



# BUILDING AN EFFECTIVE TESTING PROGRAM

A NEW APPROACH TO MEETING CURRENT AND FUTURE NEEDS





## MARKET OVERVIEW

With the biomedical landscape undergoing constant transformation, mechanical testing capabilities continue to rise in importance among startups vying for competitive advantage and greater market share.

There is a growing focus on mechanical testing in the biomedical market. Competition and customer preferences have accelerated market innovations for emerging technologies such as at-home devices, wearables, and new sensors to generate health-related data. In addition to consumer-driven innovation, companies are also adopting dual sourcing strategies in an effort to navigate supply chain issues, creating additional need to evaluate new materials and components.

These activities are introducing new types of testing while also increasing the volume of testing being required. As startups contend with these changes, they're also experiencing time-to-market compression, with venture capitalists heavily investing in disruptive competitors.

To succeed in this environment, startups must be able to perform testing in a way that meets rigorous regulatory requirements while also helping them be first to market with new products and services.

# CHALLENGES

Startups face multiple challenges as they seek to satisfy performance and compliance demands under increasingly tight timelines.



## **It is difficult to build a flexible testing program able to grow from conception to market.**

- Making the wrong decisions about testing equipment during the proof-of-concept stage can have significant negative repercussions as startups prepare for the later phases of product development.
- The amount, variety, and complexity of required testing will increase as startups move through the product life cycle. This often requires them to quickly adapt their equipment and methods to perform new, unanticipated tests.
- The need to expand or modify a testing program causes setbacks to startups preparing to move to the next step in the product lifecycle. Many find it difficult to track, control, share, and consistently perform validated methods from proof of concept through later phases.



## **A poorly operating lab can delay the product development timeline.**

- To maintain data integrity and regulatory compliance, startups must ensure that their operators are only using approved test methods. This becomes difficult to manage as the volume and complexity of testing increases.
- Bringing new operators up to speed during onboarding can be extremely time consuming, making it challenging for startups to keep up with training demands as testing pressures build.
- In addition to worrying about invalid test results, labs must constantly be concerned about the possibility of damaged equipment and/or personal injury caused by the equipment.



## **Testing requirements can experience a sudden—and forced—change in direction.**

Unexpected circumstances can cause disruptions and/or impact the organization's existing commitments to budget and staff:

- A need arises for the organization to quickly evaluate new materials or new vendors.
- The organization encounters new demands during the regulatory approval process.
- Startups may be uncertain how to act quickly and correctly in response to first-time organizational changes, such as expanding or moving to a new location.

How organizations tackle these challenges determines whether they will be able to achieve desired outcomes from their testing programs. Let's examine two different approaches and what startups can expect from each one.

# WAYS TO ADDRESS TESTING CHALLENGES

## Approach 1:

### Focusing on short term requirements

Startups commonly approach their testing needs with a short-term view of the staff and equipment needed to support their current situation. Because they want to get up and running as quickly as possible—and typically only have a few people performing testing—organizations often rely on manual operator workflows to record data and share methods, even though they know this will cause delays down the line. They may buy inferior equipment to save on costs, even if this limits their capabilities in the future. And to avoid up-front costs, some startups rely on third-party testing services, even though they may lose control and access to data as a result.

The assumption is that after prototyping and design refinement, the organization will move through a series of predictable steps towards production and ongoing quality testing, with enough time in between to prepare and adapt for the next phase. However, today's market forces are making these steps shorter—and the stakes are higher for each step.

Most organizations realize that there are mission-critical moments of transition as they work to achieve each step-change. However, they often underestimate the impact that shorter transition time will have on their testing. This short-term approach to testing creates some bigger-picture issues that bear consideration. These include:

- Critical gaps that may be causing missed handoffs and increased complexity
- Data inconsistency and security deficiencies when transitioning into manufacturing
- The inability to address sudden supply chain or regulatory-driven design changes in a time-sensitive manner
- Unplanned effort and expense from unforeseen testing requirements, training, and/or retesting with more complex criteria
- Test data that lacks the rigorous traceability needed to comply with the regulatory approval process

## Approach 2:

### Anticipating and accounting for all stages of the product pipeline

Under this approach, startups are not only considering their current testing requirements but also thinking about future needs as their organization transitions into production and quality control or into new ownership. Building a testing program that anticipates and accounts for all stages of the product pipeline involves establishing a complete platform that can adapt to new testing requirements, scale with data collection, and perform near- and long-term data analysis.

As startups employ this approach, they must be able to embed their future needs into their current testing—managing data in one place at every step—with flexibility, accuracy, and traceability. By doing this they can adapt to new criteria quickly and efficiently while steering clear of risks to timelines and compliance. To be most effective, they also need to apply ongoing efficiencies to their testing lab in a way that is simple and intuitive, with optimized processes to avoid unexpected delays, CapEx costs, and safety risks.

#### **Those evaluating this option would gain the following benefits:**

- The ability to run a simple test without the need for custom method development
- A flexible software and hardware testing combination that extends testing capabilities as needed
- A centralized system that can remotely control user security settings and method permissions on a global basis while simultaneously monitoring all method changes and test results
- The ability to lock down test methods from outside interference along with ongoing automatic recording of testing activities to stop needless mistakes
- Built-in operator assistance and team permission management capabilities to speed up the training of new hires
- A platform that improves the safety of people and the protection of equipment
- Access to a team of experts with extensive knowledge of regulatory demands and an active commitment to developing effective test methods
- Tools for testing results trend analysis, enabling seamless integration with electronic signatures and approvals, maintaining file revision history, and automating audit trails

# SUMMARY

With customers demanding innovative technologies and growing competitive threats, startups are likely to remain under constant pressure to rapidly introduce new products and services. To respond effectively, they must be able to address critical challenges involved in enabling more flexible testing, improving operations in the lab, and adapting to sudden changes in testing requirements.

Approaching testing requirements with a short-term outlook can cause critical gaps, missteps, and errors as you move toward production. As a result, you can be forced to perform costly retesting or experience non-compliance, among other risks. In the end, these issues can result in costly delays that push out timelines and hurt your credibility, reputation, and valuation.

Instead, you need to **build a testing program that anticipates and accounts for all stages of the product pipeline**. As you evaluate how to accomplish this, you must ensure you have the ability to embed future needs into today's testing, apply ongoing efficiencies to your lab, and adapt to surprises as they come. Armed with these capabilities, you can position your lab to meet product development needs—now and in the future. At the same time, you'll have greater confidence in your ability to pass audits, meet regulatory requirements, and get to market faster with safe and innovative products.

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