WHITE PAPER

Medical Device Regulatory systems, more critical than you think

With a 2-sided impact, on one side Global Regulatory requirements keep changing frequently and on other side competition pressuring for faster product life cycle updates or new product introduction, Regulatory teams need up-to-date information, real-time data, impacts of changes, quick what-if analysis, and more. With limited resources (and time) it's tough for teams and companies to accomplish these efficiently and cost-effectively. And another risk is when people leave, all the product activity, regulatory correspondence, and requirements are either gone or stuck in email boxes that will be very tough to pull them out, meaningfully on a contextual basis.

Other challenges include

- Companies existing systems like QMS, ERP, PLM, EDMS have a different purpose and clearly, they are not meant for Regulatory (and Regulatory teams know this well). Excels, of course, is free but you know that beyond a point they don't work for you.
- Manufacturers looking forward to expanding their scope globally often fall short to keep a track of the time and place of registrations, what's due, when, and what document versions used in those dossiers.
- Registration procedures are separate from the device data and hence keeping track of the both becomes difficult and this leads to never-ending excels after excels
- The global changes in regulations are a continuous process and maintaining compliance is challenging as these country regulations may not be in English and increase your dependency on everything and anything.
- When a change request comes in, to do impact analysis becomes a mini-project in itself gobbling a lot of Regulatory member time.

Some Benefits of Regulatory system

- **Revenue:** Eliminates license renewals and other commitments date miss out risk. Also ensures minimize compliance issues that usually are a drain of internal time for audits, CAPAs, etc

- **Agents & Distributors:** Collaborate with them seamlessly with cloud-based system by providing basic access to files, data that they would need. Helping them will help your teams in saving time in attending/serving repeated requests

- **Confidence & Strategy:** Know exactly what product is what stage in what country accurately. This will help make companies make the right decisions with new products or life cycle changes as there will be constant changes from marketing and commercial teams on posing different scenarios and options frequently. The right information can help you give strategic inputs for different scenarios

- **TF/Dossier builds:** With proper Reg Intel built-in, a Reg data system ensures you get the right dossier checklists by country accurate and UpToDate all the time, This will lead to fewer delays in HA/NB queries or rejections.

- **Regulatory source of truth:** A proper system tries to bring together accurate information from various functional areas into one place. This tends to increase the efficiency of the organization as it can use accurate details without having to collect it from teams (or form documents or archives) repeatedly.

- **HA/NB formats:** The same data goes to different countries in different formats, not just the dossiers or tech files but going forward in digital formats of UDI in different countries coming up (EU, Australia, China). One tool to churn out these formats easily is a big help to teams to avoid mistakes and duplication.

- **EDMS:** With built-in EDMS, teams do not need a separate document management system

- **eIFU:** Will help move slowly towards digital labeling to minimize cost and efforts with paper/pdf copies

A proper Regulatory & Submission management tool can help minimize pain. A cloud-based intuitive system increases productivity and efficiency as well while maintaining proper compliance

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