



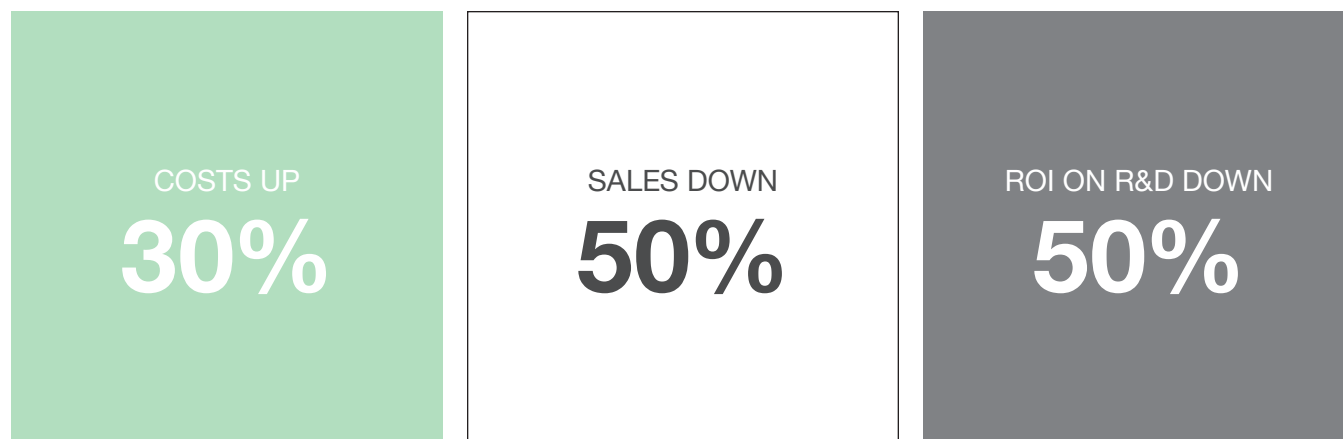
Streamlining Pharma Drug Development: Yes, It's Time.

"We've always known that working with multiple CMOs is inefficient — there are handoff issues and no incentive for vendors to work together to speed the process. An integrated CDMO could eliminate many steps and save time by parallel processing other steps. Reducing time to milestone is a top priority for us — this would be highly valuable."

— Small pharma CEO¹

The path from molecule to market isn't getting any easier.

The costs of drug development continue to rise. Dramatically. According to a 2015 report by Deloitte, costs have increased by a third in just the last five years². If that weren't trouble enough, sales during the same time frame have tumbled 50%³. Increased expenditure and decreased income are a bad combination — especially in an industry where the average cost to bring a new product to market approaches \$2.6 billion⁴. It also helps explain why the ROI on R&D is also down 50%⁵. Obviously, these numbers are not sustainable in the long run. A fundamental change needs to be made, and soon. But this isn't news. Nobody in the pharmaceutical industry is unaware of these trends — or their underlying meaning. So what's the solution?



A new model for success: focus on what you do best — and outsource the rest.

While the largest pharmaceutical companies have done well over the years, many now trail their smaller brethren. Small to mid-size pharma companies have higher average peak sales — 130% higher, in fact⁶. They spend 25% less per therapy. And, perhaps most significantly, they achieve dramatically higher ROI on R&D: 17% for smaller companies vs. just 5% for large companies. What's going on? According to Deloitte, one reason is that smaller companies are renting expertise, rather than trying to own it.

Smaller pharmaceutical companies don't have the internal infrastructure and resources to support all job functions in development and manufacturing, so they don't even try. Instead, they focus on the critical

areas of vision and therapeutic expertise. Every other specialty can be contracted for far less than it would cost to bring in-house. And the quality is often higher because industry-leading Contract Development and Manufacturing Organizations (CDMOs) now have the scale, resources and complexity of work to attract top talent from the rapidly downsizing traditional pharma industry.

While outsourcing more of the critical path is a requirement at smaller companies, the thinking can be applied at any size company and work equally well. Once again, according to the Deloitte report,

“...the [small and midsize] extension cohort shows the levels of R&D returns that are achievable if some of their attributes can be replicated within larger organisations.”⁷

– Deloitte Centre for Health Solutions

Think about outsourcing differently and it works differently.

While outsourcing is nothing new, there are new ways for pharmaceutical companies to be more successful with it than they may have been in the past. In much the same way Contract Research Organizations (CROs) streamlined and accelerated clinical trials, CDMOs with the right skills and mindset now have the ability to spark similar improvements in development and manufacturing. A quick look at the three major outsourcing methods highlights the relative strengths of each.

Procurement

Those who prefer the procurement form of outsourcing are driven by price. Simply bid out each step of the process and see who is willing to do it the cheapest. While this may seem like an effective method on paper, the truth is less appealing. Internal resources become spread thin trying to manage multiple vendor relationships, and in the end the much more valuable attributes of speed and accuracy are sacrificed. The true cost here, though, is one of opportunity. How much does one lose by spending more time in development than necessary? Consider that nearly \$1.2 billion of the development cost of a therapy comes from income that can't be generated while it's still in development. The short-term savings of a low-cost provider are therefore significantly undermined by the losses its delays represent in terms of foregone revenue.

Best-in-Breed

With best-in-breed, sponsors can find and retain vendors of choice for every step of the drug development process. This sounds like the best choice, because capability and quality should never be compromised. But this process is expensive and time-consuming. And managing the

complexity of a large number of vendors will increase the overall expense of everything on the sponsor side: contracts, management personnel, etc. It also increases timelines as each service provider has to validate what has been done before them in the process.

Perhaps the single greatest drawback of both these methods, however, is that multiple vendors, no matter how committed to quality, have no incentive to work together to solve issues that might come up. It's always up to the sponsor to manage the process and try to keep it on track. That brings us to the third method of outsourcing.

Single Source

To be clear, the idea of single provider outsourcing isn't new. For years companies across industries have promised to streamline the process by handling more of the critical path. But today there is a fundamentally different solution available for this industry: a single company that is expert at both the drug product and drug substance sides of the development process for both small and large molecules.

And while size may not be an asset for pharmaceutical companies, it most certainly is for CDMOs. Here, size brings a collective level of capability and expertise not attainable from smaller development partners. To see the proof of this, just scan these statistics:

THE MOST PREFERRED CDMO IN 2015⁹:

ACHIEVED THE HIGHEST
NUMBER OF APPROVALS
IN THE LAST 10 YEARS:

86 vs. 45

FOR THE #2 CDMO¹⁰

MANUFACTURED

20

OF THE TOP 100
DRUGS IN 2015

MANUFACTURED
AND DELIVERED TO
MORE THAN

70

COUNTRIES

Niche vendors simply can't compete at this level. And successes build on each other since a CDMO with this kind of track record can more easily attract and keep the finest talent in every service offered; which, in turn, improves quality and capabilities even more. The ultimate result is that the age-old question of quality from best-in-breed suppliers vs. the convenience of a one-stop shop becomes moot. They are one and the same.

WAS INSPECTED AND
APPROVED BY

20+

REGULATORY
AUTHORITIES

The Patheon OneSource™ offering takes outsourcing **where it's never been before.**

It is precisely because Patheon comes from a merger of excellent constituent companies that single source outsourcing can finally live up to its promise. For example, according to a 2014 McKinsey report¹¹, of the multiple sources of time savings an integrated outsourcer could offer, three held exceptional value for pharmaceutical companies:

- **Elimination of redundant activities**
- **Parallel processing of activities**
- **Improved scheduling of drug product development**

Thanks to the expertise of our people, and the processes they've created, Patheon OneSource™ is able to dependably deliver these three sources of savings. And the savings are significant: 8-20 weeks or more, depending on molecule type. They come from **creating a unified quality system** to reduce lead times; **reducing the number of interfaces and operational models** to quickly and accurately share vital information; **optimizing intermediate inventories** to reduce bottlenecks; and **validating multiple production sites** to increase flexibility.

When all steps of the drug development process are handled by one unified team, and led by one program manager with responsibility for the entire project from beginning to end, outsourcing works the way you always hoped it could.

To learn more about Patheon OneSource™, please call **1-866-PATHEON**

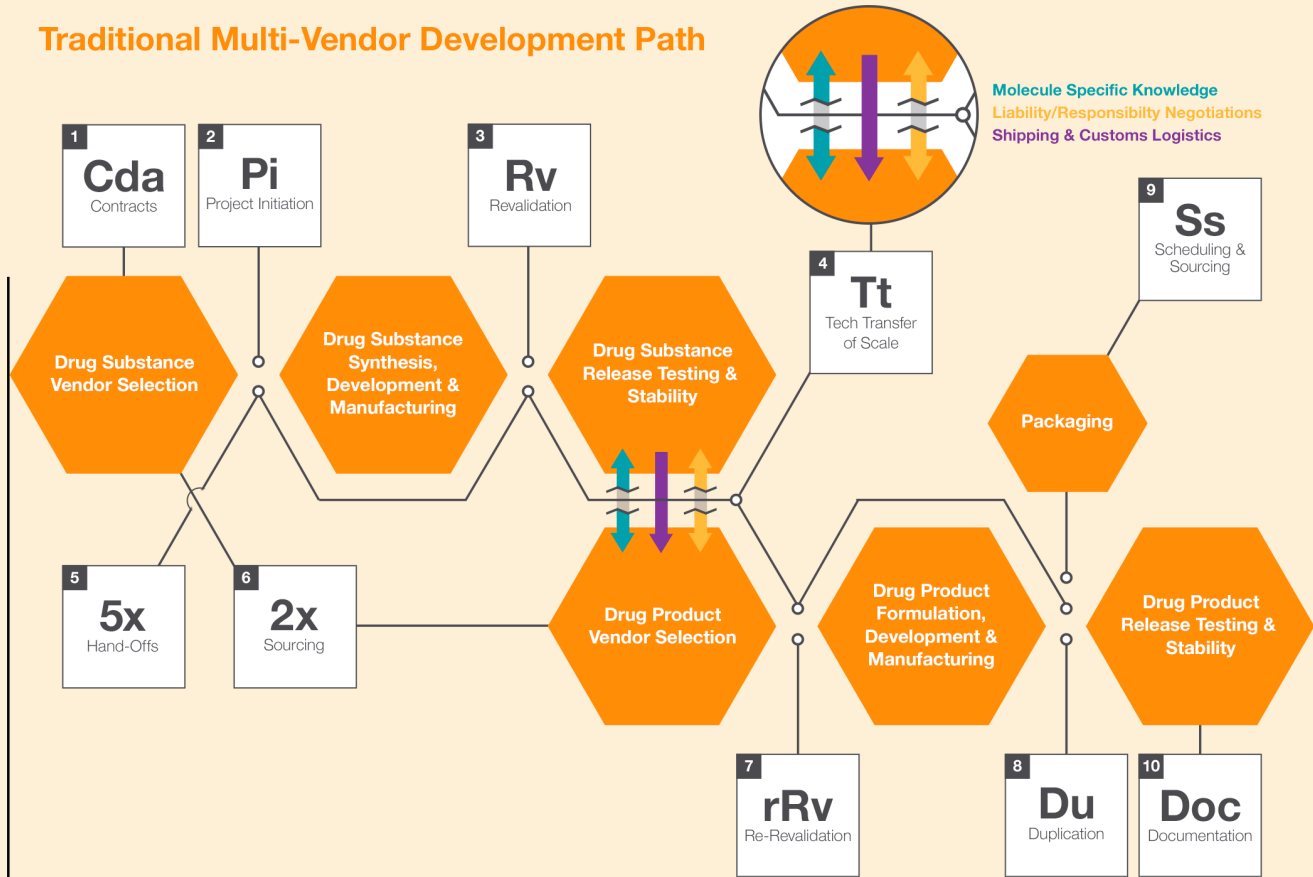
326
EMPLOYEES WITH
ADVANCED SCIENTIFIC
DEGREES

86
NME & NDA APPROVALS
IN LAST 10 YEARS¹²

RANKED
#1
CDMO¹³

10 Inefficiencies Solved by Single-Source Outsourcing

Traditional Multi-Vendor Development Path

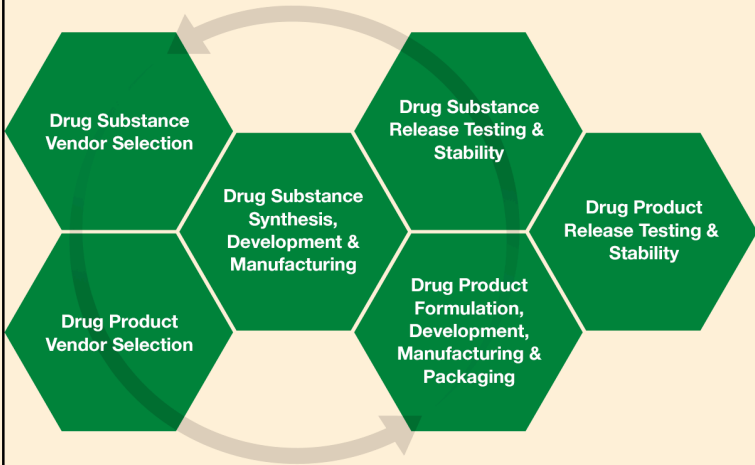


Phase I Industry average 15 – 24 months (small & large molecule) Phase IIb

Phase I Phase IIb

Patheon OneSource™ Development Path

Cross-Team Collaboration



8-20 weeks saved

Patheon OneSource™
We eliminate the steps between the steps to get you to Proof of Concept faster.

- Reduce contract negotiations
save 2+ weeks
- Co-develop analytical methods
save 1+ week
- Co-validate to eliminate revalidation
save 1+ week
- Eliminate incomplete information transfer
save 1+ week
- Create unified quality system for DS & DP
save 1+ week
- Negotiate single Harmonized Quality Agreement
save 2+ weeks

To learn more about Patheon OneSource™, please call **1-866-PATHEON**

ABOUT PATHEON:

Patheon is a leading global provider of pharmaceutical development and manufacturing services. With approximately 8,400 employees worldwide, Patheon provides a comprehensive, integrated and highly customizable set of solutions to help clients of all sizes satisfy complex development and manufacturing needs at any stage of the pharmaceutical development cycle. A Healthier World. Delivered. www.patheon.com.

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FOOTNOTES:

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3. Deloitte Centre for Health Solutions report, 2015
4. Tufts Center for the Study of Drug Development study, *Cost to Develop and Win Marketing Approval for a New Drug is \$2.6 Billion*, 2014
5. Deloitte Centre for Health Solutions report, 2015
6. Deloitte Centre for Health Solutions report, 2015
7. Deloitte Centre for Health Solutions report, 2015
8. Tufts Center for the Study of Drug Development study, 2014
9. Patheon ranked #1 most-preferred CDMO by ISR, 2015
10. PharmSource NDA Approvals 2014 Edition CMO Scorecard Outsourcing of NDA Approvals (2004-Present)
11. McKinsey report for DPx, 2014
12. PharmSource NDA Approvals 2014 Edition CMO Scorecard Outsourcing of NDA Approvals (2004-Present)
13. ISR, 2015