

## MDBR Interviews Harry Glorikian About the Growing Significance of *In Vitro* Diagnostics

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Sharing his insight with MDBR, Glorikian discusses the recent release of his Manual, **Commercializing Novel IVDs: A Comprehensive Manual for Success**, and the role of *in vitro* diagnostics (IVD) today.

Harry Glorikian writes for Insight Pharma Reports, a division of Cambridge Healthtech Publishing.

**MDBR:** What prompted you to write, *Commercializing Novel IVDs: A Comprehensive Manual for Success*?

**HG:** For the past several years, especially, I've run a "Commercialization Boot Camp" at the Molecular Med Tri- Conference. This short workshop is designed to give attendees an overview of the process from start to finish. But as you might expect, it's impossible to condense the immense amount of information, from design considerations to regulatory pathways to reimbursement and market launch in a few hours. I was hearing the same questions over and over after the workshop and decided there was a real need to put this information in a single manual that people could refer to or that they could use as a kind of roadmap of the commercialization process.

**MDBR:** Did you see an unmet need in the industry to write *Commercializing Novel IVDs: A Comprehensive Manual for Success*?

**HG:** Absolutely! I do think there's a real need for a manual like this. I've not come across any other book as comprehensive that covers the entire IVD development process from start to finish like this one does. Each part of the development process is highly specialized, so to have information on each step in one location can be incredibly helpful.

**MDBR:** What makes *Commercializing Novel IVDs: A Comprehensive Manual for Success* unique, and something that diagnostics community should have on their desks?

**HG:** What makes this manual unique is that it goes beyond the 'checklist' mentality of things to do. This manual provides an overview of the key trends affecting the IVD industry, from the expansion potential of global markets to the aging population to the impact of regulatory uncertainty and evolving reimbursement models. To be competitive in today's market, companies must understand where their device fits in the bigger picture. Often, the development process is silo-ed and it's easy for companies to go off track because each part of the process is isolated from the others or because external pressures weren't considered adequately (or even at all). This book describes how all the parts fit together at a high level, while mentioning the potential pitfalls to avoid.

**MDBR:** How do you provide an overview of the major components to IVD development in *Commercializing Novel IVDs: A Comprehensive Manual for Success*?

**HG:** The book starts out with an overview of global and regional trends that have a significant impact on the IVD industry and Chapter 2 is focused on understanding the patient experience and identifying the unmet need. These both influence product design. Good Manufacturing Practices and FDA's Design Control Guidance are frameworks that are included in Chapter 3, where I write about the iterative nature of the design process and what specific requirements pertain to IVDs.

Chapter 4 outlines the evolving regulatory space around IVDs. I discuss the different development pathways an IVD might take, for example, an analyte-specific reagent or a lab-developed test. Reimbursement and coverage determination are described in Chapter 5. As with regulatory issues, reimbursement is changing and companies need to understand that a move away from fee-for-service makes demonstrating that your product can reduce overall costs and/or improve patient outcomes essential. What data to collect, how to structure your clinical trials and cost-effectiveness studies, and understanding how IVDs are analyzed by payers and other third party organizations is included in Chapter 5. I discuss commercialization strategies, including how the sales force, customer service, and marketing staff roles in Chapter 6 and end the manual with a look ahead at emerging technologies and how data analytics are beginning to change the industry.

**MDBR:** Who should read *Commercializing Novel IVDs: A Comprehensive Manual for Success* and why?

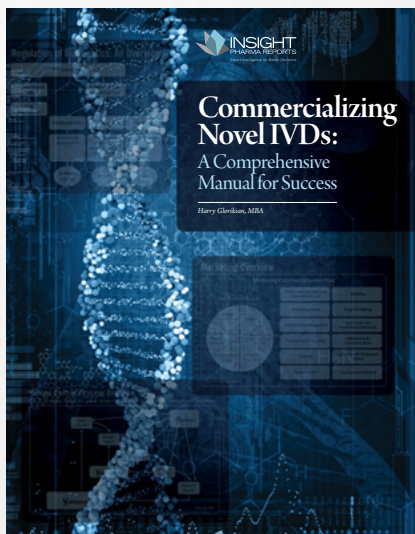
**HG:** I think this manual is beneficial for everyone involved in the IVD industry. Knowing what pitfalls to avoid, alternative pathways to consider, and which job roles you need to hire for, at the very start, make this manual informative for individuals looking to bring their idea to fruition, those who are just beginning the development process. Experienced individuals can find valuable information about emerging trends, evolving regulatory requirements, and reimbursement processes that are impacting the market.

**MDBR:** What do you think are the reader's key take-aways from *Commercializing Novel IVDs: A Comprehensive Manual for Success*?

**HG:** I think the two most important things readers can walk away from this book with are making sure you've clearly defined the unmet need your device will fill and how essential it is to have the right team in place from the very beginning of the process. Each component of the commercialization process is highly technical and you need to have people who are experts for each step of the process. Find someone who understands the reimbursement process, someone who can manage the regulatory pathway, someone else who can handle the design component. Having a project manager who can make sure nothing slips through the cracks, who can communicate with all the stakeholders, from scientists to sales staff, and who can make sure that the development process stays on budget and deadline is also crucial. In the end, who you have on your team can mean the difference between a successful product and one that fails.

Harry Glorikian's other work on *in vitro* diagnostics can be found here on the MDBR.

*As a thank you for reading this interview, Harry Glorikian would like to extend a special discount to you for his Novel IVD Manual. Please Contact Dan Miller for special discounts and site/global site licenses at 781.972.5492 .*



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