

# Avoid Drug Development Derailment

Quality is crucial to customer satisfaction and public trust. Quality regulations continually grow more complex, and it can be easy to overlook some critical quality components.<sup>1</sup> FDA inspections correlate with improved product quality, which positively impacts the bottom line.<sup>2</sup>



## Key 1

### Implement Quality systems programs immediately because:

- **Sponsor's responsibilities go beyond auditing and weekly production updates**
- **Waiting too late in development is dangerous to patient safety and poor business practices.**

## Key 2

### Create Standard Operating Procedure (SOP) manual that:

- **Do not duplicate processes of vendors.**
- **Do not contradict Vendors.**
- **Are specific to in-house processes.**
- **Provide key instructions for oversight and details for in-house processes.**
- **Vendor risk assessments are needed to justify oversight levels.**

## Key 3

### Find the right manufacturing and clinical partners.

- **Due diligence must include assessing quality systems and communication.**
- **Assess sites' regulatory track record.**
- **Will this be your commercial partner?**

## Key 4

### Build a Strong Quality Culture from the beginning:

- **ELT must be engaged in quality-related activities.**
- **Develop a mindset that quality is everyone's job.**
- **Develop key performance indicators for vendor quality.**
- **Develop tools that allow you to continual assess risk.**

## Key 5

### Consult experts who:

- **Provides flexibility.**
- **Augment internal resources.<sup>3</sup>**
- **Review quality systems and remediation plans.<sup>4</sup>**
- **Keep projects on schedule and within budget.<sup>5</sup>**

Another benefit of engaging consultants is the wide range of expertise they can bring to a program that has multiple stages of development and testing, each with their own Quality guidelines, plans, and requirements. At the most basic level, engaging outside consultants can be highly pragmatic and drive multiple efficiencies.

#### SOURCES

- <sup>1</sup> <https://www.pharmaceuticalonline.com/doc/developing-optimal-pharmaceutical-quality-control-strategies-0001>
- <sup>2</sup> <https://www.applerubber.com/blog/the-lasting-effects-of-quality-control-on-your-bottom-line/>
- <sup>3</sup> <https://www.pharmtech.com/view/consulting-quality>
- <sup>4</sup> <https://www.pharmtech.com/view/consulting-quality>
- <sup>5</sup> <https://www.pharmtech.com/view/consulting-quality>