

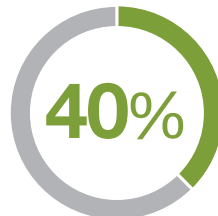
# Ineffective SOPs are Cause of FDA 483's



As the levels of complexity in quality control have risen, so have the number of FDA citations, warning letters, and consent decrees. The number of Pharma companies that have received warning letters, or that are under consent decrees, indicates that poorly structured SOPs are a significant problem in the industry.

Poorly Structured SOPs are a major concern:

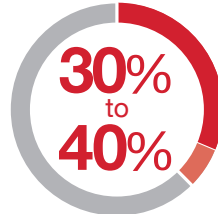
**TWO** of the  
**TOP 10**  
Pharma deficiencies  
reported by the FDA  
were related  
specifically to  
**ineffective inspection  
and maintenance  
procedures**



of drug shortages  
resulted from  
quality concerns  
while relying on  
incorrect SOPs



of 483 Letters  
involved lack  
of Management  
Oversight as the  
leading reason



of all FDA recalls  
are Center for  
Devices and  
Radiological Health  
(CDRH) related

Poor manufacturing quality is most frequently a result of poorly executed processes. It has been reported that you can essentially spend:

**\$500k**  
a year on  
compliance

or

**\$300m**  
on an FDA  
consent decree

The FDA is recording a record-breaking pace for 483's:



**10,000** issued  
**CITATIONS** a year

**1 EVERY**  
**52 MINUTES**



**Finding a new way to look at a challenge  
may be the key to finding an effective way to address it.**

See how to overcome the dangers of incorrect SOPs.



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