



Regulatory Management Trends Report

Understanding the Evolving Role & Responsibilities of the
Regulatory Affairs Professional

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Executive Summary

The Evolving Role Of Regulatory Affairs



Executive Summary

The Evolving Role Of Regulatory Affairs

After a tumultuous period for businesses across the globe, regulatory professionals have their hands full. Their teams are tasked with managing global expansions and getting products to market faster than ever before, while navigating the new complexities of keeping existing products on the shelf.

Simultaneously, they are answering demands for greater transparency and supporting increasingly ambitious corporate sustainability initiatives.

Amid mounting pressure on the work they do, the role of regulatory affairs teams has been elevated within most organizations. But regulatory professionals still feel they are not treated as true strategic decision makers in the business.

Moving forward, they want to be brought into decision-making earlier, and given more resources – both in terms of people and technology – to cope with growing workloads. Companies are investing in regulatory affairs, but not at the pace required in the rapidly evolving regulatory environment. But growth is not the only goal – companies are adopting a more holistic view of success through goals such as expanding their company's sustainability commitments or increasing transparency. These priorities signal an expansion of regulatory affairs to incorporate more holistic product stewardship.



Business Innovation Priorities for Today and Beyond



Business Innovation Priorities for Today and Beyond

In the year ahead, regulatory professionals are focused on getting products into customers' hands as quickly as possible, breaking into new markets, and advancing their company's sustainability and digital transformation efforts.

As they plan for the next five years, their ambitions broaden, with many focused on increasing operational excellence, making their innovation to market more agile, expanding into new categories, and improving the regulatory profile of their products globally. In both the near and longer term, increasing **transparency** will be a critical focus area for regulatory professionals.

Given the upheaval of the past year for businesses globally, many of these key priorities have become even more important, especially improving operational excellence and accelerating digital transformation.



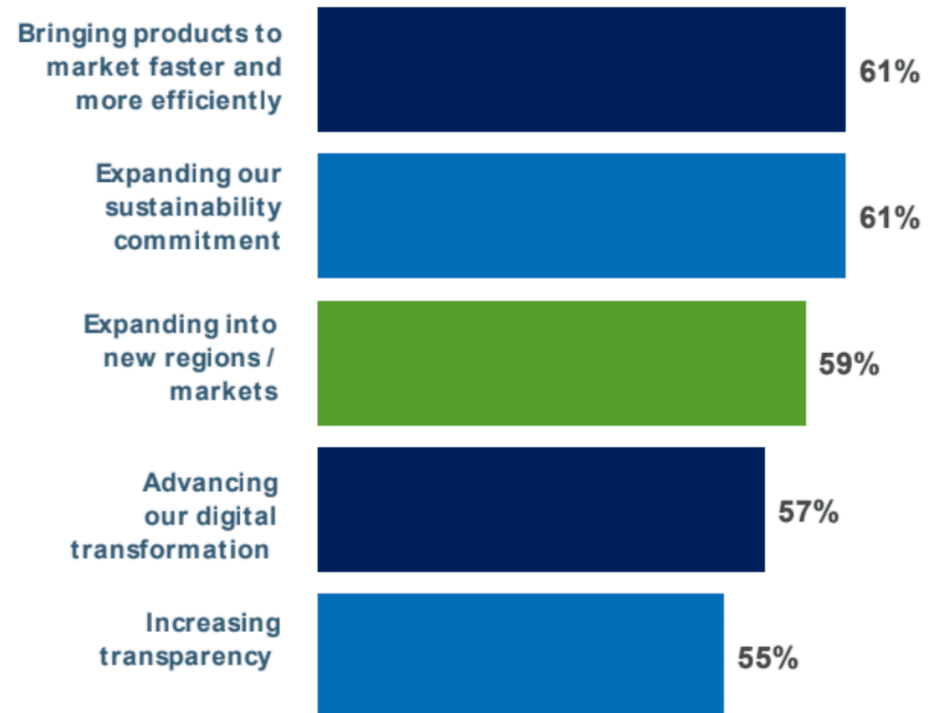
After a tough year for many global businesses, companies are focused in the short-term on maximizing growth and efficiency.

A majority of regulatory professionals report that their organization's top priorities include bringing products to market faster and more efficiently (61%) and expanding into new regions (59%). This is true across the industries surveyed and at all company sizes.

But growth is not the only goal – companies are adopting a more holistic view of success.

More than 60% of regulatory professionals indicate that expanding their company's sustainability commitment is a top objective, while another 55% say that increasing transparency is on the agenda. These priorities have expanded the responsibility of regulatory affairs to incorporate more holistic product stewardship.

Current Business Goals



Adopting and deploying digital technology to increase efficiency and virtual collaboration is vital.

Nearly 3 in 5 regulatory professionals (57%) – including 62% of those in the food & beverage category – indicate that accelerating their company's digital transformation is a key priority this year, with another 39% saying it has become more vital than ever due to the pandemic.

Whether it is replacing manual processes with digital ones or bringing in newer technology in place of older systems, such solutions may spark new types of innovation, which is a key focus area in the longer-term for many regulatory professionals (more on this in the next section).



57%

Of Regulatory Professionals
Report that **Accelerating
Digital Transformation is a
Key Priority this Year**





Food & beverage businesses are especially focused on increasing agility.

Regulatory professionals in the food & beverage space are more likely than their counterparts in consumer goods and chemical to indicate that making their innovation to market more agile is a top priority for this year (61% vs. 46%).

Making Innovation to Market More Agile is a Top Priority

61%



Food & Beverage

46%



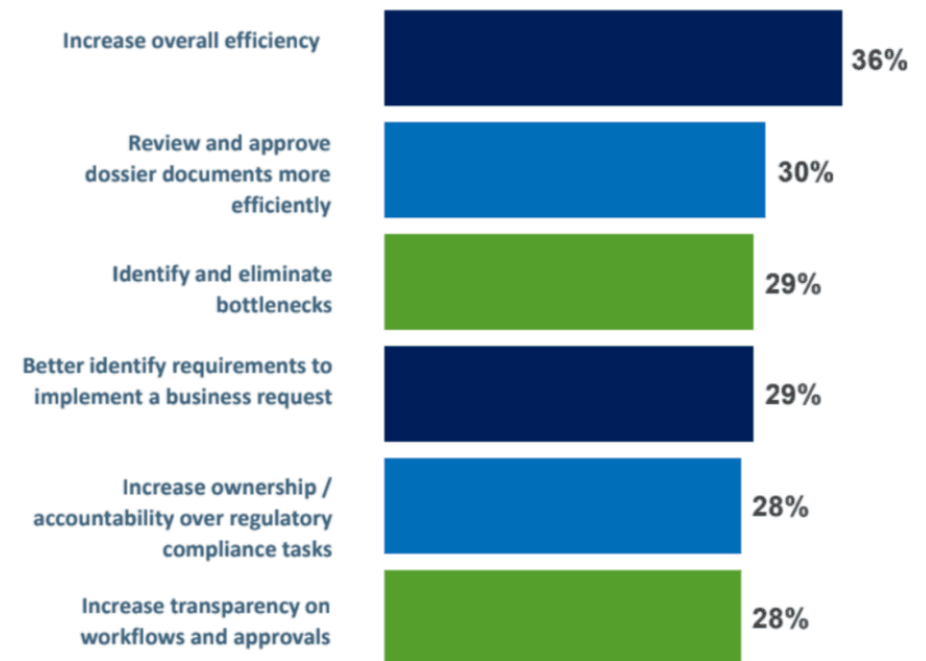
**Consumer Goods
& Chemical**

When it comes to goals specifically related to regulatory compliance, more professionals report that increased efficiency – more than anything else – is a priority.

Professionals' top regulatory compliance goal for the year is increasing overall efficiency (36%).

About one third also want to review and approve dossier documents more efficiently, identify and eliminate bottlenecks, better identify requirements to implement a business request, increase ownership and accountability over regulatory and compliance tasks, and increase transparency of workflows and approvals.

Regulatory Compliance Goals



Looking beyond this year, increasing transparency has emerged as a key business goal looking forward for the next 5 years. How to achieve transparency will need to be considered alongside the traditional regulatory affairs priorities of accelerating innovation and expansion, and revamping operations to become more efficient.

Regulatory professionals indicate their top priorities for the next 5 years include furthering existing priorities such as making their innovation to market more agile, increasing operational excellence, expanding and improving the regulatory profile of products globally, and expanding into new product categories will continue to be critical focus areas in the longer-term. The survey results indicate that consumer demands for transparency are flowing through to business priorities.

Food & beverage businesses are especially focused on driving efficiency in the long-term.

Regulatory professionals in the food & beverage space are more likely than their counterparts in consumer goods and chemical to markets indicate that bringing products to market faster and more efficiently is a key longer-term goal (58% vs. 41%).

Business Goals For The Next 5 Years

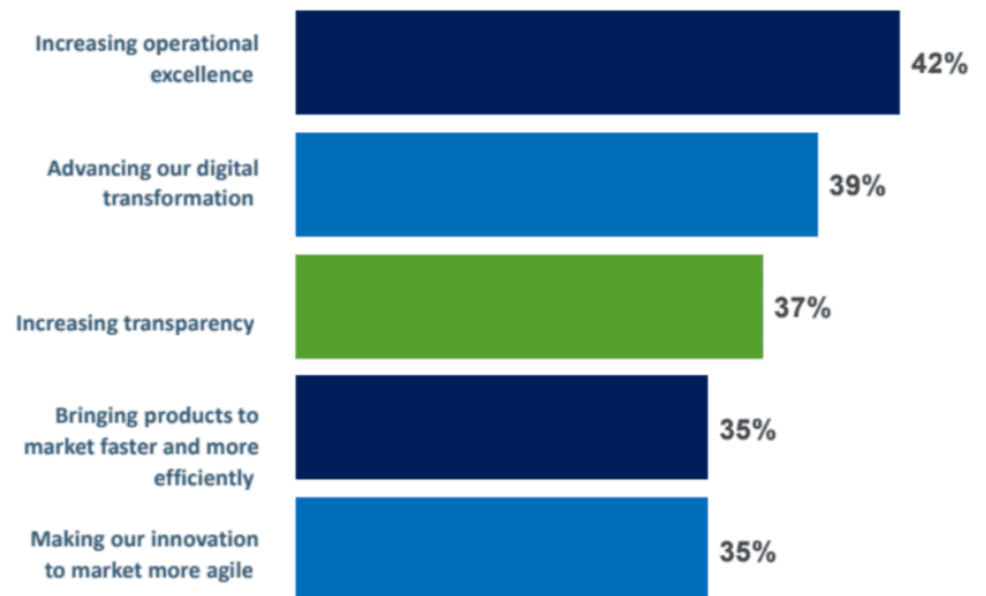


Existing business objectives have shifted to become top priorities as companies endeavor to provide essential products and services to customers despite the tumult of the past year.

As companies strive to stay above water – and even potentially grow – in a chaotic and uncertain environment, certain business goals are more urgent than ever. Regulatory professionals believe that increasing operational excellence (42%), advancing digital transformation (39%), and increasing transparency (37%) have all become more important because of the pandemic.

COVID-19 disrupted existing business operations, exposing the true cost of legacy technology and moved Digital Transformation up the priority list. Surprisingly, digital transformation now ranks higher in priorities than bringing products to market faster. This points to the importance of modern technology as an enabler.

Priorities That Have Become More Important Because Of Covid-19



The Evolving Role Of Regulatory Affairs



The Evolving Role Of Regulatory Affairs

The past few years have provided both challenges and opportunities for many businesses and their regulatory professionals. The pandemic has thrown unprecedented obstacles in the path of regulatory teams, including rapidly changing customer needs, a more complex regulatory landscape, increased workloads, and greater pressure to perform.

But it has also helped elevate the role of regulatory affairs within businesses, demonstrating the adaptability and resilience of the professionals and their teams.

Still, not all regulatory professionals feel their organizations treat them as true partners and they would like to see a more collaborative relationship as they look to the future.



The past few years have been difficult for businesses as they work to adapt to a rapidly evolving business environment.

Nearly all (92%) regulatory professionals report that their company has struggled to adapt to new customer demands over the past several years.

The coronavirus pandemic has upended previous regulatory processes and added to workloads.

Nearly all regulatory professionals (93%) agree that the pandemic has created a more complex regulatory landscape while demanding they get products to market faster and more efficiently than ever before. As a result, the same number (93%) believe that their company must spend more time creating new regulatory strategies to respond to the long term impact that COVID-19 has had on the business.

How Recent Events Have Impacted The Regulatory Landscape



ADMIT THEIR COMPANY HAS **STRUGGLED TO ADAPT** TO NEW CUSTOMER DEMANDS



AGREE THAT THE PANDEMIC HAS CREATED A **MORE COMPLEX REGULATORY LANDSCAPE**



BELIEVE THEIR COMPANY MUST **SPEND MORE TIME CREATING NEW REGULATORY STRATEGIES** TO RESPOND TO COVID-19

The role of regulatory affairs has been elevated within most companies by necessity.

Nearly all regulatory professionals (94%) agree that their teams have become more of a strategic partner within their organization due to COVID-19 as businesses have scrambled to conform with rapidly changing consumer demands and regulatory pressures.

Another 92% indicate that their employer has placed greater importance on the work happening across their team due to the pandemic.



94%

Of Regulatory Professionals Believe their Teams Have Become **More of a Strategic Partner** within their Organization





However, most regulatory professionals still feel under-resourced, and that regulatory compliance is not driving overall strategy at their organization.

While the pandemic has placed more importance on the work of regulatory affairs, these overburdened teams are not necessarily getting all the support they need.

More than 9 in 10 (91%) regulatory professionals assert that their company expects them to do more with less right now.



91%

Of Regulatory Professionals
Say their Company Expects
them to **Do More with Less**
Right Now

Many regulatory affairs teams still feel siloed from the greater organization. While businesses have leaned on regulatory affairs in times of crisis, professionals are skeptical that their organization will treat them as strategic allies in the longer term.

Fewer than 3 in 10 (29%) believe that their organizations treat them as true partners, helping to drive strategy. Instead, a majority (56%) indicate that they are informed of and responsive to critical business decisions after they are made. And many are left in the dark, as 16% of regulatory professionals report that they are not always informed of decisions that impact them.

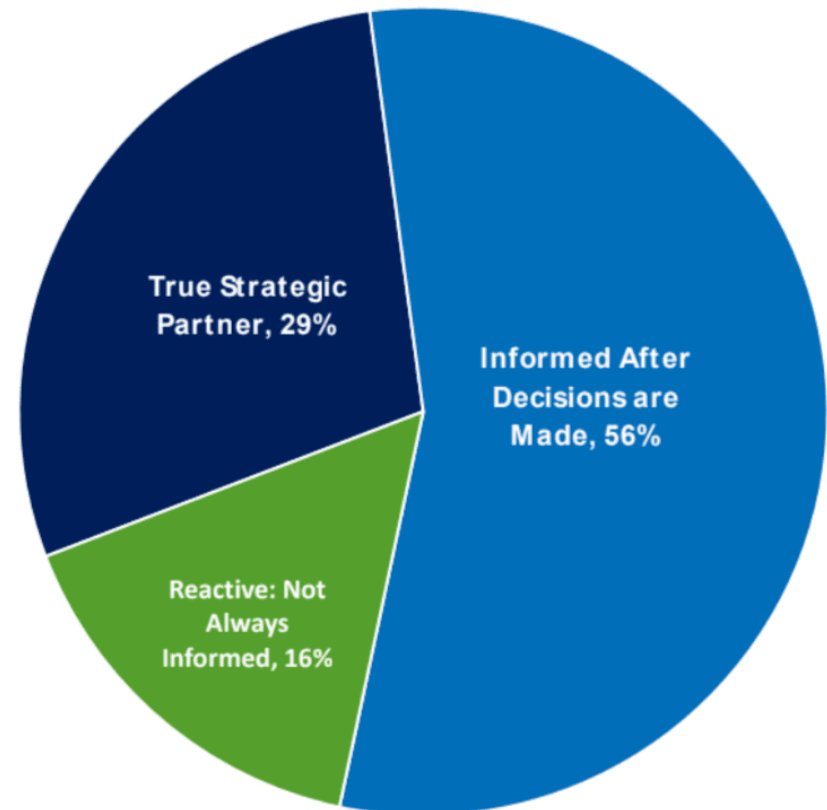


[A strategic partner would be] integrated more to the start of business decisions... Included with the idea portion before we go to the development stage of a new deal with a customer or supplier.

Manager, Food & Beverage, Wisconsin, USA



Professionals' View of their Regulatory and Compliance Teams



Challenges And Barriers Facing Regulatory Affairs



Challenges And Barriers Facing Regulatory Affairs

The task for regulatory professionals in the years ahead – and the pressure they face to do it well – is enormous. Workloads are increasing dramatically as they struggle to triage competing requests, adjust processes to accommodate new regulations, and keep on top of paperwork. Simultaneously, regulatory teams are being asked to support new business priorities like market and product expansion and ambitious sustainability goals, all while increasing transparency.

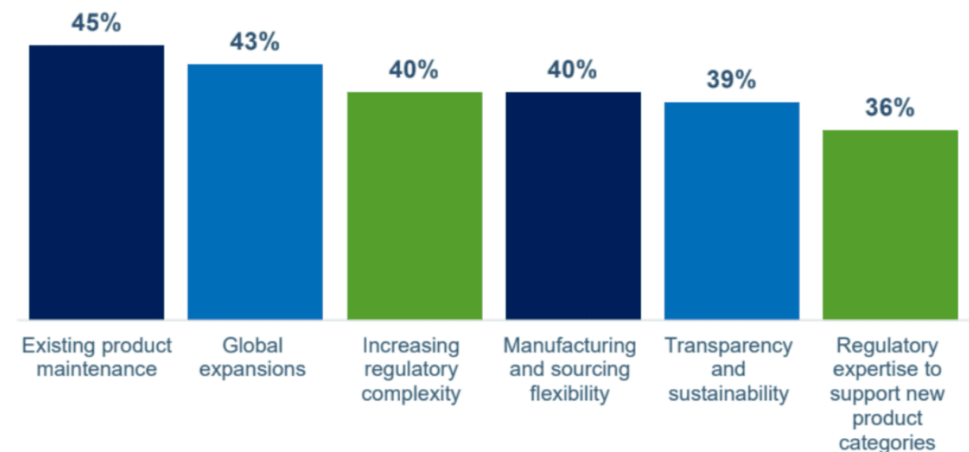


Regulatory affairs teams are tasked with supporting both expansion and product maintenance – adding to their workloads and stress.

Regulatory professionals report that existing product maintenance (45%) and global expansions (43%) will create some of the biggest regulatory challenges this year for their teams.

They also contend that increasing regulatory complexity (40%), manufacturing and sourcing flexibility (40%), transparency and sustainability (39%), and regulatory expertise to support new product categories (36%) will be major challenges.

Current Major Regulatory Challenges

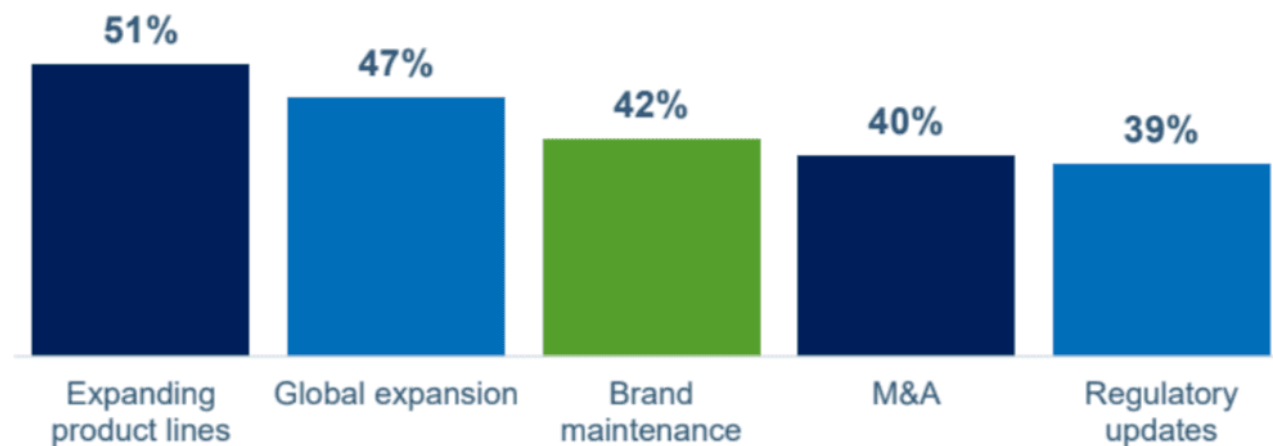




Businesses are looking to expand their offerings and move into new markets, piling work onto regulatory affairs teams as they fight to keep up with their existing responsibilities.

Professionals report the greatest sources of increased workloads for their team are expanding product lines (51%) and global expansion (47%). Almost 50% report that they are getting additional work from brand maintenance (reformulation, rebranding) and M&A and regulatory updates.

Sources of Increased Workload



The growing ambitions of corporate sustainability efforts at many organizations today means that regulatory professionals are now tasked with more holistic product stewardship – in addition to their traditional responsibilities.

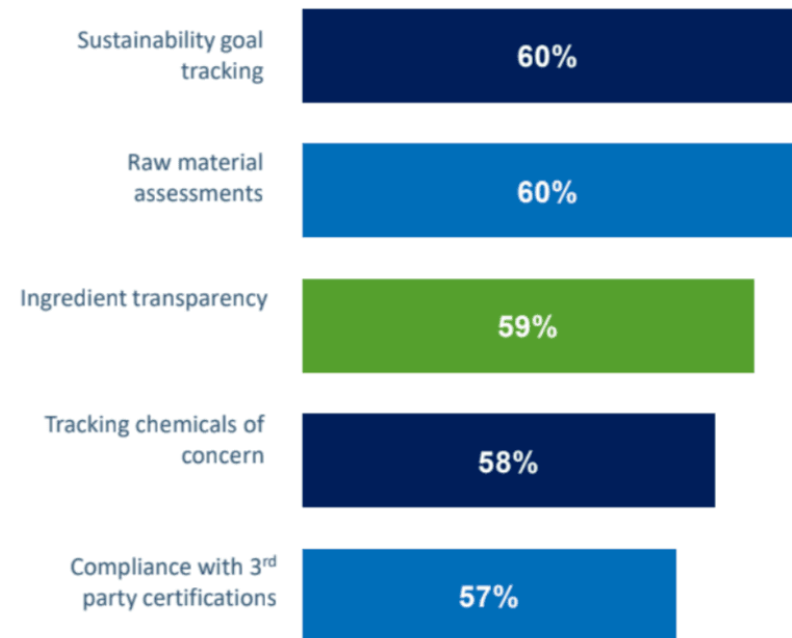
More than 50% of regulatory professionals believe that their company's sustainability efforts are adding to their workload. Their growing list of responsibilities include tracking chemicals of concern, achieving compliance with 3rd-party certifications, ingredient transparency, raw material assessments, and sustainability goal tracking.



3 in 5

Regulatory Professionals Believe that their Company's
Sustainability Efforts are Adding to their Workload

Top Sustainability Efforts Adding To Workloads



In light of these growing demands, regulatory professionals believe that balancing it all and staying agile in the face of shifting priorities will be their greatest challenge in the medium-term.

Looking ahead to the next 12-18 months, regulatory professionals have identified several areas that will continue to impact their team's responsibilities and resources. Top challenges are all related to juggling their growing workloads, including balancing competing requests, managing team commitments and tasks, adjusting processes and expectations with new regulations or partnerships, and implementing and enforcing policies to adhere to new and existing guidance.

Administrative duties are also adding to their plate, such as tracking priorities and alignment with regulatory activities.

This is in line with with past Regulatory Trends Studies, in which regulatory professionals indicated that major sources of increased work included adjusting processes/expectations (31%), managing team commitments and tasks (25%), and tracking priorities and alignment (24%).

Top Challenges For Regulatory Teams



Managing internal and external stakeholders while keeping timelines intact is another key challenge.

Regulatory professionals indicate some of their top concerns when managing product dossiers or technical files include tracking internal stakeholders' input into the submission (36%), difficulty managing launch timelines (34%), and keeping up with the complexities of regulatory requirements (33%).

In addition, 3 in 10 are worried about building best practices to enable efficiency, lacking resources to support all business initiatives, and tracking launch updates to products and dates (30% each).



The Cost Of Regulatory Delays And Errors



The Cost Of Regulatory Delays And Errors

As regulatory professionals struggle with increased workloads and conflicting demands, the high cost of regulatory errors weighs heavily on their minds. The vast majority acknowledge that their organizations have made regulatory mistakes that have cost them time and money – issues they hope to eliminate – or at the very least, reduce – going forward.



Regulatory errors are frequent, and usually have financial consequences.

About 4 in 5 (78%) regulatory professionals have experienced regulatory errors that have cost their business money. Almost one-quarter (21%) acknowledge that these incidents happen multiple times throughout the year, while another quarter (26%) report occurrences about once per year.

This aligns with findings from the past Regulatory Trends Studies, in which respondents said the top concerns about risk of regulatory error are consequences like time to market and fines.



4 in 5

Regulatory Professionals have **Experienced Regulatory Errors that have Cost their Business Money**





Regulatory errors and delays often have 6-figure financial impacts

About half of regulatory professionals report that their business typically loses \$100k or more per mistake when they make errors across each of the following activities: finding documents in internal systems, completing product registrations, handling customer requests, requesting documents internally and externally, providing feedback to R&D and Innovation teams, preparing assessments/certifications, and document creation.

Some mistakes can be even more expensive: 17% of professionals report that errors in completing product registration and finding documents in internal systems typically costs \$500k+.

Delays in shipment and product release as well as recalls cost organizations valuable time.

More than 4 in 5 regulatory professionals (81%) have experienced delays that impacted shipment dates. More than 2 in 5 (42%) say they happen at least once a year.

Some delays are caused by decisions not to release a product, or even to recall it - voluntarily or not. Nearly half (47%) of regulatory professionals acknowledge that their company has experienced a voluntary recall or audit due to a compliance error or delay, and 43% have experienced a mandatory recall.

Meanwhile, 44% admit that they have decided not to release product inventory.

43%

have received a warning letter from an agency.

Regulatory professionals across food & beverage are more likely than their counterparts in consumer goods and chemical to have dealt with a mandatory recall (51% vs. 36%).





The biggest causes of regulatory delays are external, and some interruptions can go on for months.

Regulatory professionals assert that the issues come most frequently from suppliers, regulatory authorities, and third-party testing labs/CROs (all 43%), as well as external business partners (39%).

About 1 in 3 regulatory professionals contend that external business partners (34%) cause delays lasting 5 weeks or more.

About 1 in 4 say the same of regulatory authorities (28%), third-party testing labs (26%), suppliers (25%), and customers (22%). Though 6+ month delays are rare, regulatory authorities are the most common culprit (7%).



43%

Of Regulatory Professionals Say that **Suppliers, Regulatory Authorities, and Third-Party Testing Labs** Typically Cause Delays

Internal counterparts also cause delays, albeit relatively shorter.

Nearly 2 in 5 regulatory professionals contend that internal non-regulatory (38%) and regulatory (38%) teams tend to create interruptions in their work.

These delays are slightly shorter than those caused by external entities – usually lasting 1-4 weeks.

About 3 in 10 regulatory professionals report that internal non-regulatory (30%) and regulatory (28%) teams typically cause delays stretching beyond 5 weeks.



2 in 5

Regulatory Professionals Contend that **Internal Teams Regularly Cause Delays in their Work**



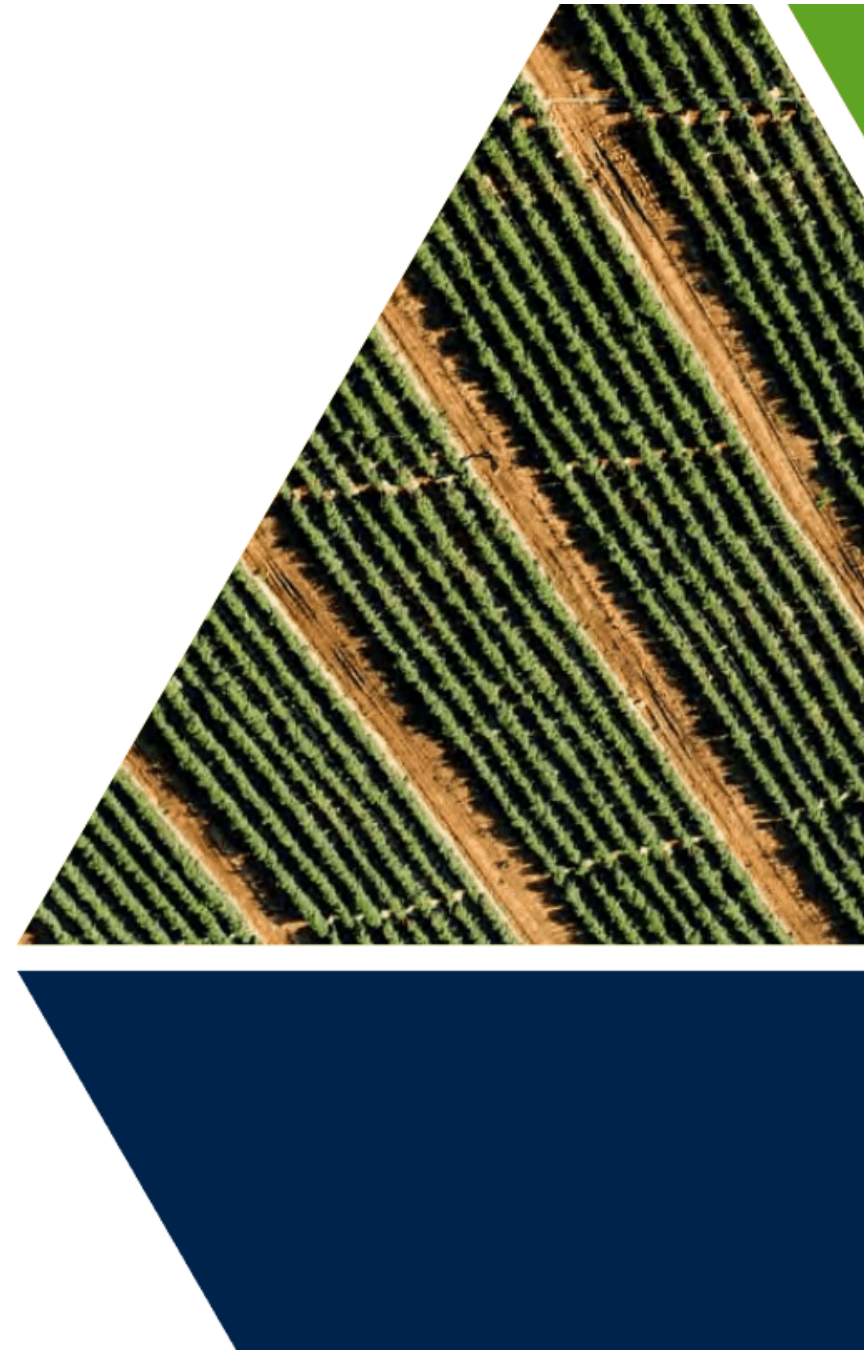
Current Regulatory Tools And Processes



Current Regulatory Tools And Processes

Regulatory professionals are generally confident in their organization's overall strategy when it comes to compliance.

But they note that certain processes like finding documents and completing product registrations are particularly error-prone, while others, like preparing assessments and certifications, or responding to customer requests, are time-consuming and could use more automation.



Overall, professionals feel confident in their company's regulatory strategies and processes.

Nearly 9 in 10 feel assured that their company's regulatory strategy is the right one (87%) and that they have adequate visibility into the regulatory & compliance work occurring at their organization (87%).

Additionally, 82% maintain that they can easily track and manage their regulatory and specialist work to make sure efforts are successful.



9 in 10

Regulatory Professionals Feel Confident that **Their Company's Regulatory Strategy is the Right One**

Professionals' Confidence in their Company's Regulatory Strategies and Processes



FEEL ASSURED THAT THEIR COMPANY'S
REGULATORY STRATEGY IS THE RIGHT ONE



BELIEVE THEY HAVE **ADEQUATE VISIBILITY**
INTO THE REGULATORY COMPLIANCE WORK
OCCURRING AT THEIR BUSINESS



CONTEND THEY CAN
EASILY TRACK AND MANAGE
THEIR REGULATORY SPECIALIST WORK



Dealing with customers and doing paperwork are major time-hogs that regulatory professionals would love to see automated.

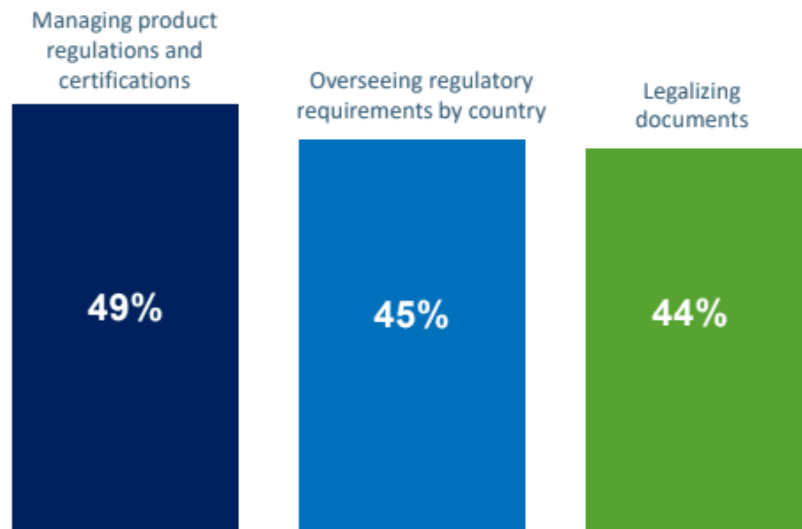
Regulatory professionals indicate that customer requests are a time-consuming area of their day (34%), followed by finding documents in internal systems (33%) and preparing assessments and certifications (33%).

It's no wonder these are also the areas where they would like to see greater automation: Nearly 2 in 5 (38%) assert that automating assessment preparation would lead to the greatest efficiency gains followed by finding documents internally (34%), responding to customer requests (33%), and providing feedback to R&D and Innovation teams (33%).

Regulatory requirements and documents are not easy to track and manage.

Regulatory professionals admit they have the greatest difficulty managing product regulations and certifications (49%), overseeing regulatory requirements by country (45%) and legalizing documents (44%).

Regulatory Processes Causing the Greatest Challenges for Professionals



Businesses are using a mix of software solutions to manage their daily regulatory processes. However, this mix does not meet their current and projected business needs as 39% recognized the increased need for digital transformation related to regulatory affairs.

Regulatory professionals have a wide range of responsibilities – from dossier management to responding to customer requests to collaboration with R&D and Innovation teams. To get it all done, they rely on a siloed assortment of legacy tools, from shared Excel sheets to custom-built software.

Standard enterprise tools like the Microsoft Office Suite and Google Docs are the most widely-used (94%). A major concern of some professionals is the lack of uniformity of the tools used by regulatory stakeholders.



I would like it if our software was completely uniform with everyone else's.

- VP, Chemical, Virginia, USA



Tools Used For Regulatory Compliance Processes



Standard enterprise tools remain the most commonly used by regulatory teams for basic documentation.

About half of regulatory professionals use standard enterprise tools (like MS Office, Google Docs) for processes like document creation (55%), finding documents in internal systems (50%), and requesting documents internally and externally (48%).

This is in line with the findings from the past Regulatory Trends studies which found that spreadsheets, email, shared folders and standalone documents were the top 4 tools.



94%

Of Regulatory Professionals
Use **Standard Enterprise
Tools** for their Compliance
Work





Businesses also rely on third-party cloud-based software tools and custom in-house software tools for a variety of functions.

Third-party tools are most frequently used for providing feedback to R&D and innovation teams (45%), completing product registrations and dossier management (41%), and preparing assessments and certifications (40%).

Spoke software is most commonly used for handling customer requests (44%) and providing feedback to R&D teams (41%). Additionally, 38% of professionals use it for preparing assessments and certifications, 34% for dossier management.

This is on par with the past study results, when nearly one-third of respondents said they used custom-built software for dossier preparation and product registration.

Looking Ahead: Businesses Must Invest In People And Technology

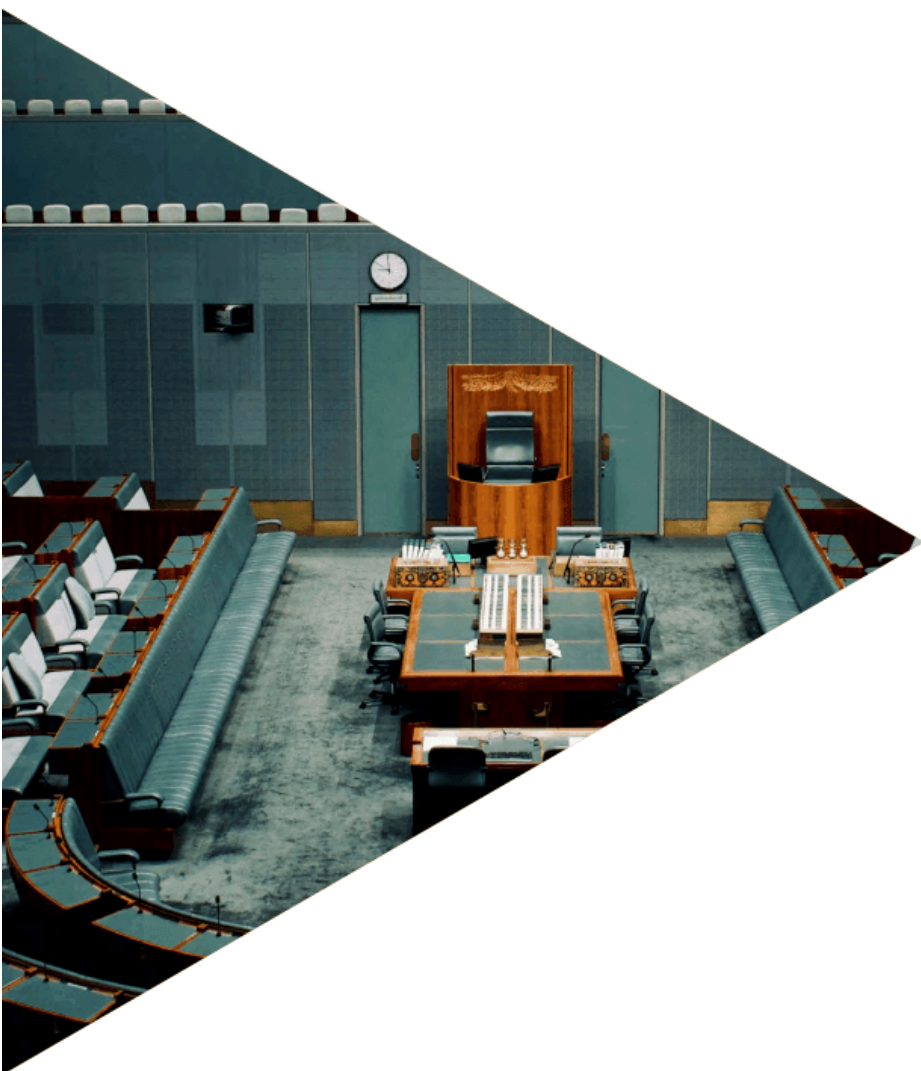


Looking Ahead: Businesses Must Invest In People And Technology

R&D is not the only department that drives innovation at most businesses – the work of regulatory affairs is a critical component in how quickly a company can develop a new product and get it to market.

As regulatory professionals think about what they need in order to do their jobs better, it all comes down to investment in people and technology. With their mounting responsibilities, regulatory professionals say they would benefit from more staff in general, employees with greater technical skills, and better software to automate time-consuming processes and allow them to work more nimbly. But it's not always so simple – even when they get the tools they need, they often face challenges regarding integration with legacy systems at their organizations.





How efficiently regulatory affairs can operate has a major impact on business innovation.

There are some aspects of a regulatory professional's job that they cannot control: close to 9 in 10 (86%) professionals acknowledge that government regulations have a big effect on innovation at their business.



86%

Of Regulatory Professionals
Acknowledge that
**Government Regulation
Impacts Innovation** at their
Business



80%

Of Regulatory Professionals Report that **Regulatory Software Solutions Impact Innovation** at their Business



I think what is most needed at this stage is new software solutions, because the traditional software solutions are no longer suitable for our development route, and we also need to provide more professional technical personnel

- VP, Consumer Goods, Pennsylvania, USA



While adapting to evolving government rules is a part of any company's life, how an organization goes about it can be a major factor in whether staying compliant means slowing down.

The software solutions (80%) and budgets (77%) allocated to regulatory teams significantly impact how efficiently regulatory affairs carries out their work, as do the people – both in terms of technical expertise (84%) and overall staffing levels (78%).

All of this ultimately affects how agile a company's innovation to market can be.

Despite the challenges of the past several years, investment in regulatory technology is expected to increase.

Given the increasing complexity of regulatory workloads – and the need to collaborate more efficiently than ever, often remotely - most businesses are poised to invest in their regulatory technology.

These budgets are overseen by a variety of stakeholders, including C-Suite (44%), Regulatory Affairs (43%), and Legal (41%).





Corporate investment in regulatory technology is expected to grow across industries.

More than three-quarters (77%) of regulatory professionals expect their company's investment in regulatory technology to grow (50%) or stay the same (27%).

The average budget increase for regulatory tech is expected to be 33%.

Professionals in the food & beverage industry are expecting an even larger increase of 41% on average (vs. 27% across chemical and consumer goods).

Regulatory Technology Budgets Are Expected To Increase



33%

Average Expected Increase In
Regulatory Technology Budget



41%

Average Expected Budget Increase
In Food & Beverage Sector



Beyond increased automation across processes, mobility and simplicity of regulatory functions is on the wish list.

Nearly 9 in 10 (87%) regulatory professionals believe that having access to their regulatory systems via mobile devices like phones or tablets would allow them to work more efficiently.

One big roadblock to implementing new regulatory technology is integration with current systems.

Despite the strong desire to upgrade the tools they use to manage mounting workloads, sometimes it can be a challenge to deploy. One of the biggest obstacles they typically encounter is difficulty integrating new approaches with legacy technologies and processes (36%). This challenge may contribute to the desire for both digital transformation and technology consolidation.

Staffing is also critical. Tools are nothing without the people who use them – especially true when it comes to regulatory affairs.

To carry out their work, almost half (45%) of regulatory professionals argue they need more staff at a higher level of technical capability. And 53% say their teams also need more people resources at the same level of technical capability.

Training is critical – top barriers regulatory professionals encounter when upgrading regulatory technology at their organizations include challenges training staff (39%) and lack of technical expertise (37%).



KEY TAKEAWAYS:



Regulatory Affairs Faces Existing and New Challenges, with New Technology Positioned to Transform How Work is Done

✕ in f



57%

Of Regulatory Professionals Report that **Accelerating Digital Transformation is a Key Priority this Year**



91%

Of Regulatory Professionals Say their Company Expects them to **Do More with Less** Right Now



9 In 10

Regulatory Professionals Feel Confident that **Their Company's Regulatory Strategy is the Right One**



43%

Of Regulatory Professionals Say that **Suppliers, Regulatory Authorities, and Third-Party Testing Labs Typically Cause Delays**



80%

Of Regulatory Professionals Report that **Regulatory Software Solutions Impact Innovation** at their Business



33%

Average Expected Increase In Regulatory Technology Budget

SHARE YOUR PERSPECTIVE

How does your experience compare with the findings of this report?

Share your insights in this brief survey.

[Share insights](#)

Appendix



Quantitative Methodology

Sample

This survey was fielded among 200 regulatory professionals working in the chemical, consumer goods, and food & beverage industries in the United States and Canada. All respondents work at companies with annual revenues of at least \$250mn USD.

The survey was conducted online during the period of February 10-February 24, 2021 and has an overall margin of error of +/- 6.9%.

Methodology

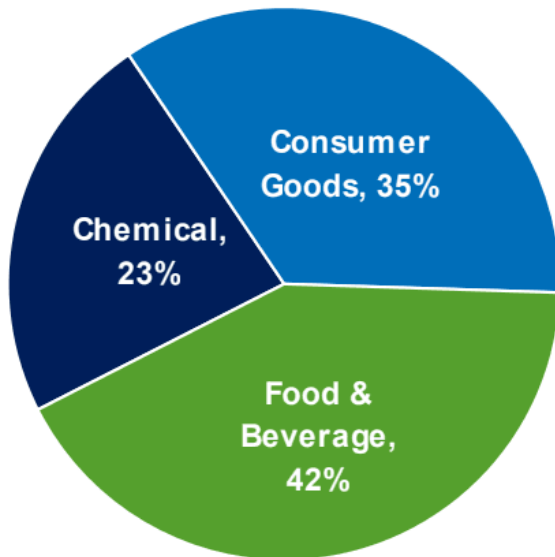
Results of any sample are subject to sampling variation. The magnitude of the variation is measurable and is affected by the number of interviews and the level of the percentages expressing the results.

In this particular study, the chances are 95 in 100 that a survey result does not vary, plus or minus, by more than 6.9 percent, from the result that would be obtained if interviews had been conducted with all personas in the universe represented by the sample. The margin of error for any subgroups will be slightly higher.

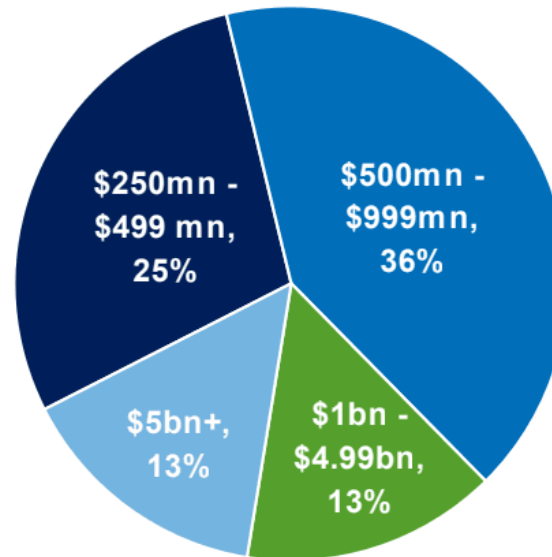
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Respondent Details

Industry



Company Annual Revenue



This study was commissioned by

Veeva

A Public Benefit Corporation

We build cloud applications that help consumer products and chemical companies bring high-quality, safe, sustainable, and compliant products to market faster.

Founded 2007 • 950+ customers • 4,500+ employees • \$1.5B+ revenue
Global company, San Francisco Bay Area HQ

Forbes #8 Fastest Growing
Public Tech Company

Deloitte Fastest Growing
Technology Fast500 Company

FORTUNE #2 Future 50
Company

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COMPLIANCE

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UNIFIED

SPEED TO MARKET

REDUCED RISK

DATA DRIVEN INSIGHTS



Regulatory Documents

- Document control and library
- Predefined Regulatory Document types
- Integrated documents and data
- Modern collaboration tools



Compliance Management

- Regulatory request management and Response tracking
- Raw Material insights and attributes



Registration + Dossier Management

- All encompassing: Regulatory, Third Party & Retailer Certifications
- Requirements pre-defined
- Collaborative dossier assembly
- Completion status tracking
- Global Transparency

Regulatory Management Trends Report

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