

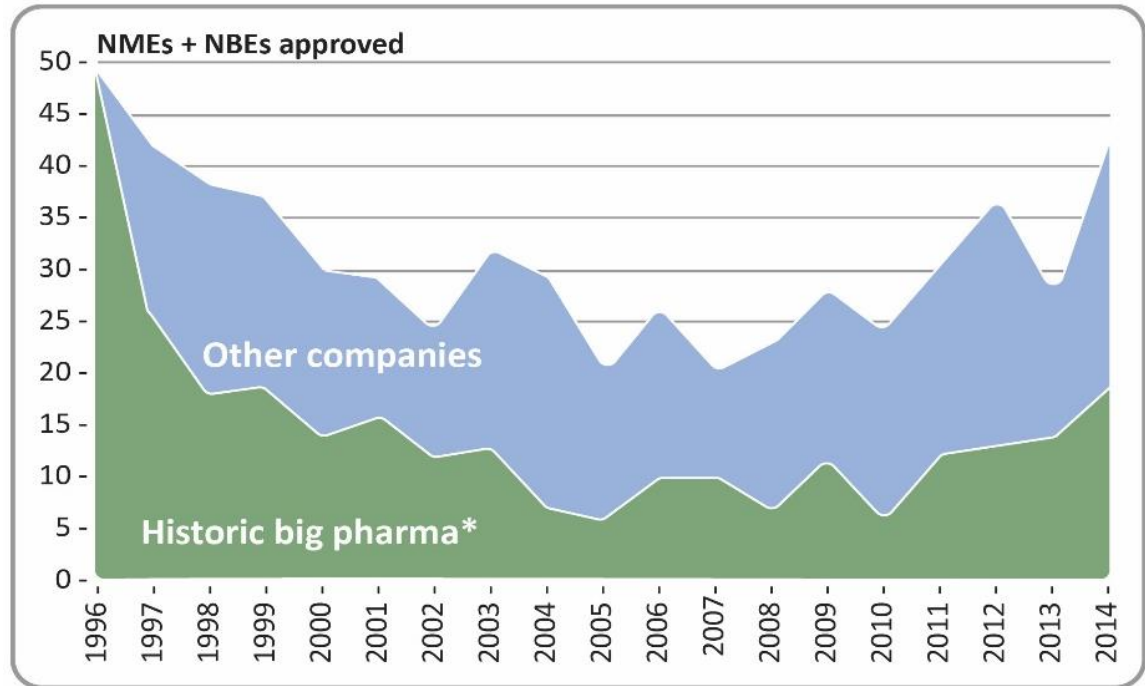
The Strategic Role of Reg Ops in the Transformation of Pharma

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The Problem

R&D Spending

| Year | PhRMA Members |
|------|-----------------------|
| 2014 | \$51.2 billion (est.) |
| 2013 | \$51.6 billion |
| 2012 | \$49.6 billion |
| 2011 | \$48.6 billion |
| 2010 | \$50.7 billion |
| 2009 | \$46.4 billion |
| 2008 | \$47.4 billion |
| 2007 | \$47.9 billion |
| 2006 | \$43.0 billion |
| 2005 | \$39.9 billion |
| 2000 | \$26.0 billion |
| 1990 | \$ 8.4 billion |
| 1980 | \$ 2.0 billion |



*ABBV, AMGN, AZN, BAY, BMY, GSK, JNJ, LLY, MRK, NVS, PFE, ROC, SNY

Development Costs

Average cost to develop a drug
(including the cost of failures)

- 2000s – early 2010s = \$2.6 billion
- 1990's – early 2000s = \$1.0 billion
- 1980s = \$413 million
- 1970s = \$179 million

80%

Drugs that fail
to break even

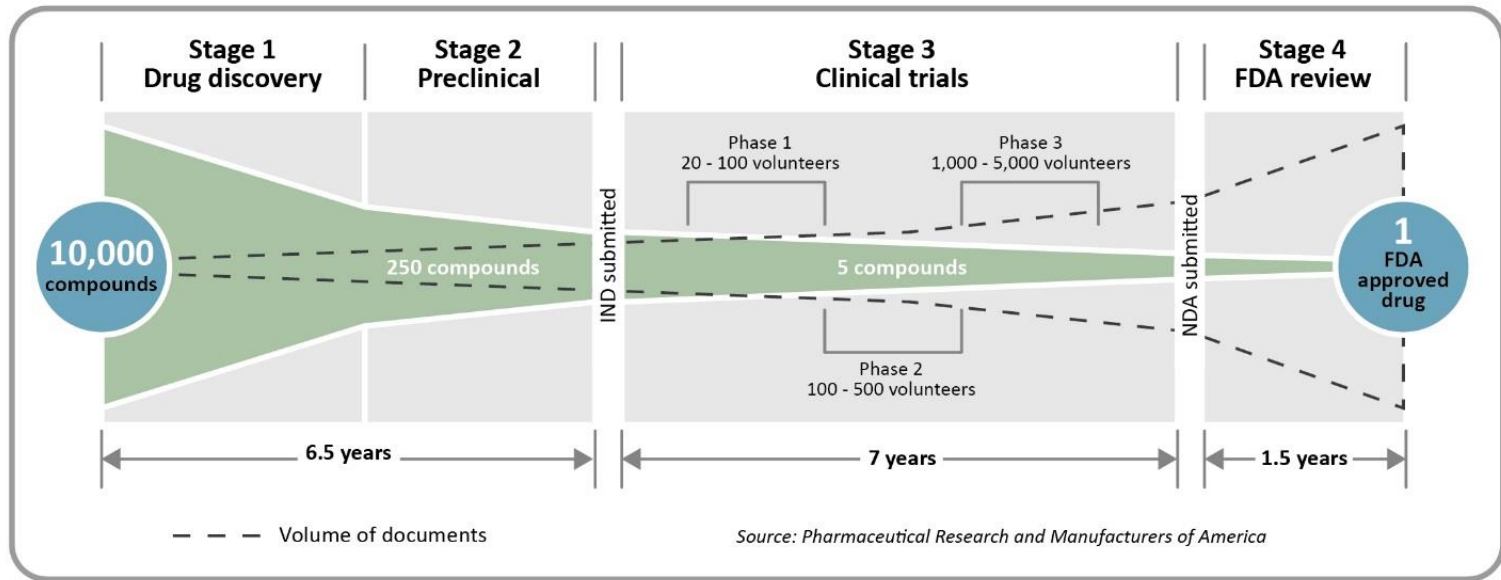
\$10,844

Spend per US
diabetes patient

\$420

Spend per
India diabetes
patient

The Problem



Reg Ops has worked overtime for years to keep up with the breakneck pace of product development. Let's channel that hard work to more efficient ends

Expectations of the larger organization are not realistic, given the systems and capabilities provided to Reg Ops by IT

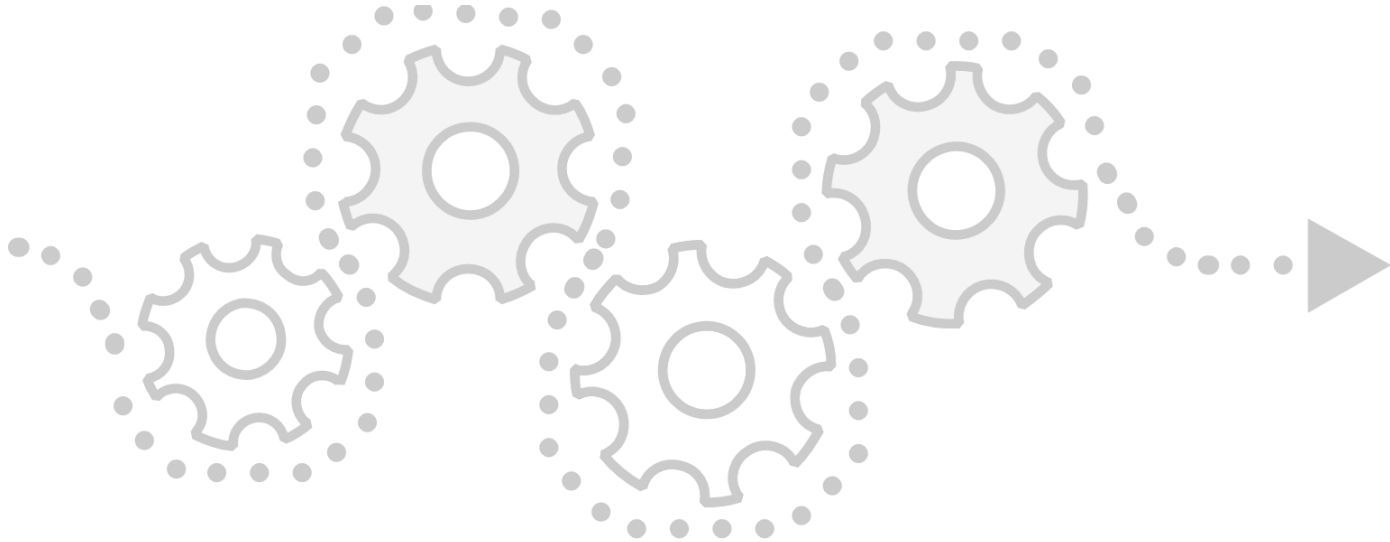
“Death-march” timelines

Keeping Reg Ops out of the loop on pipeline management, M&A planning/scoping

Vastly understaffed

The Solution

- Approach Pharma with a manufacturing discipline
- Approach Reg Ops as a critical path activity, strategically

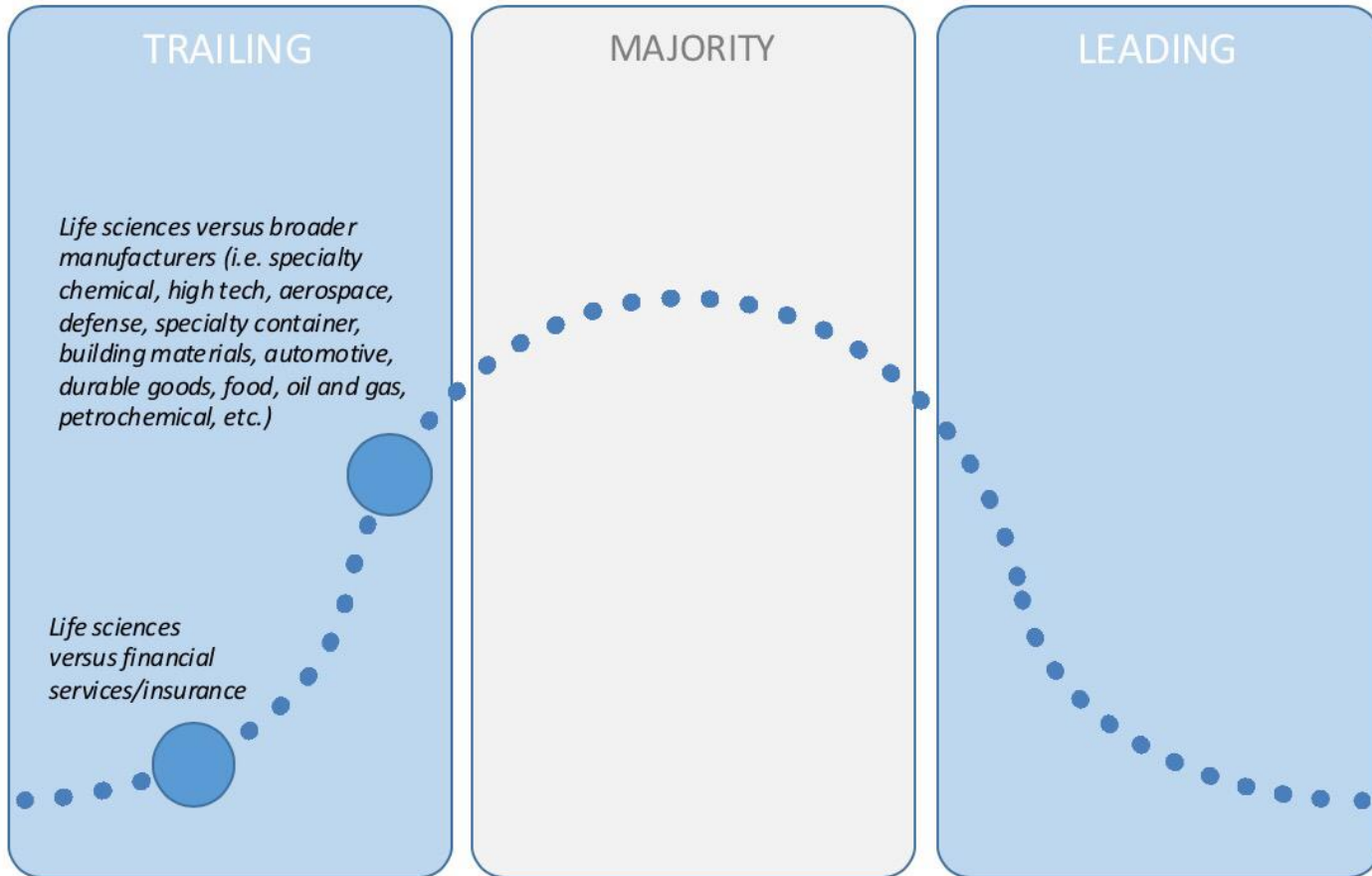


- Address core Reg Ops document-centric processes to shorten time to market and improve quality

Your Peers

- Most – ignore Reg Ops as value driver
- Some – are narrowly optimizing processes (not strategic)
- A Few - are beginning to address Reg Ops as strategic capability (very early stages)

The Wider World



Lessons from the Wider World



- Optimize at the enterprise level
 - Focusing on discrete, siloed processes only gets you so far, and can actually set you back in the long run



- View compliance as a motivation rather than an excuse
 - How can overcoming compliance hurdles drive innovation, strategic advantage, competitive differentiation?



- Document management has no value for its own sake
 - It's a means to an end, driving business value through process transformation

The Benefits

- **More efficient** submission prep
- **Cleaner** handoff to affiliates
- **More consistent** interactions with HAs globally
- **Faster** time to market

Thank You

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