted at the time of the OD.
- Eligibility for EU-funded research grants.
- National benefits including higher price lists, tax exemptions, benefits during Health Technology Assessment (HTA) which can differ on a country-by-country basis.
- Fee reductions for regulatory activities as listed in the table below for SME vs non-SME sponsors. For more detailed info, see our article on 'How SME accreditation can maximise your benefits with the EMA?'

SME versus non-SME orphan designation fee reductions comparison

Regulatory activities	SME	Non-SME
Protocol assistance:		
non-paediatric related	100%	75%
paediatric related	100%	100%
Initial MAA application	100%	10%
Inspections:		
Pre-authorisation	100%	10%
Post-authorisation	90%	0%
Post-authorisation activities, first year annual fees after authorisation	100%	0%

Cooperation between EMA and FDA

The EMA and Food and Drug Administration (FDA) have established a close collaboration on orphan medicines, facilitating the sharing of information under their confidentiality arrangement. Despite differences in the United States (US) and EU OD application procedures, including prevalence criteria, dossier structure, assessment timelines, etc., the two authorities have successfully developed common procedures for applying for OD and submitting annual reports on the status of the development of designated orphan medicines. Notably, both the EMA and the FDA will now accept the submission of a single annual report from sponsors of orphan products designated for both the US and the EU, streamlining the process for stakeholders.

Impact of the new EU pharmaceutical reforms on orphan designations

In April 2023, the EC proposed changes to the current EU pharmaceutical legislation, marking a significant reform. This reform consists of two proposals: one directive and one regulation. The European Parliament (EP) has made amendments to some of the proposed changes in April 2024. Following this, the EC's position will be adopted, and trilogues (negotiations between the EC, EP, and Member States) are expected in Q1 or Q2 of 2025, followed by a second reading and final adoption.

The new proposals impact the ODs in many ways.

Structural and responsibility changes:

- The responsibility of ODs is transferred from the EC to the EMA.
- OD applications must be submitted to CHMP as the COMP committee will not exist anymore, but its expertise will be retained and reorganised in the form of working parties and a pool of experts.

Procedural and eligibility criteria changes:

- The criterion 'return on investment' has been abolished, as it was never used. Whereas the remaining eligibility criteria are the same.
- Definition of 'Significant Benefit' is updated to state that an advantage or contribution has to benefit a substantial part of the target population.
- EC proposed to setup specific designation criteria for certain conditions, if the ones provided for are not appropriate due to scientific reasons. However, the EP amendment proposed to delete this.
- Validity of OD has been set at 7 years (currently unlimited validity) with the possibility of extension by the EMA under certain conditions.
- Phased review of completed at a package for individual modules maybe available for MAAs.

Changes to market exclusivity incentives:

- Reforms propose a variable duration of market exclusivity, based on the type of orphan medicinal product:
  - 10 years for High Unmet Medical Need (HUMN) (*EP proposed 11 years*).
  - 9 years for new active substances.
  - 5 years for well-established use applications (*EP proposed 4 years*).
- A 'bonus' market exclusivity extension of 1 year, based on patient accessibility in all relevant Member States for HUMN products and new active substances. EP proposed to delete this point.
- An additional period of one year of market exclusivity is granted for a new therapeutic indication with a maximum of two indications.

- A six-month Supplementary Protection Certificate (SPC) extension following completion of a Paediatric Investigation Plan (PIP) is proposed for orphan medicines, instead of existing restriction in incentives to market exclusivity.

Conclusion

Successfully obtaining and maintaining orphan designation (OD) in the European Union (EU) through the European Medicines Agency (EMA) is a crucial step for companies aiming to address rare diseases. This designation provides significant benefits, including market exclusivity and regulatory support. Key to success is a thorough understanding of the EMA's requirements, including clearly defining the condition, demonstrating the treatments' potential benefit, and maintaining early and continuous engagement with the EMA. Strategic planning and robust data are essential to align with regulatory expectations to navigate the complexities of the OD process, as well as how to tackle the challenge of maintaining OD at time of MA review and beyond.

In summary, effective OD applications in the EU hinges on a well-informed, patient-focussed approach that integrate scientific rigour with proactive regulatory engagement. As rare disease treatment evolves, this approach will remain vital in bringing innovative therapies to market and improving patient outcomes.

DLRC's orphan designation expertise

DLRC has extensive experience in obtaining OD and has assisted numerous clients in various countries. Our experts guide clients through all aspects of OD application preparation and submission, especially in light of newly proposed EU pharmaceutical legislation, to maximise their chances of obtaining OD status and beyond.

DLRC's expertise in rare diseases and regulatory affairs:

- Provide bespoke advice to sponsors on OD eligibility criteria.
- Serve as your EU representative and hold your OD for sponsors that are not established in the EU.
- Support in drafting and submitting OD applications and provide key inputs related to key sections in the application dossier such as prevalence and significant benefit.
- IRIS and EMA systems support.
- Communicate with the EMA on behalf of clients during the evaluation process.
- Submit OD Annual reports and OD transfers.
- Support with OD maintenance activities and submissions.

About DLRC

DLRC is an award-winning consultancy team of more than 80 highly qualified, experienced regulatory professionals operating from our offices in the UK, Germany, and US. With a deep commitment to excellence, we are dedicated to helping clients navigate the complex regulatory landscape of the life science industry. We develop and execute innovative phase-appropriate regulatory strategies, providing comprehensive support from early development to post-licensing activities for medicinal products and medical devices. Our team comprises consultant experts in nonclinical, CMC, clinical and MedTech from pharmaceutical, medical device and regulatory agency backgrounds. We have proudly served companies of all sizes and backgrounds in various regulatory jurisdictions.

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