



Regulatory Automation (RegMation), it's matter of when!

Automation and AI are a reality in several industries. In life science companies these areas are making good strides in some pockets, much deeper in some functional areas and just some pilots in other areas. In vastly regulated life sciences environment, it's essential for Regulatory Ecosystem to embrace Automation to decrease compliance burden and at same time increase efficiency. Forward looking companies realized well that Automation is a reality that helps them efficiently use current teams and systems.

When Regulatory Automation is at place, the work force has more time for innovative and strategic projects as well, in addition to daily routine tasks. Automation helps Regulatory Ecosystem to efficiently provision resources, reduce operational costs and optimize overall utilization.

Regulatory Automation (aka RegMation)

RegMation is when Regulatory Ecosystem utilizes machine intelligence technology to complete routine and unskilled tasks. Regulatory Automation is cost-effective, resourceful, and can streamline several Regulatory processes. It also gives employees more time to complete tasks.

RegMation can be chosen for a process if:

- » The process is repetitive in nature
- » It doesn't require intermittent gated decisions or logical thinking or heavy cross-functional involvement for completion
- » It is important for the process to have consistency across the business organization
- » It needs to be error-free

RegMation can be implemented in several processes within Bio-Pharma Regulatory which includes Regulatory Affairs, Regulatory Operations (Publishing), Regulatory Writing (CMC, Labeling, Safety). Regulatory automation engages from planning to execution.

Benefits with Regulatory Automation

Minimizes Outsourcing:

RegMation makes Regulatory functions to perk up their efficiency and helps to lessen Process time. Automation assures that Regulatory life-cycle keeps pace. This will help minimize unnecessary Outsourcing/Offshoring

Reduce operational costs:

Bio-Pharma Regulatory is no doubt an important process but comes with heavy manual process burden. Automation can significantly help in reducing unnecessary efforts/costs (for example, several processes have QC check lists for everything and anything).

With RegMation, Regulatory Ecosystem won't have to worry about human errors, because human errors lead to delay in go to market and unforeseen/unnecessary expenses every year. Automation can assist in improving effectiveness and ensuring accuracy.

Results in happier employees:

Regulatory function, in most companies, is a cost center. So focus is more on productivity and headcount constraints, irrespective of work burden or peaks. Though not intentional, these objectives lead to manual, and often boring & tedious responsibilities to their employees. On the other hand, this can have a stern consequence on employee morale.

Morale, it's that additional kick employees have so that they don't come to work and seems to be a robot. Setting up a positive work atmosphere and enhancing employee morale is the key to stay away from monotonous whirr from clocking in and out each day.

Boring & Tedious responsibilities are typically the most hated. People don't like doing grunt work, no matter how necessary it is. With automation, employees won't have to do that anymore. This will result in happier employees who are empowered to do other creative and complex tasks that will facilitate them to expand a sense of purpose with regard to their regulatory work.

Enforcing Governance:

RegMation is a splendid approach to execute governance in organizational Regulatory processes, though, it is rarely considered as one. Any assignment that an automated process completes is documented. For every task, it orchestrates to provide clear reports when, where and who executed in a single interface. As acknowledged previously, automation plays a vital role in reducing human in accuracy and speeds up tasks that require to be performed repetitively.

More Mileage from your existing systems

Most companies have significant investments in several tools (like EDMS, RIM, Content, Change Control, others) and more importantly, engineered most of their processes with these systems in mind. RegMation, with system interfaces and connectors, compliments these tools and leverage them to the fullest.

Bottom Line

Automation, if implemented in the approved manner, can help Regulatory Ecosystem in Improving the efficiency and accuracy of regulatory processes. The workforce can spend their valuable time on significant projects/tasks and not get bogged down with other time-consuming tasks.

It's impractical to accurately forecast what the potential of automation in Bio-Pharma Regulatory will look like, but Regulatory Automation will seize a considerable position in the discussion. Regulatory functional heads & leaders would do well to keep an eye on the latest advancements and the progress so that they can stay informed and all set to shift when the time is right for their company to start.



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