The Journey Toward
Launch Excellence

Harnessing the Power of Experience and Insights

By Timo Schwemer and Rohit Sood

Achieving launch excellence is a journey—a journey of learning from the successes and mistakes of the past, as well as adjusting to changing market dynamics. To achieve launch results that consistently exceed expectations, companies need to consider developing in-house launch excellence capabilities, supported by dedicated staff.

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Health

The Journey Toward Launch Excellence

A universal launch excellence approach can accelerate launches by integrating and leveraging learnings from within and outside the organization. Key elements of "excellence" as we apply it to the concept of launch include:

- Ensuring common language
- Excelling / communicating in a matrix organization
- Establishing a common standard
- Empowering organizations to deliver on expectations
- Enabling best practices and innovation

It can be difficult for life sciences companies to successfully develop launch capabilities or core competencies, especially as portfolios and product area focus changes. Frequently, launch teams are structured functionally rather than by the value streams, which are the key steps in the launch process. In a siloed structure, it is challenging for an individual or a team to learn from the experience of the teams that managed previous launches. When teams do not share institutional knowledge and industry best practices to achieve launch excellence, each launch will be different and produce inconsistent results. Some launches, for example, may be led by strong strategic leaders, whereas others may emphasize detailed tactical plans that do not always support the brand strategy.

After working over a decade to help companies execute more than 500 global launch engagements, Syneos Health Consulting has developed a proprietary approach to building launch excellence as a core capability, training a team to deliver it expertly, and creating a process for knowledge transfer across an enterprise.

This article will examine the importance of the journey toward launch excellence and show why many companies today are investing in developing the right launch processes and capabilities. This article also will examine why knowledge transfer is critical in ensuring the success of a launch given external pressures, and it will detail the considerations necessary for developing a robust and continuously evolving launch excellence capability.

2 |

Growth from Launches Under Pressure

Approximately two-thirds of all launches do not meet expectations. Of the 33 assets launched between 2011 and 2014 that were expected to hit blockbuster status, only 11 are on track to meet expectations, as shown in Figure 1 (page 5). Some of the reasons for missing launch expectations are outlined in Figure 2 (page 5).

A number of external factors can affect launch uptake, including the declining role of the physician as the central decision maker and the increasing number of influencers and stakeholders. The high degree of influence wielded by payers has created greater hurdles to demonstrating value. Meanwhile, payers and regulators are converging around the importance of economic value in granting approval. Organizations need to focus on how they can operate more successfully within this dynamic, new environment by understanding and engaging with payers, patients, physicians and other stakeholders—and not accept that these pressures may reduce the potential of a brand.

Numerous internal factors can impact launch uptake as well, including starting launch preparations too late, a high volume of launch activities that are not prioritized or over-complicated dependencies between activities. Uptake can also be impeded by a lack of alignment between global, regional and country teams, a lack of alignment on strategy and execution, a lack of alignment between clinical and commercial, or a lack of transparency across functions and geographies. Leaders can often underestimate recurring, internal constraints, such as a lack of appropriate or sufficient resources or a lack of consistency in execution. Fortunately, these are all factors that can be mitigated by embedding a robust launch excellence capability.

Finally, the very definition of success should be examined. Typically, a product launch is considered a success when it reaches its share and revenue forecasts. But organizations should ask, "Could we have done more?" True launch excellence comes not from hitting a forecast but from maximizing the product's opportunity. Maximizing the potential for the brand is all the more critical in our current environment. It has never been more important for companies to recognize launch excellence as a separate, core capability with a single focus on maximizing an asset's potential (see page 4).

" Organizations need to focus on how they can operate more successfully within this dynamic, new environment by understanding payers, patients, physicians and other stakeholders better, rather than simply accepting that pressures reduce the potential of a brand. "

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Industry Trends Driving Companies to Make Launch Excellence a Core Capability
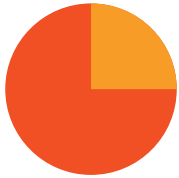
Markets **Targets** **Value**

- As many of the existing blockbuster products reach the patent cliff, companies are focusing more on niche markets, requiring smaller, highly targeted launches and special expertise that resides within the launch excellence capability.

- Niche markets tend to be competitive spaces with lower revenue potential, requiring a greater number of product launches to maintain margins. This can lead to multiple launches in a short timeframe, making it essential to develop processes, approaches and best practices that could be leveraged from one launch to the other.

- Increased merger and acquisition activity is creating the need for standardized launch processes that can be shared as new products and teams are brought into the organization.

- Companies are under pressure to demonstrate product value and differentiation in order for the launch to be successful.

- In the case of medical devices, the short lifecycle of the products means companies must make a big impact with limited resources and budget.

Figure 1: WW Product Launches by Year 2010-2014

Generics/Biosimilars · Label Change · New Molecular Entity
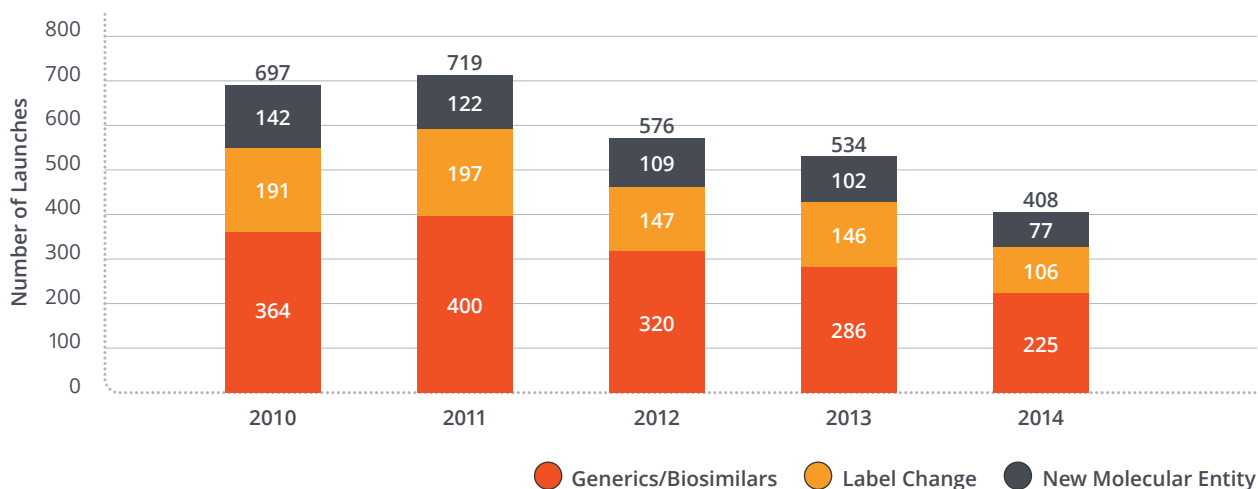
WW New Molecular Entity Forecast (2011-2020)*
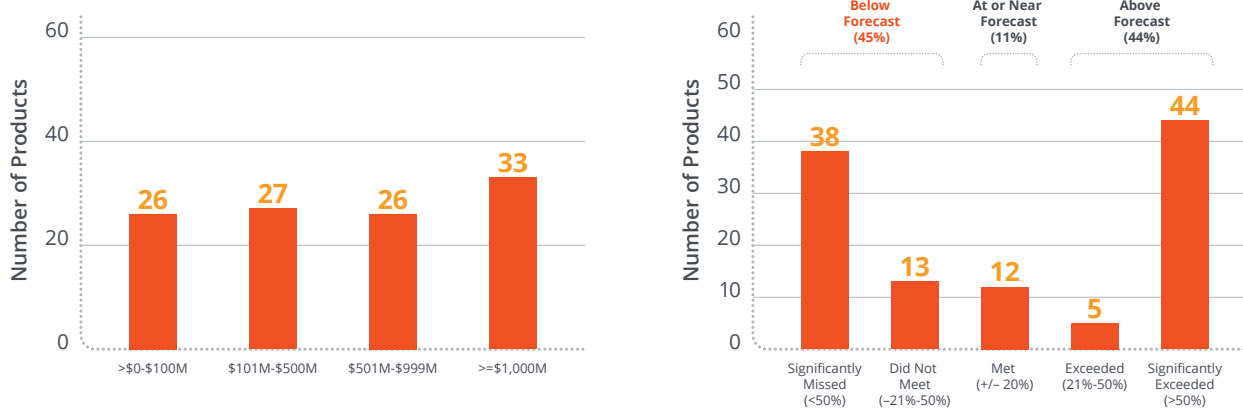
*N=112 NME launch products with a forecast available the year prior to launch.
Source: Evaluate Pharma pull of all product launches from 2011 – 2014. Evaluate Pharma Forecast Report February.
Launch Excellence at Syneos Health Consulting, 2015.

Figure 2: Reasons for Missing Launch Expectations

1	2	3	4	5	6	7
Lack of meaningful clinical evidence	Murky insights on priority customers and their preferences	Delay in regulatory approval	Unrealistic forecast	Inadequate value proposition for payer coverage	Unprepared supply chain	Poor commercial model design and execution

Note: Based on Syneos Health Consulting Insights.

A Universal Launch Excellence Approach

A universal launch excellence approach can leverage best practices from successful launches and lessons learned from unsuccessful launches. These insights can come from looking at the experiences of other companies both inside and outside the industry to supplement the experiences within the company. For example, why did one affiliate launch better than another? What did they do differently? It should not be necessary to spend resources on relearning lessons that others have learned. Instead, launch leaders should "steal" with pride. Past experience can be adopted and improved. This is where a single, integrated launch excellence approach adds value. The more that is shared, the more time will be available for other things, such as focusing on the customers, tailoring activities to local needs and innovating processes.

Sharing best practices and learnings and excellently executing the launch will ultimately result in accelerated uptake. A universal launch excellence approach will provide more focus on customers, leading to reduced duplicative efforts between functions/geographies, better coordination, and hands-on support with launch management. It also will break the siloed way of thinking between functions and geographies. The approach helps to develop and challenge robust launch strategies that are supported with tactics across functions and geographies.

Global alignment is needed to eliminate organizational inconsistencies. Alignment can provide clarity on what to do and when to do it, as well as clarity on what good looks like. Improved synchronization/coordination between global, regional and country processes will lead to harmonization, on-time inputs and maximized synergy.

❝ **Improved launch preparedness will deliver improved margins, forecast accuracy and more appropriate resource allocation. Better communication helps manage expectations.** ❞

Drive Change

Change Management
Drive and sustain changes that fundamentally improve the organization's commercialization approach and culture

Manage Processes

Implementation
Develop and manage processes by which teams can use and implement the frameworks with the right level of support

Raise Skills

Training & Development
Provide training, coaching, best practices, expert network and collaboration to develop the right skills

Build Foundation

Commercial Framework
Build commercial frameworks that ensure that the right groups of people do the right things in the right sequence

Considerations for Developing Robust Global Launch Excellence Capability

- Develop a broad and flexible launch excellence toolkit

- Dedicate adequate and appropriate staff to lead the development and implementation of the launch excellence capability

- Build upon existing processes and structures

- Emphasize the adoption of core processes and tools, as well as collateral and expertise, as resources that can enable success

- Explicitly acknowledge and address typical launch situations and archetypes

  - New chemical entity

  - Label expansion

  - New formulation

- Robustly train, communicate and implement the launch excellence methodology

- Create collaboration and peer-to-peer forums to foster innovation and problem solving

- Balance qualitative and quantitative success factors/KPIs pre-, peri- and post-launch

- Consider launch excellence as a vehicle for providing exposure to talent across functions and developing future leaders

- Build in a feedback and improvement mechanism

Roadmap to Launch Leadership

Achieving launch excellence is a journey with multiple stages requiring constant engagement and refinement. Factors to be considered across the following four stages are outlined in the sidebar on page 7.

1 ## Stage 1: Define & Build

In the first stage, companies need to define global, regional and country launch excellence for their organizations. Existing materials can be leveraged to build the launch excellence framework and tools. Next, define a plan for launch excellence implementation and change management/communication. This is the most important step in building a robust foundation for launch excellence within the organization. This stage takes time as it touches on sensitive topics and requires changes in how the organization operates in a launch mode. For example, roles and responsibilities need to be established between geographies and functions by defining launch governance, establishing core launch excellence requirements and developing capabilities to embed launch excellence across the organization.

2 ## Stage 2: Process Training & Roll Out

In stage two, launch excellence can be piloted with launch teams to test the process and ensure it works. The process built in stage one may need to be refined based on the pilot studies. The launch excellence resources, such as framework, tools and templates, can then be rolled out with training materials to ensure quality execution is continuously being developed.

3 ## Stage 3: Transform & Perform

In stage three of the journey, ongoing launch excellence support should be provided to the launch teams. Leaders must drive sustained launch excellence utilization, measure impact and maintain and refine processes. Successes and best practices should consistently be captured and shared across the organization.
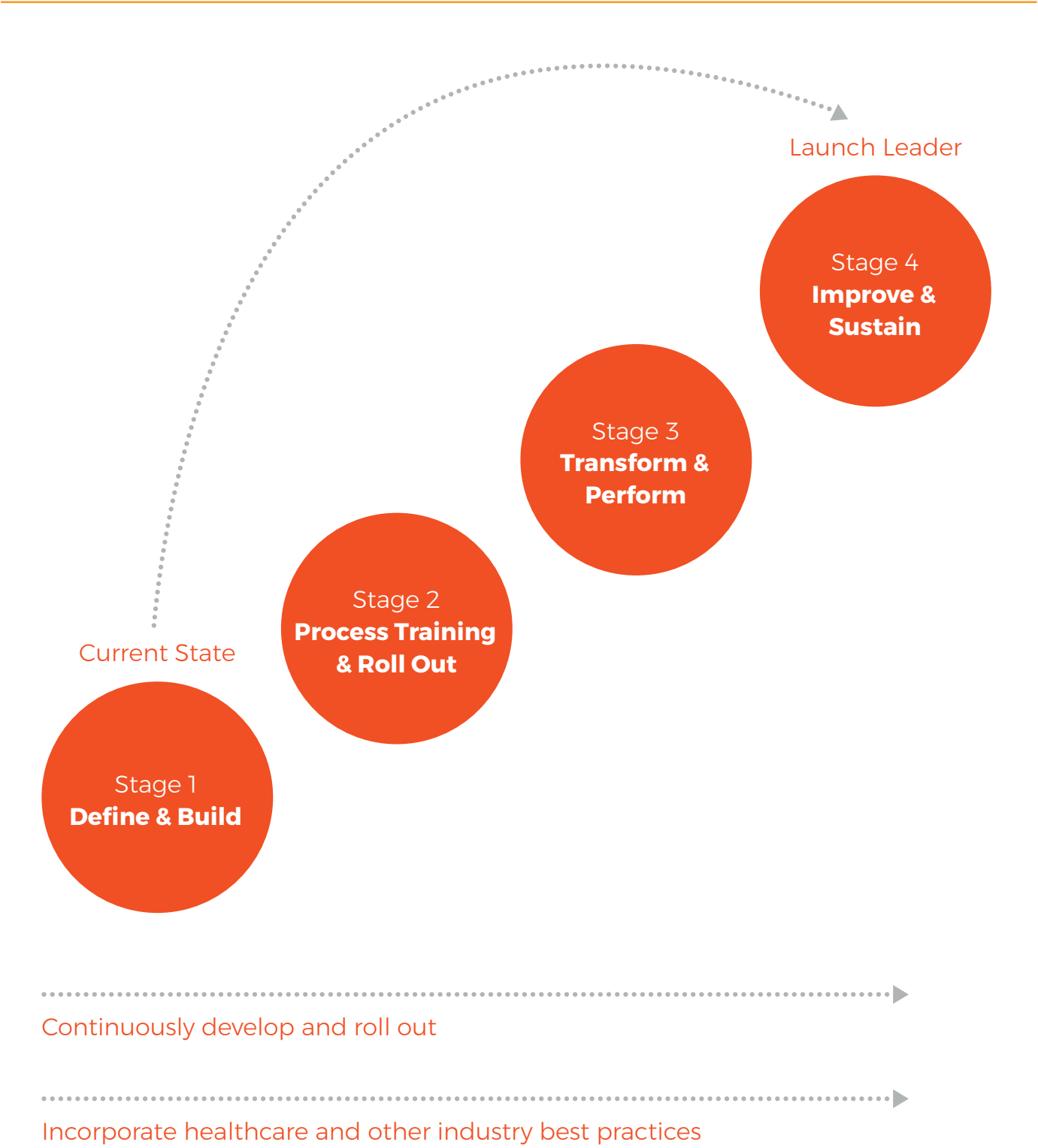
4 ## Stage 4: Sustain & Improve

Stage four involves managing launch excellence processes, collecting and incorporating feedback and adapting to business-driven changes. Successes and best practices should continue to be shared while developing launch excellence experts to build sustainability. Peer forums can be created so that when there is a question about launch, people can be connected to the launch experts within the organization. This feedback loop helps ensure that the organization stays abreast with and incorporates best practices from the healthcare and other industries to become a formidable "launch machine."

Conclusion

The ultimate success of a brand is often defined at launch and in the months that follow. The pressure is on companies to get it right—and to do so in a way that can be replicated. Companies that achieve excellence in launch will find greater efficiencies, lower costs and far greater market success. Experienced counsel and expertise in developing launch excellence will have both immediate value to an organization and long-term benefits that more than offset the investment.

8 |

The Roadmap

Launch Leader

Stage 4
Improve &
Sustain

Stage 3
Transform &
Perform

Stage 2
Process Training
& Roll Out

Current State

Stage 1
Define & Build

Continuously develop and roll out

Incorporate healthcare and other industry best practices

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Results

It's a pretty simple word that's used a lot in the business world, but what does it really mean? When you cut through all the clutter, "results" means performing beyond expectations, eradicating challenges and achieving your business goals. It means not just dreaming it. But actually doing it.

Syneos Health Consulting is purpose-built to help biopharmaceutical and medical technology companies achieve results. Whether it's seizing the leadership position in a new market, solving seemingly impossible challenges or developing innovative approaches for success, we don't quit until the desired results are delivered.

We offer the insight to help leaders develop powerful strategies, as well as the knowledge to ensure they'll work in the real world. As part of Syneos Health, we bring the global implementation capabilities needed to put even the most ambitious plans into action.

Delivering results is what we do. Let's get to it.

10 |

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Syneos Health Consulting is an established, industry-leading consulting firm dedicated to the biopharmaceutical industry.

We partner with customers to solve critical business challenges by delivering valuable insights, strategies to capitalize on opportunities and achievable recommendations for execution.

Our team has access to the clinical research and commercialization expertise of the global Syneos Health network, giving us the distinct ability to address customer needs with data-driven and experience-based insights.