The Life Science Quality Leadership Report & Benchmark: 2020

Compliance, Performance & Resourcing Emerge as Top Priorities

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Executive Summary

Life science quality leaders operating in FDA-regulated industries will be anything but bored in 2020. We recently surveyed 29 of them working inside organizations of all sizes to answer the critical questions. What goals are quality leaders are working to achieve? What challenges stand in their way? What are they going to do to overcome them and stay competitive? This report offers more than just an "industry outlook." It should serve as a unique benchmarking tool for orienting your own goals, challenges, and actions in 2020 and beyond.

Before we dive into the details, however, here are the main takeaways our survey uncovered: among life science quality leaders, two 2020 objectives stand out at the top: the longstanding, but rapidly growing struggle to ***achieve and maintain compliance*** and stepped-up pressure from executive leadership to ***improve manufacturing and production performance.***

While compliance comes naturally as a priority for quality teams, our survey revealed it to be both the top objective and the top challenge within quality systems heading into 2020. Given just how much is evolving on the regulatory front, this probably comes as no surprise. Navigating today's regulatory environment is demanding enough. Tomorrow promises to bring even higher expectations and standards, especially for teams managing products both inside and outside the United States. Concerning challenges, we asked respondents to identify the top three obstacles to achieving their department-wide objectives in 2020. The predictable and incumbent issue of budget limitations was revealed to have a challenger: ***staffing and resourcing***. "Limited headcount" and "limited skillsets" landed in the number one and number three spots respectively, with budget sitting in between them.

Get the expert quality and compliance resources you need to be successful in 2020 and beyond.

If any of these, or other challenges stand in the way of reaching your goals in 2020, contact us today to get expert help assessing and addressing your quality and compliance needs. The trends we're about to explore are precisely the areas we've helped thousands of life science companies improve and maintain, whether through externally-led project-based consulting engagements or by filling key internal roles through contracted staff augmentation or direct hire recruitment.

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QUALITY OBJECTIVES

Compliance & production represent the top quality goals in 2020.

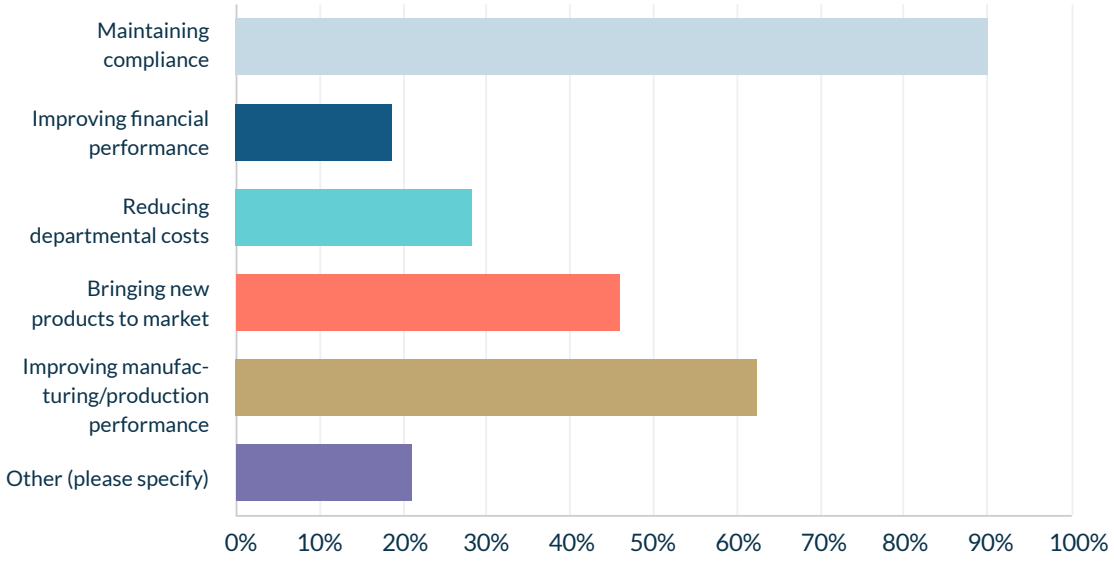
A whopping 90% of respondents identified "maintaining compliance" among their top three challenges in the new year. "Improving manufacturing/production performance" followed at 63%, and "bringing new products to market" took the number three spot at 46%.

The overwhelming focus on compliance falls in line with findings of a similar study conducted by Deloitte, which interviewed 11 major life science leaders to take a more granular look at the specific challenges life science firms are facing in the realm of compliance. In its report, the firm eloquently sums up the nature of today's (and tomorrow's) compliance challenges while going a step further to break out seven key insights, which we've included on the following page.

90%

of quality leaders we surveyed identified ***"maintaining compliance"*** among their ***top three challenges in 2020***.

What are 1-3 of your top quality objectives for 2020? (Select up to 3)



> *“ The life sciences industry continues to face unprecedented challenges amid increasing regulatory scrutiny. Globalization, alliances and partnerships, heightened transparency expectations, increased emphasis on innovative technologies, and the ever evolving needs of existing and emerging customers are driving companies to re-examine their approach to compliance.”*
>
> **– DELOITTE CENTRE FOR HEALTH SOLUTIONS**

Deloitte’s Seven Key Insights:

1. Life sciences companies often lack an enterprise-wide view of compliance risk.
2. Big Data’s role in compliance is often overlooked.
3. The competitive advantages of ethics-driven cultures are being recognized.
4. Companies with the most mature compliance functions will win the talent war.
5. A lack of dedicated, local compliance resources presents a significant risk for global companies.
6. Major opportunities exist to optimize compliance effectiveness and efficiency.
7. Leading companies build regulatory engagement into their innovation models.

The challenge of compliance in Life Sciences: Moving from cost to value

Read Deloitte’s Full Report »

The conversation around compliance flows into the second most-identified goal: improving manufacturing/product performance. Since quality teams are naturally intertwined throughout the entire production chain, their effectiveness is often a signal of broader operational and organizational health. Issues in quality operations, whether due to chronic understaffing, skillset gaps, process problems, or any other underlying problem, inevitably increase risks and costs. On the flip side, high performing quality teams keep these issues off the radar entirely by putting a premium on preventive action. When problems do arise, they can more quickly identify and resolve them to avoid impacting production performance. Prior research has indicated a growing shift toward performance-oriented goals for quality operations, which by our numbers, seem to be holding in 2020.

OBSTACLES TO ACHIEVEMENT

Resourcing and budget are expected to be significant obstacles to success.

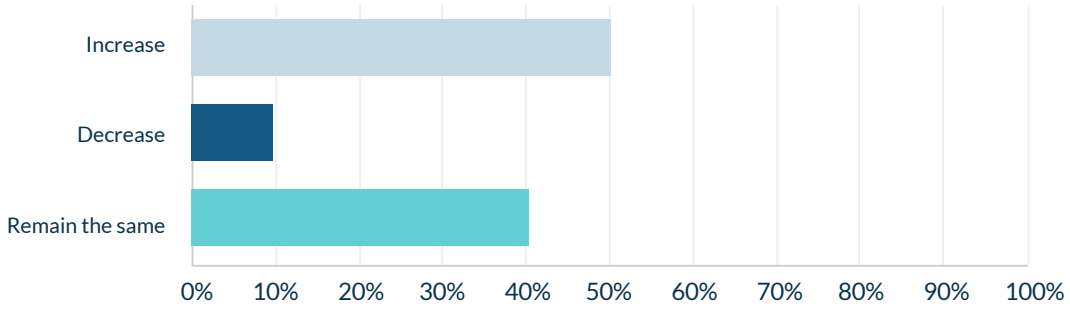
Quality leaders identified "limited headcount," "limited budget," and "limited skillsets" as the top obstacles to achieving their goals in 2020.

Concerning ***budget***, most quality teams also reported they anticipate holding steady at their current rate of investment or expect to receive more support over the next year.

63%

of quality leaders we surveyed identified ***"limited headcount"*** as the top obstacle to reaching their goals in 2020.

How do you anticipate your budget will be affected in the next 12 months?

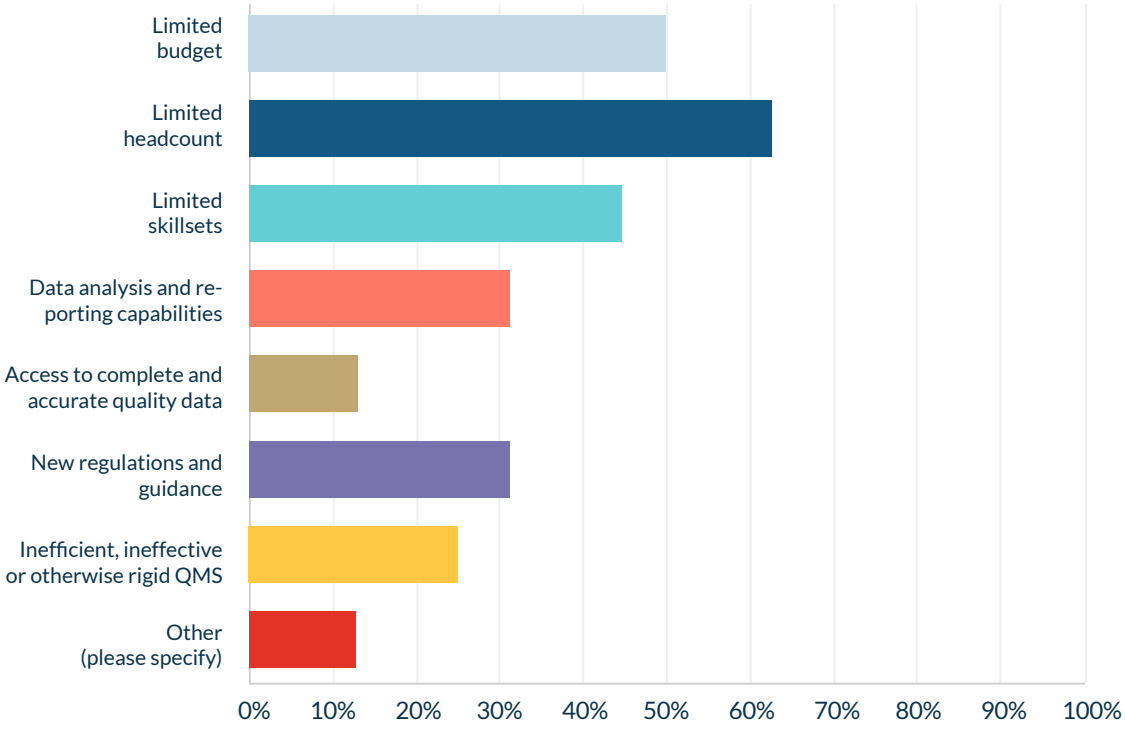


These findings may indicate that while quality leaders are getting more of the budget they need, the challenges on the horizon will require even greater support from within. This harkens a point that is in no way novel, but perhaps more salient than ever: freeing up more budget requires demonstrating the value that quality and compliance brings to the organization. In this way, the growing role of quality teams can be seen as an opportunity to clearly show executive management both the raising stakes of quality and compliance as well as the progress made towards accomplishing a growing list of goals. Provide metrics that show the contributions your team has made and make a case for quality assurance in the context of leadership's broader goals.

In addition to increasing investment in quality operations, the rapid rise in contracted engagements has demonstrated that leaders are not only adept at pursuing cost-effective outsourcing measures to free up internal resources, but are finding themselves more empowered to do just that. When the right balance is struck, quality leaders can redirect their focus on planning and overseeing more significant initiatives and mitigating risks proactively.

With regard to ***resourcing***, under which we can broadly group headcount and skillset deficiencies, it appears a tightening labor market is compounding with a growing array of resourcing needs that are more particular in the skillsets and competencies they demand.

What are the 1-3 top obstacles to achieving your objectives in 2020? (Select up to 3)



Projects that could have otherwise been scheduled with concurrent timelines now have to be arranged back-to-back due to personnel bandwidth. In more serious situations, project plans have to be halted altogether due to skillset or capacity gaps.

Specifically, while technical expertise remains essential, quality teams are also seeking people who can navigate complex external and internal changes while driving continuous improvement. New and varied regional challenges have also emerged as companies search for specialized talent, adding yet another layer to the problem of finding the right people, where and when they're needed.

In response to these challenges, which, by all indications, will only accelerate, many manufacturers are adopting innovative hiring structures and targeted partnerships with resourcing firms. These firms can work directly with hiring managers to circumvent the traditionally slow and arduous hiring process and provide access to large benches of talent to fulfill the specific needs of the hire through either a contracted or direct hire arrangement.

The FDA Group helps thousands of life science companies find precisely the resources they need.

At The FDA Group, we connect life science companies to the resources they need in the hiring arrangement that's best suited to the project, role, or function, whether it's a contracted full-time engagement or direct hire.

Learn more about our staff augmentation and recruiting services and contact us today to connect with the resources you need to accomplish quality goals in 2020 and beyond.

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QUALITY SYSTEM

Compliance and resourcing are the biggest upcoming challenges within the quality system.

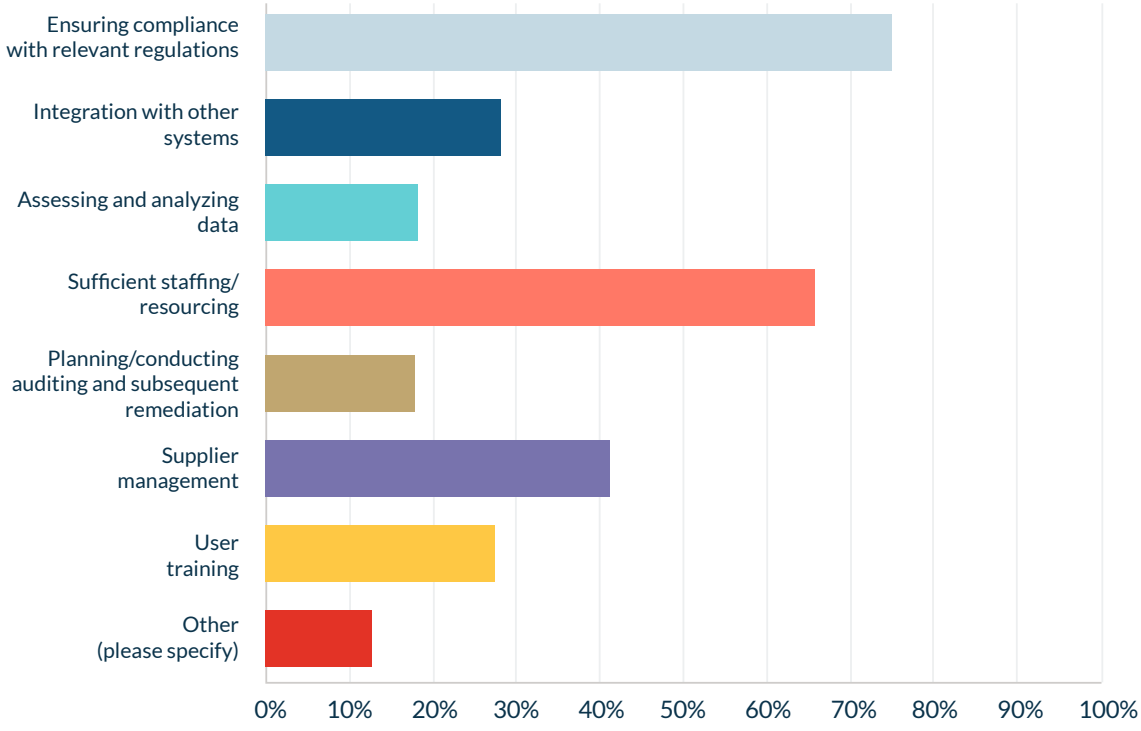
The focus on compliance and resourcing in 2020 also extends directly into the quality system itself. 73% of the quality leaders we surveyed identified "ensuring compliance with relevant regulations" among their top three quality system-specific challenges.

Just as notably, the pervasive personnel problem emerged in a very close second place, with "sufficient staffing/resourcing" receiving 66%. Supplier management, system integration, and user training took the next three positions, respectively.

66%

of quality leaders we surveyed indicated ***"sufficient staffing/resourcing"*** as a ***top quality system challenge in 2020.***

What are 1-3 of the biggest current or upcoming challenges to your quality system? (Select up to 3)



In considering what practical steps to take based on these findings, perhaps the best place to start in preparing your quality system for a compliant 2020 is reviewing the most recent compliance trends throughout the previous year.

For drugmakers, the most frequent known compliance issues over the last fiscal year primarily concern the basic requirements that every pharmaceutical company should have established as a matter of course. Here are the top five trending issues for drugmakers by the number of warning letters issued over the previous fiscal year, as reported by the ECA.

1. Responsibilities of the quality unit (21 CFR 211.22) – ***41 Warning Letters***
2. Written procedures; deviations (21 CFR 211.100) – ***32 Warning Letters***
3. Testing and release for distribution (21 CFR 21.165) – ***29 Warning Letters***
4. Production record review (21 CFR 211.192) - ***27 Warning Letters***
5. Testing and approval or rejection of components, drugs product containers, and closures (21 CFR 211.165) & Stability testing (21 CFR 211.166) - ***22 Warning Letters***

For device makers, far fewer publicly-available enforcement actions make trends far more challenging to define, however, recent data shows that most quality system issues fall in line with those that routinely get the most attention from regulators, namely:

1. CAPA (21 CFR 820.100)
2. Design controls (21 CFR 820.30)
3. Purchasing controls (21 CFR 820.50)
4. Process validation (21 CFR 820.75)
5. Complaint files (21 CFR 820.198)

While it's no surprise that compliance tops the list of quality system challenges, resourcing as a close second appears to be an emerging point of focus, especially given how little comparative attention it garners among industry thought leaders.

While not quite as cut-and-dried as regulatory compliance, resourcing is one area where regulators have spelled out specific expectations. For drugmakers, specifically, FDA's landmark 2006 guidance, *Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations*, offers a practical explanation of the roles and responsibilities within the Quality Unit. We've highlighted a number of the critical points for evaluating whether or not a quality function is resourced sufficiently.

The duties of the Quality Unit:

- "Ensuring that controls are implemented and completed satisfactorily during manufacturing operations"
- "Ensuring that developed procedures and specifications are appropriate and followed, including those used by a firm under contract to the manufacturer"
- "Approving or rejecting incoming materials, in-process materials, and drug products"
- "Reviewing production records and investigating any unexplained discrepancies"

A checklist for resourcing sufficiency (this is not an exhaustive list of expectations):

- ❑ ***Authority to create, monitor, implement a quality system***
- ❑ ***Ensuring operations associated with all systems are appropriately planned, approved, conducted, and monitored***
- ❑ ***Assessing the suitability of incoming components and related materials, labeling, in-process materials, and finished products***
- ❑ ***Ensuring procedures and specifications are appropriate and followed, including those under contract to the manufacturer***
- ❑ ***Ensuring controls are implemented and completed to standard during manufacturing***
- ❑ ***Evaluating manufacturing process performance against specifications and limits***
- ❑ ***Reviewing and approving production and maintenance procedures and associated records***
- ❑ ***Reviewing production records and investigating discrepancies***
- ❑ ***Auditing and performing trend analyses***
- ❑ ***Approving or rejects incoming materials, in-process materials, and finished products***
- ❑ ***Determining the acceptability of each batch for release***

- ❑ ***Promoting quality in throughout general practices***
- ❑ ***Encompassing both quality control (QC) and quality assurance (QA) functions***
- ❑ ***Remaining independent of product and process development units***

In addition to outlining the Quality Unit's responsibilities, FDA notes that under a quality system, "it is normally expected that the product and process development units, the manufacturing units, and the QU will remain independent."

Regulators specifically warn against assigning a single individual to perform both production and quality functions except in "very limited circumstances."

> ***" In very limited circumstances, a single individual can perform both production and quality functions. That person is still accountable for implementing all the controls and reviewing the results of manufacture to ensure that product quality standards have been met. Under such circumstances, it is recommended that another qualified individual, not involved in the production operation, conduct an additional, periodic review of QU activities."***

This expectation is especially salient given the uptick in Warning Letters citing Quality Unit deficiencies in 2018 and 2019.

As we explore in another white paper, many of these issues are rooted not only in establishing and documenting quality roles and responsibilities but sufficiently staffing the unit with the personnel required to adequately carry out the unit's duties as they've been established and documented.

As these Warning Letters demonstrate, regulators expect firms to staff their Quality Unit to reflect the scope and complexity of the manufacturing operations under their oversight. When regulators discover that such a vital function is under-resourced (whether in terms of the number of personnel or the qualifications they carry), it's often a signal that other deficiencies may exist due to resourcing—sparking further investigation and scrutiny.

Overcoming the Challenges of Resourcing Quality Personnel

Staffing quality personnel per regulators' expectations can be a challenge. This is especially true in a tightening labor market where the need for specialized skills and experience has made high-skilled resourcing extremely competitive, expensive, and fraught with risk.

For these reasons and others, life science firms are increasingly turning to more attractive alternatives to traditional full-time hiring. Sophisticated staff augmentation models, for example, are specifically designed to give firms easy, convenient access to the "unicorns" they need: those with specific skill sets, experience, and qualifications—all without the challenges that often result in delays and setbacks when resourcing efforts fall short.

Combined with dedicated project management, these staffing solutions lift the administrative burden of recruiting, giving hiring managers the flexibility needed to complement the often cyclical nature of life science projects. Time is spent understanding needs and identifying a perfect-fit resource rather than squandered in unreliable recruiting channels, helping everyone accomplish their goals and move forward—faster, easier, and more reliably.

Learn more about The FDA Group's staff augmentation and recruitment services.

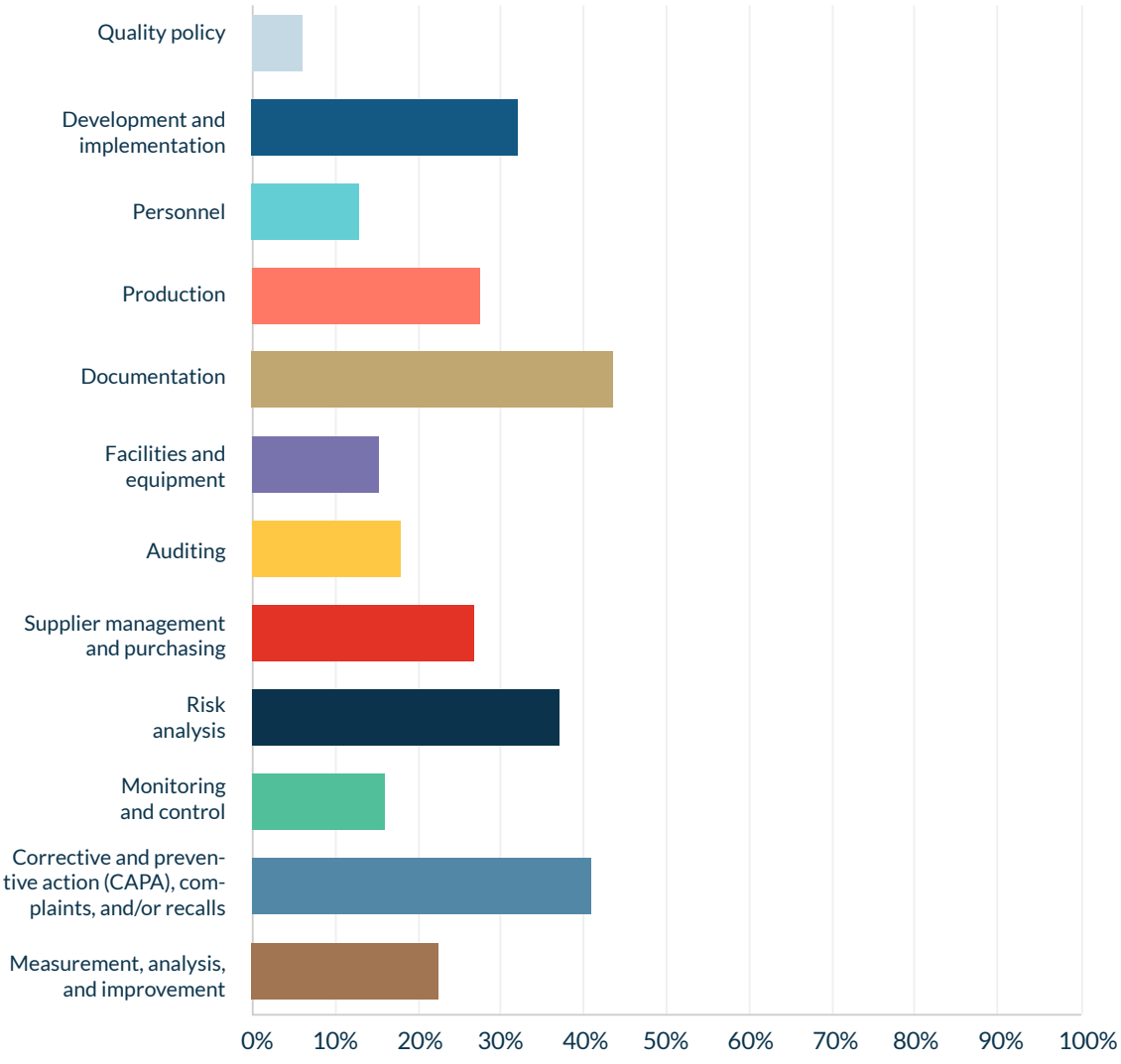
Staff Augmentation »
Recruitment »

QMS FOCUS

Quality teams have mixed QMS priorities, but documentation, risk analysis, and CAPA stand out.

The most varied responses came from our question regarding the quality management system. "Documentation" narrowly edged out "risk analysis" and "corrective and preventive action (CAPA, complaints, and recalls), at 43% compared to 40% for the two runners up, respectively.

Which 3 of the QMS elements listed below represent areas of greatest focus in 2020? (Select 3)



While these trending areas of focus have been the subject of countless thought leadership pieces, seminars, and workshops, a few points are important to highlight.

- ***Documentation:*** Whether it's a policy document, product specification, or any other type of written record, ineffective document control can significantly threaten not only the quality team responsible for managing them but the company at large. Documentation problems typically look something like these:

    - Receiving parts or products built to an out-of-date specification
    - Quality events arising from lack of awareness or inadequate training
    - Scrambling during gap assessments and audits to come up with a required process or specification documents

    While it's often assumed that something as fundamental as good document control is being managed appropriately, experience in assessing firms large and small across the world has routinely turned that assumption upside down. All too often, poor document control practices quietly create a variety of other problems that compound to create serious compliance and safety risks. In short, having a document control system integrated with your FDA compliance program is essential to keeping everything straight. Effective document control ensures you can do what you say and say what you do, which is exactly what regulators will be looking for.

- ***Risk analysis:*** Another prevalent and dangerous gap is inefficient risk management programs. This often stems from an erroneous conflation between risk assessment and risk management, when, in fact, risk assessment must be viewed as a more extensive process that encompasses hazard identification, risk assessment/analysis, control implementation, and performance evaluation. At its core, risk management is central in all sectors of life science manufacturing—from design to implementation, supplier management, and postmarket surveillance.

- **CAPA:** Given the numerous inspectional observations citing insufficient established CAPA procedures, it's worth revisiting what regulators expect to see from your CAPA process. Read our comprehensive white paper on the subject for a deeper dive into CAPA and root cause analysis in FDA-regulated industries. In addition to helping manufacturers meet the broad expectations for effective CAPA, FDA also makes public its inspectional guide, which lays out the specific objectives for investigators when evaluating a medical device CAPA system and related documentation. We've summarized its main points below for consideration.

- Verify that CAPA system procedure(s) that address the requirements of the quality system regulation have been defined and documented.
- Determine if appropriate sources of product and quality problems have been identified. Confirm that data from these sources are analyzed to identify existing product and quality problems that may require corrective action.
- Determine if sources of product and quality information that may show unfavorable trends have been identified. Confirm that data from these sources are analyzed to identify potential product and quality problems that may require preventive action.
- Challenge the quality data information system. Verify that the data received by the CAPA system are complete, accurate, and timely.
- Verify that appropriate statistical methods are employed (where necessary) to detect recurring quality problems. Determine if results of analyses are compared across different data sources to identify and develop the extent of product and quality problems.
- Determine if failure investigation procedures are followed. Determine if the degree to which a quality problem or nonconforming product is investigated is commensurate with the significance and risk of the nonconformity. Determine if failure investigations are conducted to determine root cause (where possible). Verify that there is control for preventing distribution of nonconforming product.
- Determine if appropriate actions have been taken for significant product and quality problems identified from data sources.
- Determine if corrective and preventive actions were effective and verified or validated prior to implementation. Confirm that corrective and preventive actions do not adversely affect the finished device.
- Verify that corrective and preventive actions for product and quality problems were implemented and documented.
- Determine if information regarding nonconforming product and quality problems and corrective and preventive actions have been properly disseminated, including dissemination for management review.

If your CAPA program is set to be examined and enhanced in 2020, consider the following steps:

- Evaluate your current CAPA process on the criteria listed above.
- Highlight and remediate any gaps that exist between regulatory expectations and current processes.
- Follow up on all changes with the necessary documentation, training, or other actions needed to implement, support, and maintain those improvements.
- Note any gaps or improvements that require third party assistance from a qualified CAPA professional and contact a firm to pair you with the appropriate resource.

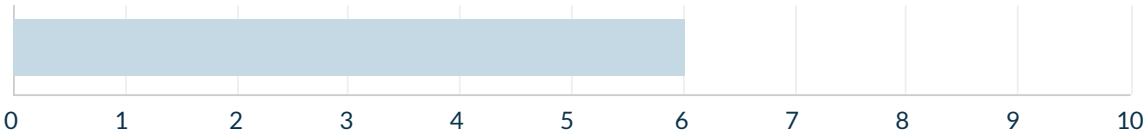
QUALITY & COMPLIANCE RESOURCING

Most quality teams see resourcing as a challenge in 2020 and prioritize fit, skills, knowledge, and expertise over price in potential candidates.

Our survey concluded by honing in on what, as we've now mentioned multiple times, turned out to be a major theme throughout the research: ***quality and compliance resourcing***.

Specifically, when asked to place their likelihood of encountering staffing/resourcing/recruiting challenges on a scale of one to ten (one being not likely at all and ten being certain), the average score landed just over six.

On a scale of 1-10 (10 being most likely and 1 being not likely at all) how likely is it that quality staffing/resourcing/recruiting will be a challenge in 2020?

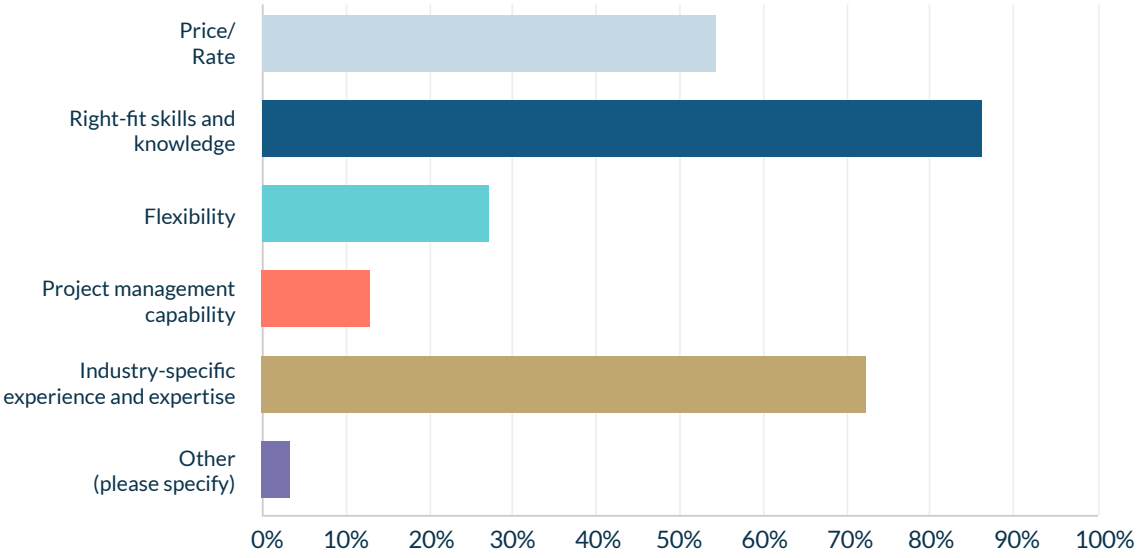


We also set out to explore the factors quality leaders prioritize when setting out to staff their team by engaging with a life science resourcing firm. While conventional wisdom suggests to many that price and/or rate is ultimately the deciding factor in a hiring decision (whether contracted or permanent placement), most quality leaders we surveyed put a higher premium on "right-fit skills and knowledge" (86%) and "industry-specific experience and expertise" (73%). "Price/rate" took the number three spot at 53%.

86%

of quality leaders we surveyed prioritize ***"right-fit skills and knowledge"*** when evaluating a resourcing firm.

What are your 1-3 top considerations when evaluating a recruitment/staffing/consulting firm?



Conclusion and next steps for quality leaders

This 2020 survey revealed compliance and performance as general priorities but indicated that resourcing has emerged as a large and growing problem as the labor market tightens for skilled professionals. With over half of our survey respondents anticipating quality budget increases in the year ahead, now is the time for leaders to carefully evaluate the demands of their goals for the upcoming year and assess their ability to achieve them.

If you need quality or compliance assistance, whether in supporting a current or upcoming project or finding a contracted or direct hire resource, The FDA Group's large network of quality and compliance specialists have extensive knowledge and experience in relevant regulations, guidance, and best practices related to quality system management throughout the regulated life science industries.

Our resources can be utilized to meet the full range of quality and compliance requirements throughout the life sciences, as well as to support staffing assignments, lead and manage related activities, bridge staffing gaps, and provide long-term or interim leadership.

Contact us to learn more about fulfilling specific quality and compliance staffing needs. We help life science organizations secure a wide variety of specialists with the perfect combination of qualifications, experience, and motivation for succeeding in challenging and demanding projects—all at a competitive rate and backed by a Total Quality Guarantee.

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