

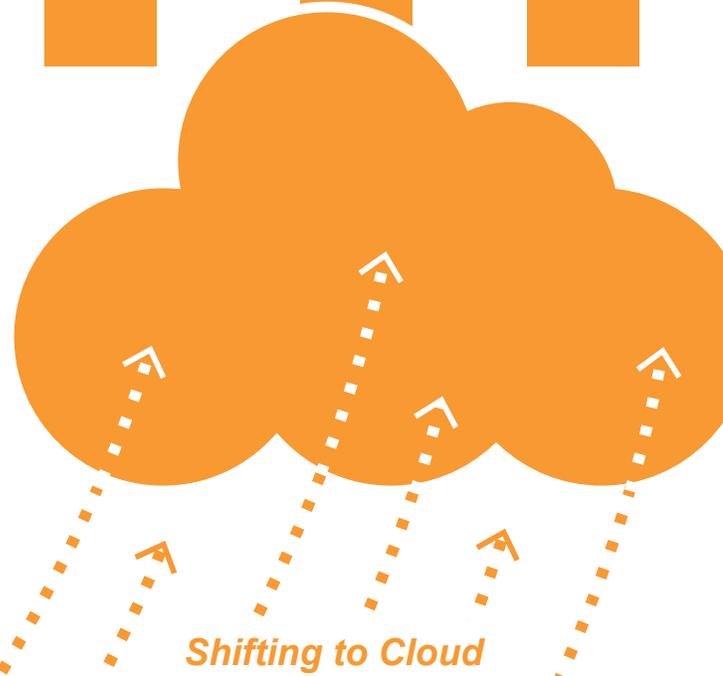


Shifting Skills



Working Across Silos

4 Trends That Will Impact Quality & Regulatory in 2019



Shifting to Cloud

Creating Transparency

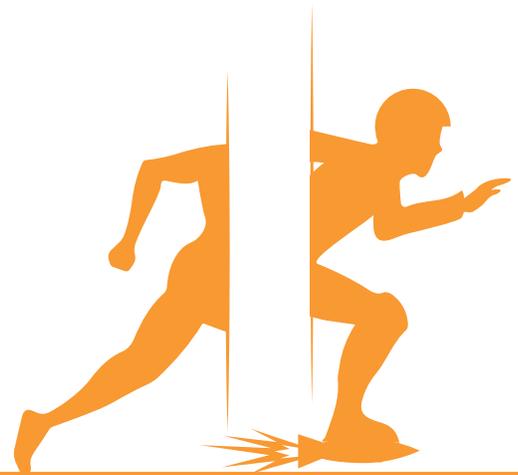


As quality and regulatory professionals, you work in a rapidly changing environment. That means that the skills, knowledge, and tools which got you and your team through 2018 may not be sufficient in 2019, and are likely to be inadequate as soon as 2020.

How well you, your team, and your company adapt to these changes will determine whether you can gain competitive advantage or risk irrelevance.

Read on to learn the four trends that will undoubtedly impact your role in 2019 so you can set yourself, your team, and your organization up for success.

#1 New technology and business models will shift your required skills



Technology is transforming every aspect of our lives; today everything from groceries to gifts to location tracking are just a click or voice command away. But for most quality and regulatory professionals, technology at work has lagged well behind the technology in our personal lives. This has (finally) begun to change.

Tablets are now common on many manufacturing floors, and increased adoption of cloud-based management systems are making documents and real-time data securely accessible from any location or device.

Companies that are modernizing report experiencing a rapid reduction of administrative “corporate cholesterol” and are freeing up time for quality and regulatory professionals to engage in higher value activities.

These new opportunities will require new skills, expanded job responsibilities, an accelerated timetable as well as greater collaboration across departments including supplier communities. Let's explore each of these in more detail:

2019 Priority Skill Areas for Quality

- Collaboration
- Data Analytics
- Work Digitally
- Efficient and Fast Audits
- Develop Suppliers

2019 Priority Skill Areas for Regulatory

- Strategic Thinking
- Detail Orientation
- Problem Solving
- Process Orientation
- Driving Change

For example, this newly available data calls for analytics skills in order to make the data-informed decisions that management increasingly expects. But many quality and regulatory professionals are untrained or out of practice when it comes to data analysis, and may not be prepared to fulfill this new responsibility.

“This larger focus is creating a new type of quality professional. One that can manage big data, use apps in real time to maintain control of processes; use scorecards from new QMS software to drive corrective actions; all from wherever they are - which may not be anywhere near the process being measured.”

- Juran Institute CEO Dr. Joseph A. DeFeo

A growing need for data analysis is just one of several related aspects of shifting role expectations going into 2019. Let's break down how these changes will impact the role of quality and regulatory professionals in 2019 and beyond.

EXPERT PERSPECTIVES

How Required Skills Will Shift for **Quality** in 2019



Dr. Joseph A. DeFeo
CEO of the Juran Institute

“Historically quality departments were made up of technical experts in statistical process control, quality systems, supplier quality and the like,” Dr. Joseph A. DeFeo, CEO of the Juran Institute shared at the 2018 Veeva Quality Summit. “Increasingly the skills needed to be successful in quality have shifted. ‘Big Q’ professionals need to be big picture business focused, not just manage production defects. They will need to know customer demand, and be able to define characteristics critical to the business and quality across all key functions and processes.”

A recent Juran Institute survey found “statistics and data analysis will become more important” for quality professionals but remains “one of the weakest skills areas.”

“Critical thinking is becoming really important, and it’s a weakness,” DeFeo asserted based on the survey findings.

“And guess what’s going to disappear, which is quality’s strength? Audit and assessment.”

Quality research firm LNS recently predicted modern QMS software to grow at 27% year-over-year, with “favorable tailwinds in 2019.” It recently reported that, “for the quality leaders, these changes mean easier and better options that drive more awareness and improved outcomes.”

How Required Skills Will Shift for **Regulatory** in 2019



Aman Khera
*Head of Regulatory
Strategy for PRA*

From cosmetics to crop sciences to personal care, most industries’ regulatory landscapes are constantly evolving. Increased scrutiny and restrictions across key markets are expected to continue in 2019 and beyond.

This is nothing new. But the global scale of many of today’s companies mean exponentially more regulations, protocols, and guidance to keep track of to remain compliant.

Keeping pace with this ever changing landscape is already a strong suit for most high performing regulatory professionals.

The new twist is maintaining this pace while adopting new technologies as regulatory moves from the excel and paper-based systems they're accustomed to, to cloud-based management systems that are increasingly required for efficient collaboration and traceability.

"In this ever changing landscape of new regulations, laws, and new pathways for product development, I think the main thing that sticks out for me is that there is less use of paper," said Aman Khera, Head of Regulatory Strategy for PRA.

"I remember preparing those enormous paper copies of submissions that were just mountains and mountains of folders; now of course submission management has evolved and electronic submissions through various gateways exist," Khera reflected.

For many regulatory professionals, this shift from paper or on-premise software to cloud can be intimidating. Excel and paper are what you know, even if it is slow and cumbersome. 2019 is looking increasingly likely to be the year that resistance to technology change in areas like regulatory is overpowered by business demands.

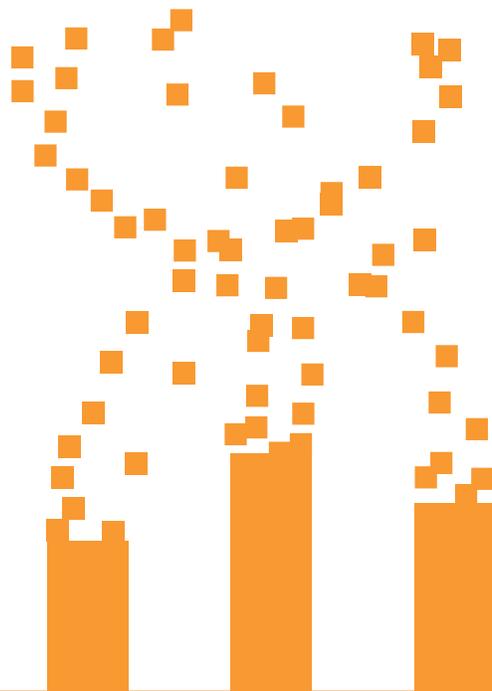
"There is pressure to ensure alignment of regulatory affairs strategy, people, processes, data and technology with the rest of the organization to ensure data transparency and enable the company to be truly insights-driven," concluded Pratyusha Pallavi at the eRegulatory Summit.

"But in order to have data at their fingertips, regulatory affairs needs a technology solution that can access data across the product life cycle."

Amidst all this change, there's good news. Just like you adapt to regulation changes, or learn about the unique requirements of a new market, your adaptability will serve you well in this time of transition. As with any change effort, adopting new technology will mean more than just ticking off a list of requirements - people and expectations management are critical. "Personal soft skills for a regulator are going to be just as important as the technology," said Khera.

#2

You'll be asked to increasingly work across silos, break down departmental barriers



Modern technologies are raising expectations for visibility and traceability across the product life cycle in regulated industries, leading to increasing pressure from leadership for system unification across departments.

This expectation threatens to break down silos around quality and regulatory departments, and will require representatives from these groups to take on more active roles across product development through the post-purchase experience.

For **quality**, this means “no longer will you be a police officer,” according to Dr. DeFeo. “You’re going to have to decide based on the data what you’re going to do, and you’re going to have to collaborate with others to do it.”

For **regulatory**, being at the intersection of R&D, manufacturing, legal, marketing, and regulatory authorities, it is impossible to be effective if you are working in silos. This may require pushing leadership to include a regulatory representative in more decision meetings earlier in the process. “If there is one thing that I say often and never enough is that regulatory must have a seat at the development table from day one,” said Khera.

For both quality and regulatory teams, you are also likely in 2019 to increase your collaboration with IT. In many companies, IT departments are, or very recently were, isolated from the rest of the enterprise. However, IT is increasingly being pushed to demonstrate closer collaboration with other business units like regulatory and quality. This is because the impact of IT’s work and decisions on the overall functioning of these departments is critical to optimize business performance. Now is the time to strengthen your relationship with your IT counterpart(s), and set common goals for your business area so technology adoption can support your business objectives.

#3

The technology solutions available to you are diversifying, shifting to cloud



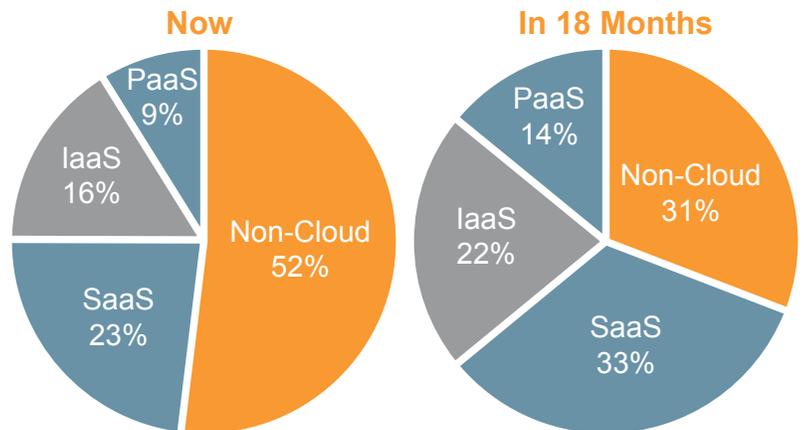
Is your company one of the many with a “cloud only” mandate? If not, 2019 is shaping up to be the tipping point for moving systems to the cloud across many industries. The 2018 IDG Cloud Computing Survey found that “cloud platforms and apps already dominate organizations' technology stacks, and the momentum will continue through 2020.”

This shift is being driven by executives that recognize the high potential of cloud-based solutions when they are unified across the product development journey.

% Of Respondents Using Delivery Models

	SaaS	PaaS	IaaS
Now	89%	61%	73%
In 18 Months	95%	73%	83%

% Of Computing Environment in Different Delivery Models



Source: 2018 IDG Cloud Computing Survey



Louis Columbus

“Simplifying complex manufacturing with an overarching cloud platform that can provide a single, unified system of record from the shop floor to the top floor is now a high priority for executive management,” reflected Louis Columbus in Forbes.

“Enabling greater supplier quality management, visibility, better manufacturing scheduling, workflow optimization, fulfillment and customer deliveries are just a few of the areas where cloud platforms are contributing to manufacturing’s growth,” wrote Columbus.

Executives are also shifting in how they quantify the value of cloud-based solutions (and what they’re willing to spend on them). Melissa Burns reports in Techgenix that, “Businesses no longer see lowering the costs as the primary advantage of investing in new technology — they seek to increase their agility and the ability to react faster and more efficiently to the changing market conditions.”

What does this mean for the quality and regulatory professional? Well to start, you’re likely to be asked to modernize the paper-based or on-premise software you’re using for process management, documents, or data, even if it’s been “cloudwashed” (i.e., old products hastily rebranded). Because your paper-based system or legacy software is holding you back, probably more than you realize.

“The root cause of a problem may never be that the supplier is using paper records, but it’s background noise that exacerbates problems. It’s slowing down critical decision making. If a supplier is still using paper inspection records, what does that say about the focus and dedication their upper management has on quality? It’s a litmus test of whether or not I want to work with them.”

- Shane Allen, Uponor



Shane Allen
Uponor

2019 is a great time to start educating yourself on the basics of cloud-based software and the efficiencies and new capabilities it could bring to your team, department, and supplier network. That way you’ll be better prepared to research solutions and provide requirements to IT when you’re asked to modernize your department. You will play a vital role in selecting a vendor and solution that truly meets your needs and will keep pace with your business.

#4 New and changing regulations, consumer demands will impact your work



In 2018 consumers were more demanding than ever before, and 2019 will take it to a new level. Few consumers understand how much work goes into providing ingredient transparency, developing new product lines with personalization capabilities, or keeping costs low. But they ask for these things nonetheless, and their demands are increasingly reflected in regulations and industry norms.

Other than seemingly creating a lot of new work for you and your teams, how will these forces impact you next year?

For **quality** and **regulatory**, 2019 will be characterized by an increased emphasis on proactively preventing issues and managing risk, as opposed to the more reactive processes and priorities that were sufficient in years past.

Shifting from reactive to proactive is being enabled by the availability of real-time data. This data creates an expectation that organizations analyze product and process risk and apply mitigations prior to launching, as well as monitor and analyze post-market data.

New techniques by regulatory bodies is also spurring changes inside companies. For example, until recently the FDA or EPA primarily conducted audits at manufacturing facilities, or less commonly at the shelf at retail. Today, the FDA can audit company websites and social media to ensure claims (and even implied claims) are consistent with regulations, and are not false or misleading.

These examples of shifting and expanding scope are putting more pressure on quality, regulatory and legal teams to increase visibility, traceability, and control across their domains.

Industry Considerations in 2019



Cosmetics

The Cosmetic industry has a rotating wheel of ingredients that are “bad” based on regulation and public perception. For example, preservatives like parabens ensure efficacy and safe formulas, however they are often petroleum based and are negatively perceived by perception. The EU now prohibits parabens in formulas and “Free From” claims. However mass retailers expect those same “Free From” claims to validate a “clean” formula. Balancing conflicting pressures like these will be more common in 2019.



Chemical

The Chemical industry will continue to face challenges with innovation and time to market due to extensive testing, regulatory processes and legal challenges calling for full disclosure on product data. On top of these are proposed regulations, like the debate over inherent hazard vs. specific product exposure and risk. For example, the EU’s proposed regulation on potential endocrine disruptors. Their criteria have been debated in the EU for several years, contributing to uncertainty over any potential final regulatory standard.



Consumer Goods

The Consumer Goods industry is facing overlapping regulations for ingredient disclosure and “Right To Know” laws. For example California and New York have recently passed laws requiring disclosure of all ingredients on label. This requires robust systems for managing raw materials and label claims to address public expectations of labels.

Ready to take on the challenges 2019 will bring for your team and your business? We can help. Contact the quality and regulatory modernization experts at Veeva to see how we have partnered with hundreds of companies like yours to achieve the agility they need to stay competitive in today's business environment. Call us today at +1 866 243 2055 or email us at info@industries.veeva.com to schedule a free consultation.

Sources:

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- PRA: <https://prahs.com/blog/2018/04/23/regulatory-affairs-past-present-and-future/>
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CHECKLIST: 5 immediate actions to set you and your team up for success in 2019

Now that you're aware of some of the major changes coming in 2019 that will impact your work, it's time to take action. Will you make time in the next month to set your team up for success this year and beyond? Here are a few suggestions to get you started:



Invest in building or strengthening the skills your role will increasingly need in 2019 such as data analysis.



Take your IT counterpart out for coffee and share your team goals and objectives. Identify potential opportunities to leverage technology to achieve them.



Educate yourself on the basics of cloud-based software and the efficiencies and new capabilities it could bring to your team, department, and supplier network.



Advocate for technology that will increase efficiency, create greater transparency and more closely align your department with business goals of agility, speed, collaboration, and traceability.



Use your quality and technology standards as criteria to select suppliers, contract manufacturers, and other vendors to ensure a robust supplier infrastructure.





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info@industries.veeva.com
+1 866 243 2055
industries.veeva.com