Optimizing Pharmaceutical Laboratory Efficiency and Productivity

Within the pharmaceutical industry, an immense pressure exists to progress potential therapeutic candidates through the pipeline quicker than ever before. With pharmaceutical laboratories being on the front-line of drug development, the pressure for lab leaders to optimize the speed and efficiency of their operation is one crucial element of this bigger picture.

When medicines have the potential to address critical unmet medical needs, the pharmaceutical laboratory's need for speed becomes vital.

Drug discovery, development and delivery: a timeline

1 Drug discovery

Drug discovery

Academic institutions and researchers identify molecules and targets that may have the potential to be developed into break-through treatments via intense disease and molecular research.

2 Pre-clinical studies

Pre-clinical studies

Molecules are tested in pre-clinical models to determine whether the molecule has a favorable safety profile.

3 Clinical trials Phase I, II, III

Clinical trials

Successful therapeutic candidates are usually then required to undergo three phases of clinical testing in humans (in clinical trials). Ultimately, at the end of Phase III studies, you should have a medicine which you can provide robust evidence for to prove it is safe and efficacious in treating a particular disease.

4 Drug approval review

Drug approval review

Data from pre-clinical and clinical trials are then submitted to regional and country-level regulatory bodies for them to make a decision as to whether they will approve the medicine and it can be made commercially available, or if more data are required.

5 Phase IV clinical trials

Phase IV clinical trials (post-approval)

The medicine is now commercially available. But even post-approval, regulatory bodies may request Phase IV trials to provide further evidence.

Drug discovery | Drug development | Drug delivery and market access

Dr. Richard Ladd is an independent pharmaceutical technology consultant with more than 30 years of experience in the industry. He shares his perspective on why speed is so important in an industry, which is ever-evolving.

https://www.agilent.com/about/newsroom/videos/2019/pharma-lab-efficiency.html

7000+ medicines currently in global development[1]

On average, the drug discovery, development and delivery process takes **12 years**[2]

Drugs tend to have **20 years** on patent[3]

What drives productivity pressures in pharmaceutical laboratories?

Increasing sample numbers

As we understand more about the human condition and disease drivers, we have more therapeutic avenues to explore. This means that pharmaceutical laboratories have substantially more samples to handle than ever before.

Complex molecules

The molecules themselves are becoming more and more complex (with biologics and gene therapies, for example), which introduces complexity in analysis and testing for laboratories. As a result, tests that would have historically been relatively quick to perform, can now take significantly longer.

Fast track regulatory reviews

Fast track regulatory processes are designed to facilitate the development, and expedite the review of drugs to treat serious conditions and fill an unmet medical need.[4] This means that laboratories are under increasing pressure to get results quickly, in order to meet regulatory requirements.

The rise of generic medicines

Because generic medicines are comparable to an 'innovator drug', companies who develop them don't actually have to prove the efficacy and safety of the generic. Rather, based on the body of evidence generated by the innovator company, they need to prove that the generic behaves in exactly the same way as the existing drug. This means that regulatory timelines for generic medicines are often shorter.[5]

Promoting efficiency to improve lab productivity and economics

The more time spent at each stage within the drug discovery process, the higher the cost for the laboratory. When working with pharmaceuticals, the need for speed and overall laboratory efficiency, must be carefully balanced with the demand for unwavering quality.

Key facts:

Cost

Between **3 billion USD** to bring a medicine to market[6]

Failure rate

Only **1 out of 10,000** medicines studied, will end up being brought to market[7]

The Pharma Lab Leaders Survey tells us that:*

Speed

Achieving quicker results is the **#1 concern** for pharmaceutical laboratories

Laboratory workflows

83% of Lab Leaders find their current workflow requires optimization

The sample chain of custody

70% of Lab Leaders say one of the most common strategies they are employing to progress medicines through the pipeline quicker, is improving documentation of the sample chain of custody

Innovations

65% of Lab Leaders would welcome new innovations to increase laboratory efficiency

The Pharma Laboratory Leaders Survey

Agilent Technologies partnered with market research company Frost & Sullivan in 2019 to run an independent, blinded survey to better understand the challenges, pain points and goals for the future of pharmaceutical laboratory leaders:

Who was surveyed?
Laboratory leaders working in big pharma, bio-tech and CRO laboratories

From which countries?
7 countries: Germany, Switzerland, Austria, India, China, South Korea and USA

How many leaders were surveyed?
650 lab leaders, globally

By finding ways to improve efficiencies, streamline workflows and boost productivity, laboratories can reduce their costs, process more samples and continue to ensure quality standards are at their highest.

Laboratories are already employing strategies to be successful in this time-driven landscape, with many now turning to instrument providers to help them take this to the next level.

Agilent Technologies is committed to supporting pharmaceutical laboratories in their mission to become more efficient by providing cutting-edge instruments, services and software that can help streamline laboratory workflows and aid laboratory leaders in meeting their organizational and personal goals... quickly!

* Data from Pharmaceutical Laboratory Leaders Survey (global data cut), commissioned by Agilent and conducted by Frost & Sullivan, in 2019. 1. The Pharmaceutical Research and Manufacturers of America, 2019, https://www.phrma.org/about 2. ScienceDirect, 2016, https://www.sciencedirect.com/science/article/pii/S2452302X16000364 3. U.S. Food and Drug Administration, https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity 4.U.S. Food & Drug Administration, https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track 5. U.S. Food & Drug Administration, https://www.fda.gov/drugs/types-applications/abbreviated-new-drug-application-anda 6. 'Innovation in the pharmaceutical industry' New estimates of R&D costs, Journal of Health Economics, (May, 2016) 7. Innovation.org, http://www.astrid-eu.su/downloads/BPL/Drug_Discovery_and_Development.pdf, 2007

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