REVIEW OF WARNING LETTERS ISSUED BY US FDA OVER PAST 3 YEARS

By

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Internship Report

At

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MBA-PHARMACEUTICAL MANAGEMENT-08

We are the leading provider of next generation solutions for Life Sciences companies. Harmony, our innovative platform combines the power of end to end label and artwork management, integrated text and graphics proofing, enterprise project management, regulatory information, quality metrics and advanced analytics into one world class platform. The software they are developing is Harmony.

End to End Labelling:

Our end to end label management platform includes state of the art tools to easily and effectively manage your label content. Right from the content creation, during early stages, to post marketing of products, one system will manage all your data related to labels. You can even analyze the impact of a change request with a click of a button.

Regulatory Intelligence:

Harmony offers a secure global repository for all your regulatory data. This gives you complete control over your team's activities, local or remote. Manage all product registrations, renewals, queries, deficiencies, post-approval variances along with key regulatory documents from one place.

Project Management:

Effective project management is the key to any organization's bottom line. Managing projects as per agreed time, scope and schedule are essential especially in the pharmaceutical ecosystem, where a single day delay can cause significant revenue loss. Be it your R&D projects, change management projects or any other ad-hoc project; we all need a good project manager. Harmony can do all the PM work for you and more.

Artwork Management:

Harmony is the leading Label Artwork Management solutions provider for the pharmaceutical industry. Our teams, with decades of global experience under their belts, have come up with a solution which is compliant with 21 CFR part 11 regulations and EU Annex 11 guidelines. Harmony is an easily configurable software platform which can be implemented in as little as six weeks.

Quality Metrics:

As per ICH, implementation of the Q10 model should achieve three main objectives which complement or enhance regional GMP requirements. Product realization, establishing and

maintaining a state of control, and facilitating continual improvement. Harmony enables knowledge management and quality risk management to achieve these objectives.

Document Comparison:

Proofreading the content of leaflets, artworks, and other regulated documents is a highly focused effort. Complexity increases when the document is multilingual and runs into thousands of words. Simple mistakes can lead to product recalls due to patient safety concerns. Harmony helps users in reducing the effort required for these checks with a variety of automated and semi-automated options.

Research Objective: To know what the major violations in case of drugs, biologicals, and medical devices from Warning Letters.

Research Methodology:

Study Type: Secondary Desk Review. Publicly available FDA letters sent to pharmaceutical companies from 2015 to 2017 were reviewed. A standard data collection tool was developed using MS Excel, including all categories violations. Other information collected included the type of regulatory letter and media in which violations were found.

Study Duration: Three Months (Feb 2018 to April 2018)

Sample Size: A total of 1875 warning letters reviewed from 2015 January to 2017 December and out of which 716 were related to drugs and pharmaceuticals and 1159 letters were related to food and food products.

For this study Warning letters issued for drugs and pharmaceuticals are considered thereby funneled sample size is 716.

Results and Conclusion:

Next to China, India got most warning letters from FDA followed by Korea, Canada and Japan. China and India together account for 80% of import alerts which are associated with warning letters.

Since 2015 warning letters to drugs are increasing rapidly for drugs and formulations. Whereas they were decreasing for medical devices and biologicals. These are significance increase in warning letters for online Pharmacies. In case of medical devices its inversely relational. Total count of warning letters with time are decreasing.

1. Violations for online pharmacies mostly are misbranding, labelling issues, sale of not approved medicines and internet marketing with false or misleading claims.
2. Violations for API, drugs and formulations include adulteration, misbranding. It also includes few false or misleading claims
3. Violations for medical devices include adulteration, QSR, pre-market approval, investigational device exemptions and misbranding.