

Interview

6 tips for early-stage MDx companies seeking successful commercialisation

An interview with Experienced Advisor, Harry Glorikian and Senior R&D Director, Sébastien Chapdelaine

Introduction

There is no one-size-fits-all blueprint for bringing a molecular diagnostic (MDx) assay to market. Alongside the core scientific problems, companies may face a variety of supply chain, manufacturing and compliance challenges. Fortunately, most can be solved, and some can even be prevented.

As a veteran board member and storied investor in MDx companies, Harry Glorikian has witnessed diagnostic success and failure first-hand. Currently a general partner at New Ventures Funds, Glorikian outlined some of these lessons in his book, *“Commercializing Novel IVDs: A Comprehensive Manual for Success”*, which has become an invaluable industry resource. One of his overarching messages is that companies need to have a macro plan in place from the very beginning.



“You need to have a really well thought out strategy from R&D through commercialisation, including regulatory,” Glorikian explains. *“Otherwise there are hiccups down the road.”*

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A key example of this is the decision-making around who supplies your assay components; whether they be oligonucleotide/probes, enzymes, extraction reagents or PCR master mixes. A lot of the major choices made during the transition phase from early R&D to manufacturing can have considerable impact when facing commercialisation. It can be tempting to choose a supplier based on short-term goals and budgets, but the implications extend all the way through to commercialisation.

In a recent interview, Glorikian shared some tips for how early-stage companies can find and choose the best suppliers, with notes on maximising the relationship and mitigating risk.

Disclaimer:

Quotes from Harry Glorikian are intended to be general lessons about choosing a supplier. In no way are they to be interpreted as an endorsement of one specific supplier over another.

Lesson 1: Find a partner

Taking an MDx assay to market requires deep industry knowledge and a range of skill sets, which may be in short supply depending on your resources and location.

“At a small company, it’s going to be difficult to get the required expertise in-house, unless they’re extremely well-funded,” Glorikian points out. *“Even then, you might not get the perfect person for what you’re trying to develop.”*

This gap in expertise can often be bridged using external resources, including a trusted component supplier. In these cases, a supplier can serve as a strategic partner, working with you to understand your current and future needs and helping you anticipate any problems

and challenges that may surface during R&D and the scale-up required for manufacturing. This virtual support can be even more critical if you’re not based in a major life science hub.

“It’s hard to have all those capabilities in a small place so it could behoove someone to ask the right partner or have the right consultants that they would utilise,” Glorikian states, noting that he sometimes encounters companies that focus too heavily on the research and thus need extra help on the commercial side.

Identifying the right supply partner for your R&D and business model may require lots of market research and trial-and-error, but ultimately it can provide additional value, such as market or customer knowledge – a useful asset as your MDx company moves towards commercialisation.



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Sébastien Chapdelaine is the Senior Director of R&D at a MDx start up company. Over the past eight years, his R&D team has relied on a raw materials supplier for oligonucleotides and fluorescent qPCR probes. In an interview with Chapdelaine, he explained some key attributes of their supplier that makes them a trusted partner for him and his team.

Q: How has your supplier helped you plan for future manufacturing and commercialisation needs?

Chapdelaine: *“When there is an acquisition or a rapid increase in sales, there can often be a risk of a back order or shortage of raw materials. We communicate the right information to them so they are aware of any potential changes in our needs. I think, the fact that we have this open discussion is a critical starting point to avoid future problems.”*

Lesson 2: Start with quality

Component quality and consistency are of the utmost importance throughout product design, manufacturing, approval and commercialisation. In early R&D, poor product quality or consistency can introduce uncertainty and make troubleshooting difficult. Ultimately, component quality affects overall product quality.

For that reason, Glorikian recommends companies looking for a supply partner understand their own strengths and gaps and ensure that suppliers demonstrate that they can provide adequate batch-to-batch consistency.

Ensuring that suppliers follow protocol in the maintenance of quality and have a quality management system in place is a key step not only for quality but also for compliance with relevant ISO or other regulatory requirements.

Glorikian explains; *“You want to make sure that [potential suppliers] are operating with any GMP and ISO certification they may need, depending on where you are in the world.”*

Q: What are the key characteristics that you value in your supplier?

Chapdelaine: *“We have been working with them for eight years now and so, when it comes to choosing an oligos and probe supplier, it was the quality of the raw materials. We’ve come to our current supplier from another supplier. We got better reproducibility and better quality from batch-to-batch.”*

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Lesson 3: Look for products and knowledge

Depth of knowledge, experience and scientific expertise as a supplier of components is crucial for solving difficult R&D problems, quality issues with components, manufacturing issues and staying on agreed-upon timelines.

“The supplier or partner should have familiarity with the reagents they are supplying,” Glorikian says.

He suggests companies vet their suppliers by letting their team connect with technical experts on the supply side to ensure they know their space and products. By doing so, team members have the opportunity to evaluate a potential supplier based on the criteria they value most. This will allow them to grow and innovate alongside your program. Plus, they’ll have a running start when it comes to solving any issues that arise.

Q: How does your current supplier handle technical questions and troubleshooting?

Chapdelaine: *“The level of expertise and the responsiveness is good. With our current supplier, we don’t need to escalate any question up two or three levels. There are a couple of people that can answer quickly by themselves. They are really managing that perfectly. They connect technical people with technical people. So, our questions and concerns aren’t going to new sales representatives.”*

Need tips on how to pick a supplier? Take a look at our guide for [early-stage companies](#).

Lesson 4: Fortify your supply

Understanding and planning ways to manage and minimise risk is a critical part of any commercialisation strategy. In the MDx industry, mitigating risk with a component supplier means not relying on them as a “sole source.”

Glorikian says that if someone informs him that they can’t make a product because their supplier is down, he immediately asks why they don’t have a second source identified. It’s a serious red flag – though in certain scenarios, supply chain issues are unavoidable.

“I think these days there’s a variety of suppliers, but if you really need something unique, you may get sort of stuck in a corner,” he says.

So what can you do to prevent and mitigate a product shortage? When an alternative supplier is available, Glorikian recommends actively keeping them as a backup option in case something unexpected occurs.

When vetting your primary supplier, ask about what backup manufacturing facilities they have and what plans are in place for a supply chain emergency. Should something happen to one of their facilities, are there alternatives that you can rely on?

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Lesson 5: Think big picture with budgets

With any purchase, it can be tempting to choose the cheapest short-term option, without considering the long-term consequences or the broader plan.

“With assay components, it’s always nice to save a few pennies,” Glorikian says. *“But you don’t want to be penny-wise, pound foolish.”*

The costs associated with switching suppliers can quickly eclipse the savings you made in the early R&D stages. This often occurs during manufacturing and commercialisation, when it becomes obvious the assay components can’t scale to meet your new demands or it can’t be done efficiently.

Lesson 6: Achieve large-scale success

It’s a good problem to have: As your program advances toward commercialisation, your team needs to determine how best they can scale-up the manufacturing, without a subsequent drop in quality or efficiency.

For some suppliers, this is not straightforward. Especially while maintaining GMP or other regulatory guidelines.

“I’m not always worried about whether or not you can just scale up,” Glorikian asserts, *“I’ve never seen a company go from zero to 100 overnight... I haven’t seen many insurmountable issues when things are proven at a smaller scale. With the right team, it is usually manageable.”*

While scalability problems may not be technically difficult and set-back timelines, it can disrupt some of the issues discussed above, such as cost and trusted partnership – benefits that it may be difficult to find with a new partner.

Q: How has your current supplier supported your manufacturing scale-up needs?

Chapdelaine: *“We are right in the middle of the scale-up now. I’m very positive about the future. Our supplier is coming for an on-site visit to learn more about what phase we are in and to be involved in the planning process. Instead of waiting for problems to arise, they are proactive.”*



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Final thoughts

Molecular diagnostics will continue to play a major role in healthcare delivery around the world, helping with therapeutic monitoring, detection of predisposition to disease, patient stratification, drug regimen selection and many more. But along the way, technologies and needs are changing, Glorikian says.

“Keeping up with the future is difficult because the market is always in a state of flux,” he notes. “What you are working on today may not be as relevant tomorrow.”

That’s why it’s critical for MDx startups to establish a path that can take them from early research right through to global commercialisation, avoiding the need to transition suppliers and component designs along the way.

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