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Guidance and Considerations on Selecting a Regulatory Consultant

Context

Because the regulatory landscape for medical devices, diagnostics, and drugs includes many factors to consider simultaneously, innovators may find it useful to engage a regulatory consultant. Developing a strong regulatory strategy – in parallel to a reimbursement strategy and other commercialization efforts – is essential for innovators seeking Market Authorization for their new product.

Research the Field and Evaluate the Options

It can be confusing to understand the key elements to consider when evaluating what person or firm will be a good fit to support the development of your technology. To start, understand there are three areas of specialization for regulatory consultants – quality, regulatory, and technical. An ideal consultant will be highly qualified in all three *and* have knowledge specific to the technology your company is developing.

Finding a consultant

- Ask your board of advisors, investors, peers/entrepreneurs, or associations for regulatory consultant recommendations.
- Contact universities with degree programs in regulatory affairs – some of their professors may have their own practices.
- Some consultants have their own companies; others may be part of boutique firms or larger law firms. There may be differences in pricing and access to resources and support staff between these options.

Consultant qualifications

- Their specialty should align with your type of product and your targeted therapeutic areas.
- They should have experience with similar sized businesses, and technologies at the same stage of development as yours.
- They should be knowledgeable about the most likely regulatory marketing pathway for your technology and be familiar with (and have some experience in) alternate regulatory marketing pathways in case your initial strategy goes awry.
- They should have current knowledge of your regulatory bodies of interest and the offices or divisions within which your product will be reviewed.

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- They must be able to communicate problems and provide solutions in a clear, concise manner so you know what needs to be addressed/corrected and how to address/correct the challenges that will arise during the regulatory process.

Depending on your budget and the services necessary to support your medical product, you may want to look at different size firms or independent consultants. Developing a Statement of Work (SOW) will help you clarify within your leadership team what you are trying to outsource and can ensure your conversations with multiple potential vendors are focused on the same deliverables (apples to apples comparison). It can be helpful to share your SOW with potential vendors. Sample SOWs for soliciting regulatory vendors can be found [here](#) and [here](#).

Schedule introductory calls with multiple regulatory experts (these calls are usually free). Ask specific questions to gauge if they truly have expertise in your field. (See checklist below.) A good consultant will also be assessing you as a potential client. They will evaluate the preliminary information you have at hand and their ability to guide you before agreeing to join the effort. Consultants typically enjoy working with responsive but not overly intrusive clients. Ask what they will need from your team, and at what points, to accomplish your common objectives.

Checklist

[The following list may serve helpful in preparation for and during the phone interview.]

It is useful to create a document in advance of your call with the questions you expect to ask and to use this document to take notes during the meeting. It is also useful to research potential consultants and support team members backgrounds before the call. Once you have a list of attendees you can search for articles they may have published, recent presentations, etc.

- Ask the key person/people who will perform your work about their track record.
 - How long have they been consulting?
 - What is their previous experience?
 - What is the most complex situation they have worked on thus far?
- What is their awareness of current trends in your drug, diagnostic, or device area? For example, you might ask for their thoughts on a relevant guidance document.
- Have they ever worked on getting Market Authorization for a new drug/diagnostic/device in your specific industry?
- How much of your work will be done by the person/people you are interviewing versus by junior team members?
- How do the people who will work on your project stay current in their field?

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- Evaluate if the consultant's fees are consistent with your need and ability to pay. What types of services do they/ the company provide, and how is pricing determined? Are you able to choose some services (a la carte) versus an entire package (fixed price) or time and materials (hourly)?
- Are past clients (of similar size to your company) willing to provide references?

Resource:

NIH: [NHLBI Small Biz Hangout video: Finding the Right Regulatory Consultant](#)

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