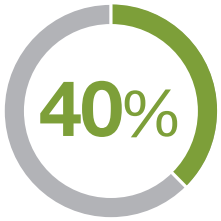
Ineffective SOPs are Cause of FDA 483's

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:

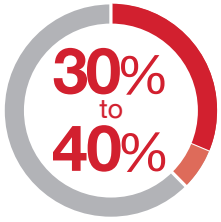
TWO of the **TOP 10**

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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