



Evolving Role for Medical Affairs in Biopharmaceutical and MedTech Product Launch Requires New Skills, New Thinking

In the pharmaceutical and MedTech industries, product launch encompasses far more than regulatory approval. And with the desire for increased speed to market of products that tend to be targeted to ever more specific patient populations in an ever-expanding information landscape, the traditional models of launch are undergoing disruptive change. The Medical Affairs function is at the forefront of this change, creating the scientific understand of a new product that helps healthcare providers optimize the use of new products to promote patient benefit in real-world settings. These activities require Medical Affairs professionals to develop new skills and new ways of thinking, both strategically and executionally.

With this need for new skills in mind, the MAPS is offering Launch Excellence MasterClass 2021 – two-day, in-person trainings in fall 2021 for up to 50 participants each in New York, Philadelphia, Boston, Chicago, Zurich and Paris. Here MAPS speaks with the following members of the Launch Excellence MasterClass Planning Committee about the changing face of pharma and MedTech launch, and how Medical Affairs professionals within these organizations can ensure they are applying best practices to the launch planning process.

Interviewees:



Marija Simin Geertsen

VP Medical Affairs, Lundbeck Pharmaceuticals



Sarah Clark

Global Head of Medical Affairs and Operations, Biogen Digital Health



Greg Christopherson, PhD

VP Medical Affairs, Medline Industries



Arron Mungul

Medical Capabilities Lead (International Markets), Bristol-Myers Squibb

MAPS: Why is now an important time to learn, relearn or refresh Launch Excellence skills?

Marija: We are facing the Future of Work shaped by learnings from the COVID-19 pandemic. As never before, whole societies with respective healthcare ecosystems and industries have embraced digital communication channels and virtual working platforms. This means that a successful launch, in this new era, will only be possible if we upgrade existing best practices. We are in a time of disruptive innovation in healthcare as a whole, therefore industry will need to adopt new skills launch products in new ways. Change is inevitable and it starts NOW.

Sarah: I'll add that as pharma moves into a new way of working post pandemic, launch success will require a deep knowledge of the treatment paradigm evolution and healthcare ecosystem in order to tailor services beyond the pill. With scientific expertise and peer-to-peer relationships, Medical Affairs is uniquely positioned to bring an understanding of this evolving healthcare ecosystem back to the organization. Utilization of digital technologies will facilitate personalized and innovative launch tactics, enabling an analytics-based approach that can iterate and improve over time.

MAPS: How will this 'new normal' shape Medical Affairs' role in pharmaceutical and MedTech launch?

Arron: Medical needs to be involved earlier. For example, because Medical hears the perspectives of healthcare providers and advocacy groups, we can help bring a patient-centric perspective to development. Say you're designing a phase 3 study – Medical could bring in aspects beyond endpoints like progression-free survival, for example quality of life surveys with patient advocacy groups, which might not be a tool from a regulatory perspective, but speaks to how a drug will eventually be used. Medical affairs can also help differentiate new product from competitors – maybe you come onto market in a study against placebo, but now as part of launch planning, Medical Affairs can work with existing data and new evidence generation to show how a product compares to competition. The earlier Medical is involved in launch planning, the more we can ensure a product's full value proposition and data package are ready for a successful regulatory submission and reimbursement decisions. The true value of engaging earlier in the product lifecycle comes from acting on insights identified by Medical Affairs teams to identify challenges and inform prioritization of launch activities.

MAPS: Greg, as a Medical Affairs professional working in MedTech, how do you see launch excellence differing between MedTech and pharma?

Greg: Generally speaking, MedTech doesn't have the level of resources and systems sophistication as our pharma counterparts, but best practices and approaches are congruent. In terms of the MAPS Launch Excellence MasterClass, every MedTech participant will need to absorb content and rationalize it for their business, but we all benefit from observing the best pathways to success and any type of dialogue with experts and peers across the Medical Affairs spectrum, regardless of industry. There really is no other forum for MedTech participants to learn launch planning at such a high level, and for those that are looking to continue to push

the success of Medical Affairs in device and diagnostics, advanced fundamentals like these are the universal building blocks for a high achieving program.

MAPS: It sounds like the changing face of product launch present opportunities for Medical Affairs...

Marija: In the last decade, we have witnessed exponential evolution of communication channels and patient access to information on digital search platforms and in social media. The innovation in the area of communication has further exploded during the COVID-19 pandemic given the necessity for virtual connectivity. Therefore, the opportunities to upgrade Medical Affairs communications with the healthcare providers to improve patient outcomes are now truly revolutionary. The other evolving opportunity on the horizon is linked to the importance of generating evidence for patient outcomes in real clinical practice. With digitalization of the healthcare landscape, the opportunities for innovation in generating real world evidence are becoming literally endless. Some of the obvious examples are diagnostic digital monitoring applications and wearable devices linked to electronic chart recording and digital registries for patient outcomes monitoring. On top of the continuous innovation in data collection, there are opportunities to innovate with data analysis via AI platforms to enhance human validation. Given that these activities will require new sets of skills, enriching the job profiles and organizational capabilities build up, we need to upgrade our launch planning efforts now, to secure successful transformation in the future.

MAPS: Does acquiring expertise in launch excellence position Medical Affairs professionals or the function as a whole to solidify its strategic role in the organization?

Marija: Medical Affairs is well positioned to take the leadership role across pre-, peri- and post-launch, which requires an upskilling across technical and human skills to lead internal and external stakeholders to achieve launch success and robust lifecycle management through cross-functional collaboration in the launch planning process and actions such as real-world evidence generation based on this plan.