EDITORIAL

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The quality in the pharmaceutical industry has become a great concern and there has been a growing awareness for the significance of the quality of the pharmaceutical products. In November 2017, USFDA delivered strong message to pharmaceutical companies on quality culture & data integrity. The US and European regulators conducted workshops on 'Advanced GMP (good Manufacturing Practices)' across four city of India between November 6th and 17th. Apart from that, significant number of warning letters issued by the Office of Manufacturing Quality of the USFDA to pharmaceutical companies, India and China are two leading countries. These warning letters used to average around 20 in a year in the calendar years 2013, 2014 and 2015. But it increased to 43 in calendar year 2016. And so far 2017, seems to be no better, since already 35 warning letters have been issued. The major findings about poor quality concerns are:

i) Releasing failing product as if it had passed.
ii) Disabled audit trail feature.
iii) Improper out of specification investigation.
iv) Inadequate Corrective and Preventive Actions.
v) Poor root cause analysis

Apart from above, the responsibilities and procedures applicable to the quality control unit are not in writing or fully followed and laboratory controls do not include the establishment of appropriate specifications, standards, sampling plans, and test procedures.
So we hope that the regulators like the US Food and Drug Administration's (US FDA), the UK Medicines and Healthcare Products Regulatory Agency (UK MHRA), the European Medicines Agency (EMA) and off course the India's Central Drugs Standard Control Organization (CDSCO) should focus on the need to adhere to better quality culture with the objectives of assessing the nature and intensity of such challenges, identifying gaps and design of policies..

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