

Choosing the Third-Party Lab with the Best Back End
White Paper
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On February 20, 2024 the FDA released a letter titled “Fraudulent and Unreliable Laboratory Testing Data in Premarket Submissions ... reminding sponsors to carefully evaluate the third parties they engage to conduct performance testing and to independently verify all testing results before submitting to the FDA.”

Third-party labs are going through a period of mergers and acquisitions. Equity groups Waters Street and Leonard Green purchased, and are struggling to integrate, labs to create entities capable of servicing the full phase of FD&C development and commercialization.

The scientists at the benchtop of these third-party labs cover a diverse range of technical experience and education. The vast majority of them, however, will have recently obtained an undergraduate degree in a relevant discipline. One third-party testing lab, having gone through a position survey following internal employee revolt, raised starting pay for these recent graduates to \$22/hr. In April, 2024, California fast food workers will start at \$20/hr.

These benchtop scientists work long hours repeating a variety of highly technical tasks. But with the variety of services offered by these labs, the recent graduate, hopefully, gets exposed to an array of experts and techniques. While the recent graduate gets a diversity of experience the labs get samples analyzed, projects billed, and, hopefully, monthly budget met.

With a growth in major pharma reliance on third-party labs, some labs are establishing revenue growth goals of 30% year over year. With these goals these entities are under pressure to get samples in and data out. This pressure combined with poor pay for a highly technical discipline and industry growth leads to these labs experiencing high turnover. Positions populated by those recent graduates experience turnover that fluctuates, on a monthly basis, between 12 to 25%; one major lab recently saw turnover of 42%!

What this means is that when interacting with a third-party lab, if they are cGMP compliant, there will always be chaos lurking in the background. I've seen PhD principal chemists leave to play professional hockey, make kids video games, and open a dance club, all early in their careers. And so, in the middle of your project analysts, QA specialists, etc. will likely be leaving. How do you pick the right lab?

When interviewing a lab ask them about trends in their laboratory investigations, those required by cGMP compliance. All labs will have investigations, and analyst turnover will contribute to the total number of investigations. But, trend indicating an ongoing increase in investigations may be a sign that the lab you are interviewing lacks sufficient back end processes and support in targeting, recruiting, onboarding, training, and mentoring, and in the keeping of quality laboratory personnel.

Because your FD&C project is likely a years-long endeavor it would be wise to use a third-party lab with sufficient back end to support your project. Asking about trends in turnover and laboratory investigations is a good place to start as any.

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