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



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.

Pre-clinical studies

Pre-clinical studies

Molecules are tested

in pre-clinical models

to determine whether

favorable safety profile.

the molecule has a

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

Drug approval review

and clinical trials are

Drug approval review

Data from pre-clinical then submitted to regional and countrylevel 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.

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



disease.

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.



pharma-lab-efficiency.html

https://www.agilent.com/about/newsroom/videos/2019/

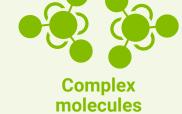


What drives productivity pressures in pharmaceutical laboratories?



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.



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 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

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.

Promoting efficiency to improve lab productivity and economics

Key facts:



Speed

#1 concern for pharmaceutical laboratories

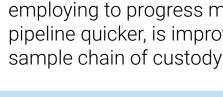


Laboratory workflows

Achieving quicker results is the

The sample chain of custody

find their current workflow requires optimization



say one of the most common strategies they are

employing to progress medicines through the pipeline quicker, is improving documentation of the

Innovations



Drug_Discovery_and_Development.pdf, 2007

would welcome new

innovations to increase laboratory efficiency samples and continue to ensure quality standards are at their highest.



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,

How many leaders were surveyed? 650 lab leaders, globally

India, China, South Korea and USA

By finding ways to improve efficiencies, streamline workflows and boost productivity, laboratories can reduce their costs, process more

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/S2452302X1600036X 3. U.S. Food and Drug Administration, https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questionspatents-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.astp4kt.eu/downloads/BPL/



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