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Common regulatory issues and challenges in dealing with eSubmissions through FDA Electronic Submissions Gateway

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The Food and Drug Administration (FDA) Electronic Submissions Gateway (ESG) is an Agency-wide solution for accepting electronic regulatory submissions. The FDA ESG enables the secure submission of regulatory information for review. The FDA ESG Web Interface improves cost savings, reduce resource requirements, and time efficiencies for both Sponsors and the Agency. FDA Centers have specific guidelines for preparing and submitting electronic submissions. FDA Center(s) will only accept specific types of submissions. The electronic submission process encompasses the receipt, acknowledgment of receipt (to the sender), routing, and notification (to a receiving Center or Office) of the delivery of an electronic submission. The FDA ESG 2011 Statistics indicate that total submissions made to CDER were 93,503 and to OC were 55,676. However these submissions were not validated completely during the first attempt and had to be resubmitted to validate the submissions completely for approval. The first attempt submission success rates for these submissions are very poor and cause delay for the product approvals. This also adds up to extra effort and cost to fix those submissions again and resubmit to the FDA ESG. Though a lot of factors cause these submission failures, the most common are erroneous information, non compliant submissions or new guidelines. But the major contributing factors are the simple recurring issues which are generally ignored and can be avoided to improve the first attempt submission success rate. Such recurring issues if converted to a checklist and prevented for future submissions will help to get validated in first attempt itself.

Biography

Jayprakash is a Senior Project Leader at Virtify Inc. He earned his MBA in Information Technology at United Business Institutes, Belgium and is a Certified Six Sigma Green Belt Professional. Jay is an SME on regional and global regulatory labeling requirements; Standards and Processes of Structured Product Labeling (SPL) and EudraVigilance Medicinal Product Dictionary (EVMPD). He was Instrumental in improving FDA ESG Electronic Submissions success rate by reducing the defect percentage by 96% (from 45.38% to 1.77%). Jay Implemented Structured Product Labeling Six Sigma Project by reducing the TAT for SPL conversions and increasing the FDA ESG submission success rate.

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