Rimsys®

MAKING THE CASE FOR A RIM SYSTEM

When it comes to tracking all of the information and processes around medical device regulatory submissions and compliance, spreadsheets and systems built for other purposes (like QMS systems and Pharma regulatory tools) just don't cut it anymore.

$30K–$50K PER EMPLOYEE

Time wasted due to inefficient processes

Searching for information, duplicating efforts among processes, & manually re-entering data

The average salary of an RA professional is $97,000 & it is estimated that they spend 30-50% of their time looking for information that would be easily retrieved in a RIM system

Public relations costs and diminishing goodwill following a public adverse event can be catastrophic and nearly impossible to plan for

$ 2000 PER DAY

One outsourced regulatory consultant

One Rimsys client was able to eliminate 15 consultants with the implementation of our RIM solution

$1MM–$4MM COST OF A SINGLE MAJOR QUALITY EVENT

Warning letter: avg. $1M
Recall: avg. $2M
Consent decree: avg. $400M

*these costs can vary widely with each event

MINIMIZE COMPLIANCE RISK

Staying on top of upcoming deadlines & changing requirements

RIM systems can automate manual process that often lead to missed deadlines & late responses to changes in regulations & requirements:

- Identify GSPRs affected by a Standards change
- Notifications of pending submission expirations & deadlines
- Automation of approval & notification tasks

80%-90% REDUCTION
in regulatory workload: data maintenance & integration

ACCELERATE TIME TO MARKET

Fully aligning regulatory activities with product development & all go-to-market functions in a unified platform significantly improves efficiency.

RIM SYSTEMS ARE BUILT FOR COMPLIANCE

Reduce impact of staff turnover

Better tools & more efficient workflows = happier employees

Employees are able to spend time on implementing regulatory strategies & managing the regulatory affairs – not looking for information!

Happier employees = less turnover

RIM system = faster onboarding of new employees

50% less time spent on regulatory submissions

90% reduction in time spent creating reports & retrieving data

REGULATIONS