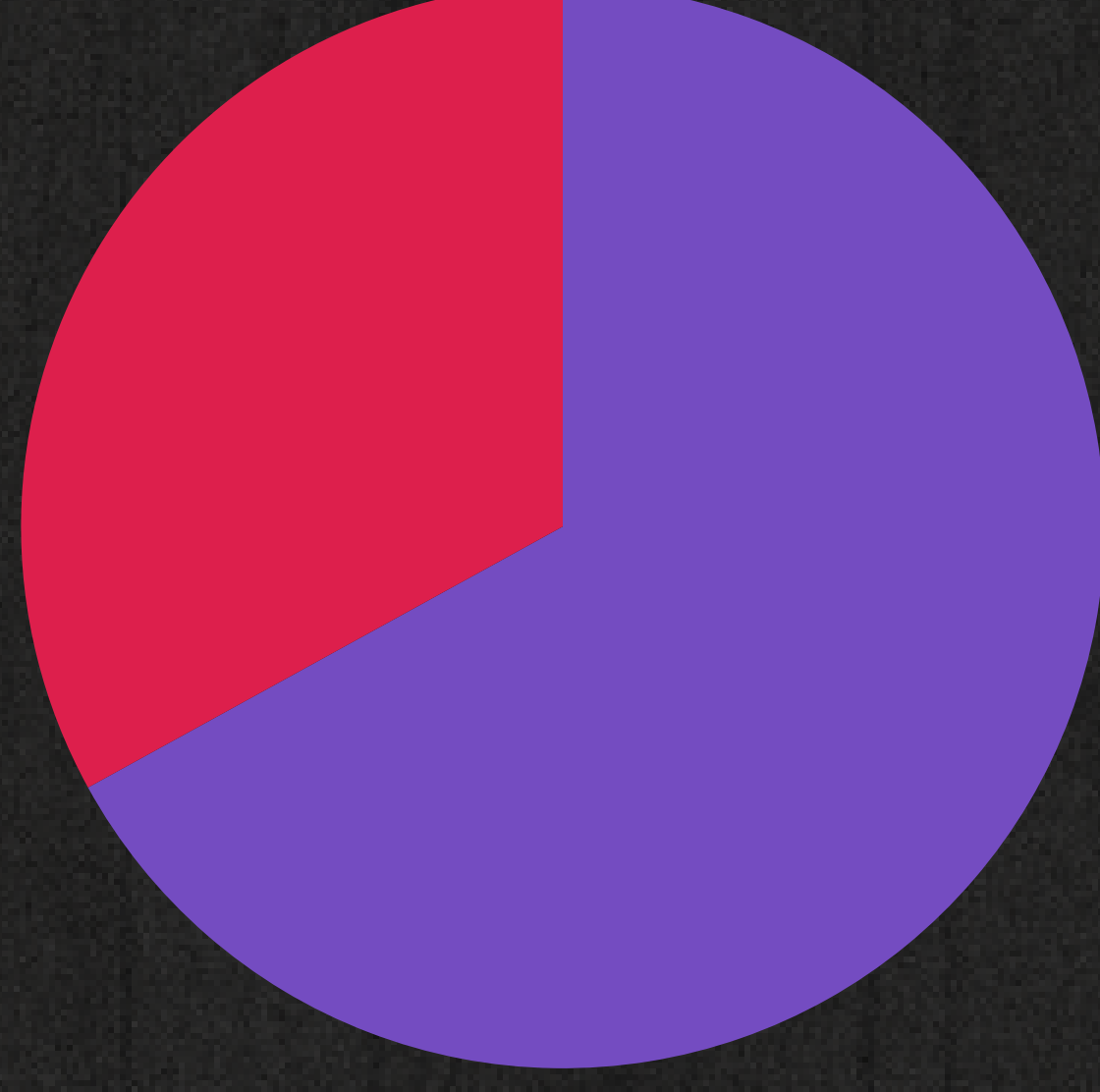


Product Launches Prove Difficult Even for Seasoned Teams

Successful product launches have never been simple or easy even for the most seasoned teams. Today, the number of new product launches is increasing and the products themselves are more complex than ever. Manufacturers face the challenge of organizing and equipping themselves to support these launches or risk not meeting the product's lifetime revenue potential.

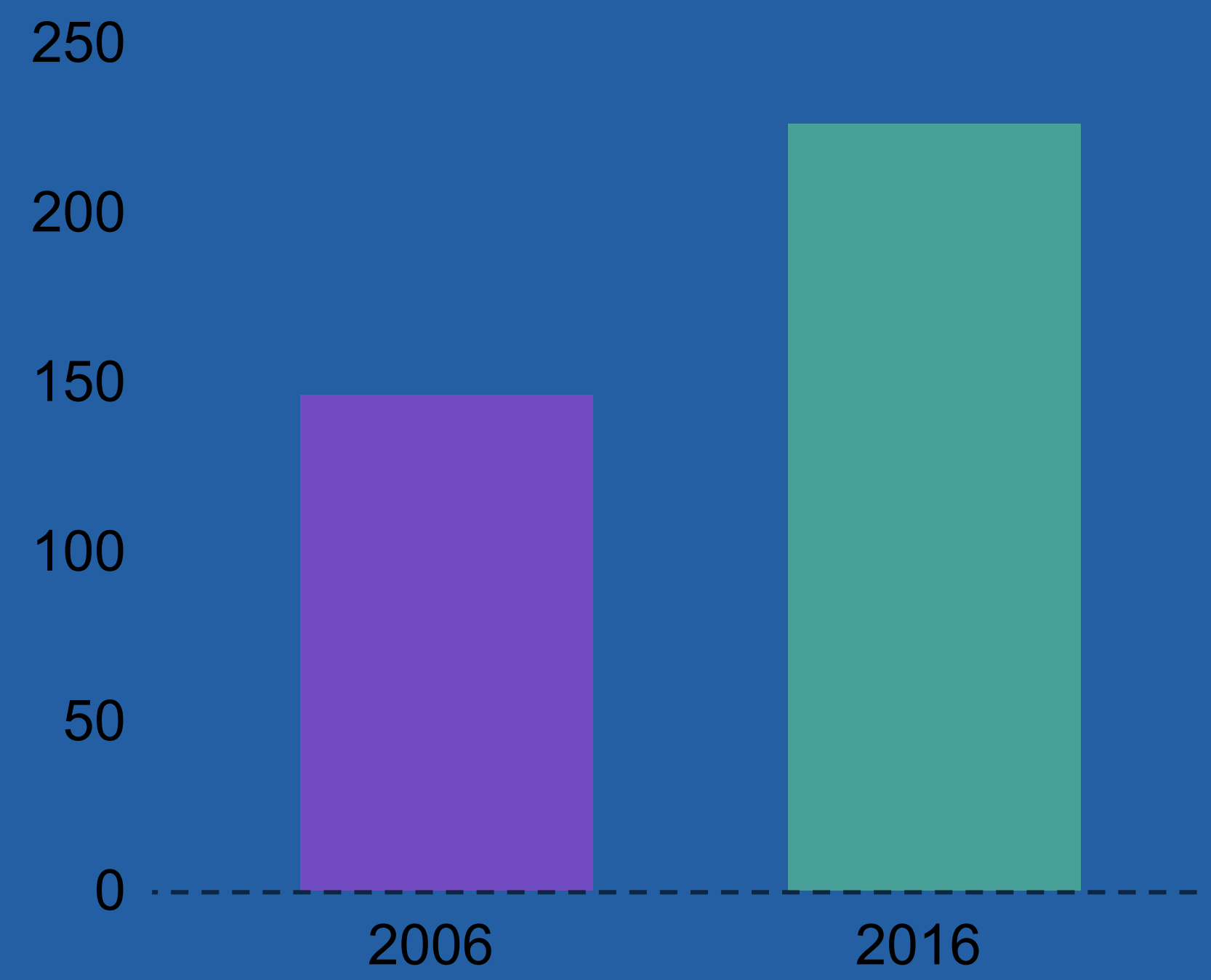
POOR LAUNCHES RESULT IN POOR LONG-TERM PRODUCT PERFORMANCE

2/3 of new drugs fail to meet pre-launch sales expectations ¹



Of launches that missed first-year forecasts, 78% and 70% missed them in years 2 and 3, respectively ³

Launches of new chemical entities (NCE) increased to 226 from 146 a decade earlier ²



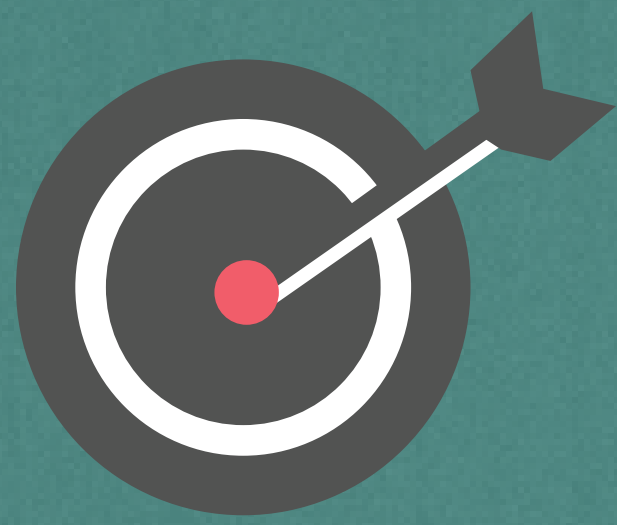
Only 24-27% of products are reaching their peak sales in less than five years ⁴

MAKING THE MOST OF MORE PRODUCT LAUNCHES



It takes a village:

Planning a launch is an intricate exercise that involves strong collaboration across an entire life sciences organization - from clinical to R&D to marketing to manufacturing.



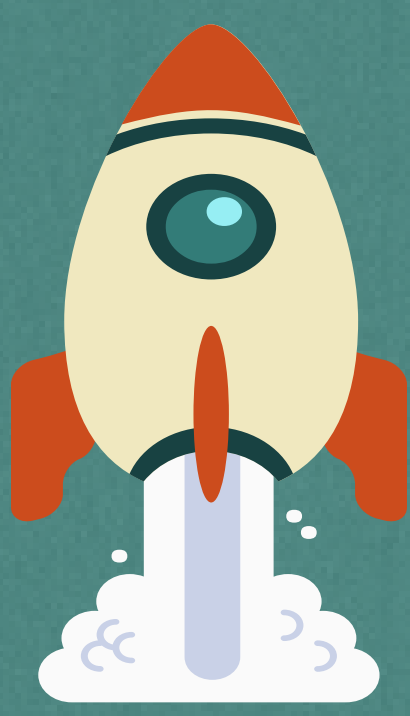
Focus on the brand itself:

Teams often expend significant effort trying to identify what is required to launch the product instead of creating differentiated strategies, tactics, and promotional content.



Launch is more than just execution:

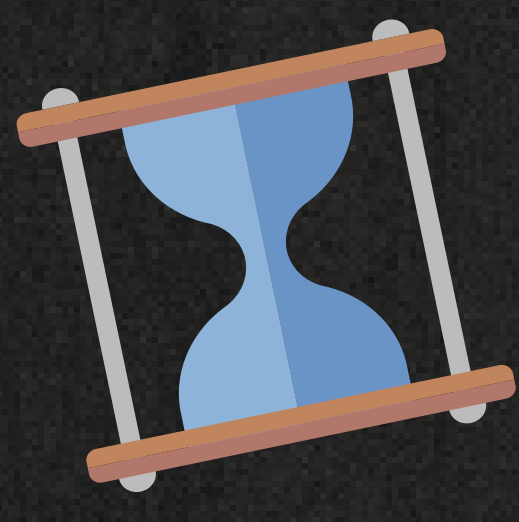
These collaborative launch efforts need to be planned with key resources and workstreams identified in advance. Being proactive by planning with a highly organized approach is essential.



Being launch-ready is a mindset:

Having that mindset across the organization is imperative to have in advance, not just when it is needed

MISSING A LAUNCH DATE IS COSTLY



Delays in product launches can cost a company an average of \$15 million per drug, per day ⁵



Five new drugs that had been scheduled for approval in 2016 ended up winning an early green light at the end of 2015 ⁶



The FDA rejected or delayed more applications in 2016 than in the previous two years ⁶



Molecules launched by the company that patented the molecule averaged 36 months shorter time to market than those that were brought to market by a different company ⁷

WHAT CAN DERAIL A LAUNCH

Regulatory / Legal

- Receiving regulatory approval for NDA/BLA earlier or later than expected
- Delay in legal/regulatory check-in with FDA

Product Supply

- Raw material shortages, quality issues, or regulatory approval
- Manufacturing capability readiness, including quality failures
- Manufacturing capacity constraints (internal or third party)
- Poor production planning
- Special shipping requirements

Medical Affairs

- Incorrect KOL identification and value messaging
- Lack of unbranded evidence development
- Advisory board not in sync

Commercial

- Delays in securing formulary coverage and pricing approval
- Disjointed customer experience and market development strategies
- Insufficient or unprepared field sales force
- Underdeveloped marketing campaigns
- Unresolved conflict between alliance partners

Successful product launches don't just happen. They begin with establishing launch capabilities and aligning your launch teams and internal stakeholders to effectively focus on achieving product performance goals. If you want to know more about launch excellence programs, contact the Paragon experts at consultparagon.com or call us at 1-800-462-5582.

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¹ McKinsey, "The Secret of Successful Drug Launches, 2014"

² Philippidis, A, <http://www.genengnews.com/the-lists/the-top-15-best-selling-drugs-of-2016/77900868>

³ Evaluate Pharma; McKinsey Analysis "The secret of successful drug launches", 2014

⁴ Aitken, M, Kleinrock, M, QuintilesIMS Institute, "Lifetime Trends in Biopharmaceutical Innovation", Jan 2017

⁵ Pharmaexec.com "No Time to Delay", Tim Noffke, 2007

⁶ Hirschler, B, Reuters, <http://fingfx.thomsonreuters.com/gfx/rngs/USA-DRUGS/01M0110L20G/USA-DRUGS-01.jpg>

⁷ Aitken, M, Kleinrock, M, QuintilesIMS Institute, "Lifetime Trends in Biopharmaceutical Innovation", Jan 2017