Veeva
COMPLIANCE CLUB

Improving regulatory compliance and agility as we prepare for the next normal

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Topic 1: Current State of the Industry

Since our last Consumer Goods Compliance Club, lockdown restrictions have evolved and consumers (and businesses) have continued to adjust. With these guidelines frequently shifting and varying by geography, continuing to deliver high quality, compliant products while keeping employees safe is still a big concern. Agility and digitization have been and will continue to be crucial to not only keep operations running now, but also to take advantage of emerging opportunities.

During the meeting we surveyed the attendees to understand the changes they made since COVID-19 hit:

- (42%) changed how they work with suppliers
- (57%) changed how they work internally
- (42%) accelerated new programs or overdue change

Regulatory and product safety workloads have also been affected by the crisis and most of us had to adjust in more ways than one. During the event we asked: **How has your regulatory / compliance / product safety workload been affected by the crisis?**

- (85%) more work due to driving new activities and moving to virtual/online
- (29%) more work diving into unfamiliar waters because of new regulations, shifts in production or new Geographical markets outreach
- (14%) more work trying to anticipate regulatory schedules

Should a second wave hit, 71% feel they'll be ready as they were already prepared for the first wave while 28% feel unprepared.
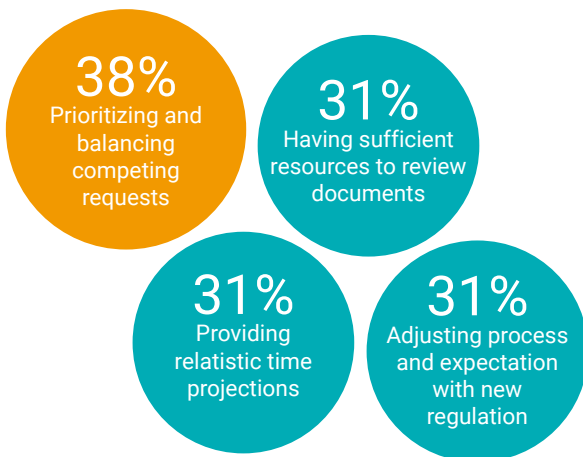
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Topic 2: Regulatory Trends Overview (Pre & Post Pandemic)

Veeva conducted the 2020 Regulatory Survey Trends Report prior to the COVID crisis in collaboration with Hanover Research, pooling 268 individuals in the CPG and chemicals space.

Key survey finding: 1 company out of 3 lacks both human and technology resources for regulatory compliance

Interestingly from our discussion during the event, it seems that regulatory concerns and challenges have remained somewhat constant during the pandemic however heavier workloads have affected the need and vigour to adapt to more digital friendly processes.

Top 4 Challenges in Managing Regulatory Affairs

38% Prioritizing and balancing competing requests

31% Having sufficient resources to review documents

31% Providing relatistic time projections

31% Adjusting process and expectation with new regulation

Greatest Concerns Managing Product Dossiers/Technical Files

Concern	Chemical	Consumer Goods/Cosmetic
Keeping up with the complexities of regulatory requirements	52%	45%
The time it takes to review/approve associated documents	42%	45%
Building best practices to enable efficiency	30%	41%
Resources to support all business initiatives	31%	35%
Difficulty managing launch timelines	17%	34%
Tracking internal stakeholders' input into the submission	29%	19%
Locating files required for a submission	25%	12%

Once a product is registered - a first crucial step for market launch - companies are experiencing significant workloads to maintain ongoing compliance.

Prioritising and balancing competing requests and having sufficient resources to review documents, adapt processes and provide realistic timelines become considerable daily challenges. When it comes to product dossiers and technical files management, experts worry about the follow-up of regulatory requirements, the amount of time spent verifying and validating documents and the establishment of best practices to boost effectiveness.

Looking to the future, capacity remains the main concern. Streamlining processes, integrating and automating all of the data, documents, workflows, and reporting, and providing anytime, anywhere access via modern cloud solutions can make a significant impact in addressing capacity concerns, while actually improving compliance and reducing risk. Yet, finding both the time and talent when everything is prioritised around a crisis becomes very challenging.

Key Compliance Club takeaway: Regulatory should not be considered just a reactive back office function. There is significant opportunity in driving regulatory intelligence to drive growth, look at opportunities, anticipate restrictions, boost effectiveness and shorten time to market.

Topic 3: Digital Transformation v Digital Migration

Many organizations fall into the trap of digital migration, doing the same things electronically rather than manually, rather than taking advantage of digital transformation. Digital transformation does start with the basis of moving to a modern, digital approach but the most successful organizations use the opportunity to **challenge long standing assumptions by putting the focus on the "what" and "why" to challenge the status quo of "how". In short, is there a better way?** With some of the changes from the pandemic and future implications beginning to settle in there is a window of opportunity to reconsider what has changed and how to move forward with agility to emerge as stronger organizations.

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