

Integrated Drug Development and Clinical Services for New and Emerging Pharma

patheon **fisher clinical**
services

Give your molecule its best shot at success

The path through drug development is marked by detours, roadblocks and very few shortcuts. At times you may feel that you're the only person keeping your molecule on its critical path. Unexpected delays can lead to missed milestones, rework and delayed timelines – all setbacks that no one wants to explain to their investors.

The Quick to Care™ suite of services delivers a streamlined drug development program, designed specifically for new and emerging companies. This program combines your drug substance and drug product development, clinical manufacturing, forecasting, demand planning and clinical trial supply execution into a single solution to accelerate your discovery to proof of concept.

By working with Patheon CDMO services within Thermo Fisher Scientific, you position your molecule for greater therapeutic and financial success because it has been formulated with scale-up in mind. In fact, our clients have reduced their development timelines by an average of 13 weeks, equating to an average of approximately \$44 million in development time costs, as reported by the Tufts Center for the Study of Drug Development.

These savings are driven by our experience guiding new and emerging clients through each phase of drug development. More than 75% of our drug development projects are with new and emerging clients – 564 projects in 2016 alone, including 221 Phase I projects, 109 Phase II projects and 234 Phase III projects. We are the leading partner for outsourced NDA launches, with 112 NDA approvals in the last decade – that's more than twice the number from the next ranking CDMO.

Whether your goal is out-licensing at Phase IIb or taking your molecule to full commercialization, your team at Patheon is with you every step of the way. Your Quick to Care™ services extend your team, providing unified program management, scientific and technical insight, and reduction of redundancies.

Here's how it works:

Comprehensive program management with a single point of contact

Your Quick to Care™ services Program Manager is your single point of contact who manages all communication and your molecule's critical path. They create, oversee and actively lead a collaborative Molecule Team of scientific and process experts across drug substance and drug product areas. All quality, safety, technology, and logistics issues flow through the Program Manager. This role was designed specifically for small pharma companies who run lean.

Scientific insight speeds every step

Your Molecule Team is assigned at project kick-off and consists of Project Managers on Drug Substance and Drug Product, as well as three scientific staff reporting to each Project Manager. As drug substance is developed, drug product technical experts enter into the dialogue so potential issues at scale-up are minimized. This ensures that your molecule is formulation-ready and simplifies your technology transfers. If a potential issue is identified, your Program Manager will pull in additional scientific experts in addition to your assigned Molecule Team, if necessary.

Assurance of Supply

An additional service offered within the Quick to Care™ program is our end-to-end demand planning which calculates the need for Drug Substance, Drug Product and Clinical Demand. This decreases the risk of stock out situations which can put development timelines at risk.

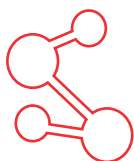
Simplified contracting and administration

We have seen our clients lose time and investment when drug substance, drug product and clinical supply services are executed in silos. We eliminate redundancies in project contracting, contract templating, negotiation, invoicing, and administration, so that you enjoy one single negotiation process and a more concise contract. A single, streamlined process simplifies your overall timeline with less paperwork and less overhead. We'll even customize the invoicing process to your company's needs – receive one single invoice or separate invoices.

With the high level of out-licensing and in-licensing M&A activities in pharma, we ensure an easy transition. Whether your molecule stays within the same partner at the same company or is out-licensed to multiple partners during the lifecycle of the program, all the financial, scientific and technical know-how and data stay with a single vendor.

Optimized technology transfers

As you move from drug substance to drug product, your Quick to Care™ services Program Manager and Molecule Team are accountable for leading all internal technology transfers and communicating progress. Our technology transfers are intensive and process-driven, ensuring complete transfer of knowledge and minimizing rework. In 2016 alone, we successfully completed 92 technology transfers.



14-20 weeks off large molecule development

Whether your project is starting at chemical synthesis or formulation, we're ready to bring new molecules into our industry-leading, single-vendor drug development and clinical supply solution. Contact us today and let us show you how our Quick to Care™ services can give your molecule its best chance of success.