Top 5 Trends in Non Compliance in Pharmaceutical Manufacturing

A total of 155 warning letters issued since 2015 by FDA's Office of Manufacturing Quality were analysed for violations of cGMP guidelines. Here are the results:

#1 What were the most frequent violations in the warning letters ?

25.1% for failure in maintaining written procedures and records

22.3% for failure in testing of drug products and containers

14.9% for violations related to cleaning of equipment and contamination

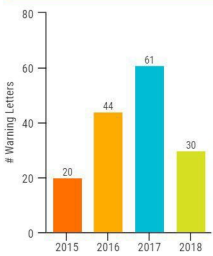
#2 Most frequently violated CFR guideline numbers

Written Records
- CFR 211.100 (11.8%)
- CFR 211.192 (7.7%)
- CFR 211.194 (6.8%)

Testing
- CFR 211.84 (10.5%)
- CFR 211.165 (11.8%)

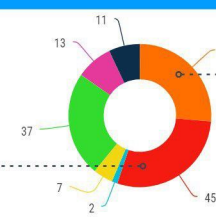
Cleaning & Contamination
- CFR 211.113 (6.5%)
- CFR 211.67 (5.9%)
- CFR 211.63 (1.9%)
- CFR 211.182 (0.6%)

#3 Year Wise Number of Letters Issued by FDA's OMQ



*The data for **2018** is only uptil June

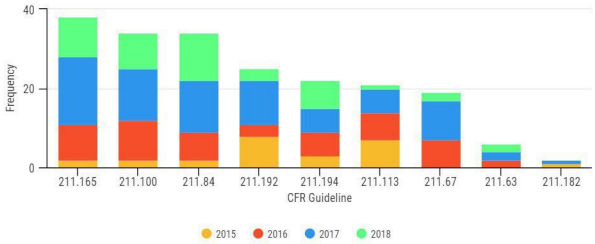
#4 Total Number of Warnings Letters since 2015 by Country



45/155
45 warning letters were given to **Chinese** Pharmaceutical companies

41/155
41 warning letters were given to **Indian** Pharmaceutical companies.

#5 Year wise trend in frequency of violations of CFR guidelines



Overall Predictions for 2019

The number of drug GMP warning letters continues to increase from 20 in FY2015 to 44 in FY2016 to 61 in FY2017. The number of warning letters for FY2018 and FY2019 is expected to maintain this trend. Focus on data integrity and data governance related guidelines will continue to increase and companies must adopt measures to ensure compliance.