



**QUALITY REPORTING STRUCTURE
LEADERSHIP SURVEY 2021**



Mark Carlson

QA Executive Search Practice Area Leader

RECENTLY COMPLETED SEARCHES:

- Senior Vice President Quality, GxP
- Vice President Quality
- Vice President Quality and Systems
- Head Quality GxP, Interim
- Executive Director Quality CMC
- Senior Director Clinical Quality
- Senior Director Quality Management
- Director Quality GCP/GLP
- Associate Director GMP Audits
- Quality Consultant

Happy New Year!

Quality Assurance is an integral part of any successful biopharma organization. Beyond planning, system governance, and initiating standard operating processes throughout the organization, a good quality team serves as advisors to all facets of the business. These professionals' partner with teams across the company to ensure compliance with standards and regulations, identify and mitigate risks, ensure the safety of patients, and help the organization navigate inspections by health authorities.

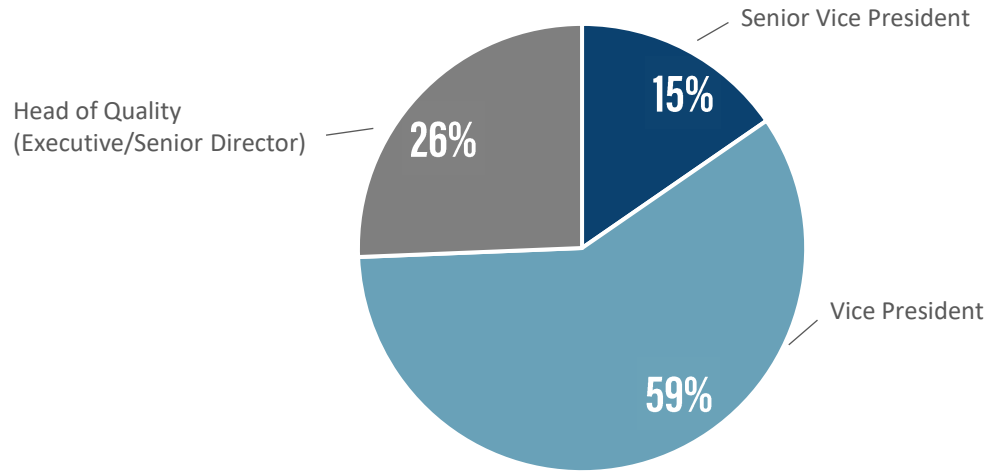
Over the past few years, we noticed a trend in working with Quality Assurance leaders of their concerns based on whether Quality should have a seat on the leadership team and who they report to in the organizational chart. We conducted a survey of over 400 Quality leaders to solicit their thoughts on who Quality should report to and the reasons why. The summary of their responses below may be beneficial to you in the structure of your organization and help successfully navigate audits and inspections with minimal risk.

We invite you to review the results of the survey below.

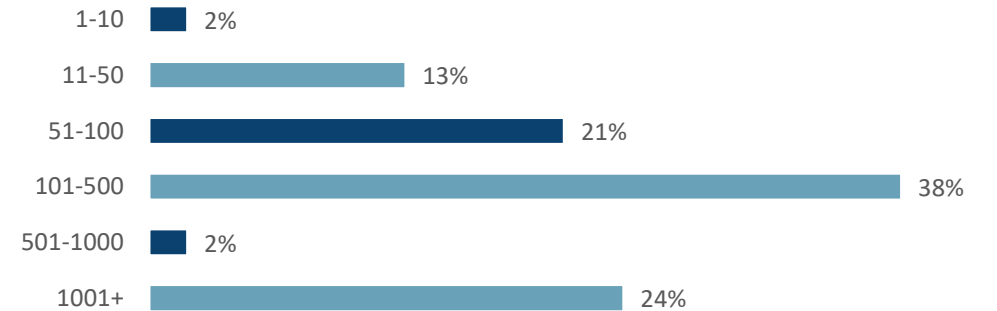
Best,

Mark Carlson, CPC
Director of Quality Assurance Executive Search

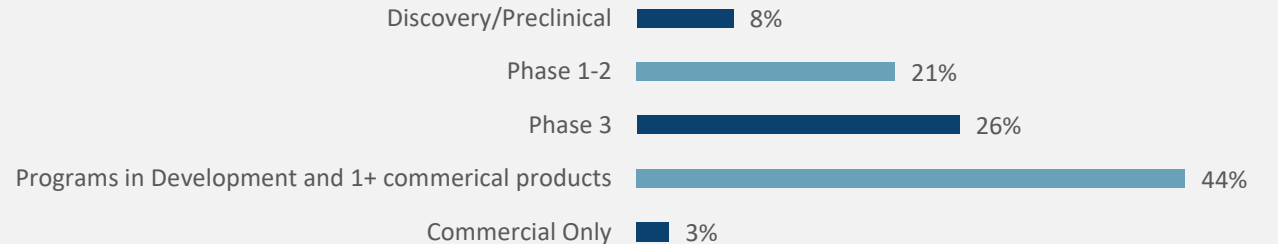
Participants were asked **what their current level of responsibility is** with the options of Senior Vice President, Vice President, and Head of Quality (Executive/Senior Director). Results showed that 59% of participants are Vice President level, 26% are Head of Quality (Executive/Senior Director) level, and 15% are Senior Vice President level.



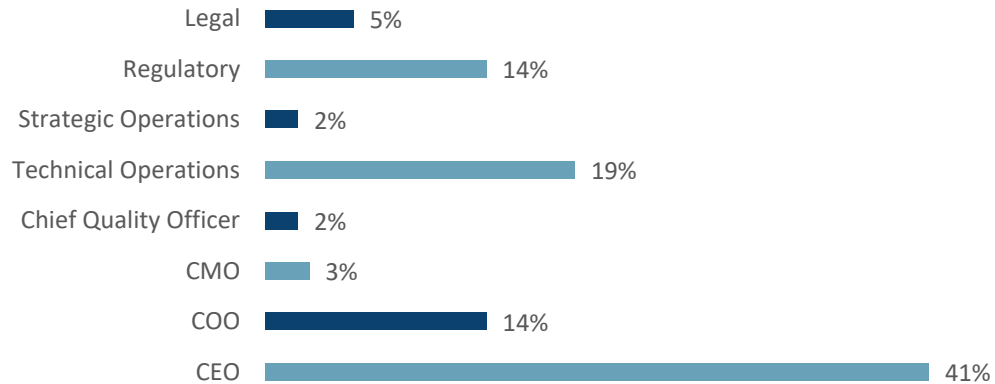
Participants were asked **what the current size of their company is (# of employees)** with the options of 1-10, 11-50, 51-100, 101-500, 501-1000, and 1001+. Results showed that 38% of participants work at companies with 101-500 employees, 24% work at companies with 1001+ employees, 21% work at companies with 51-100 employees, 13% work at companies with 11-50 employees, 2% work at companies with 1-10 employees, and 2% work at companies with 501-1000 employees.



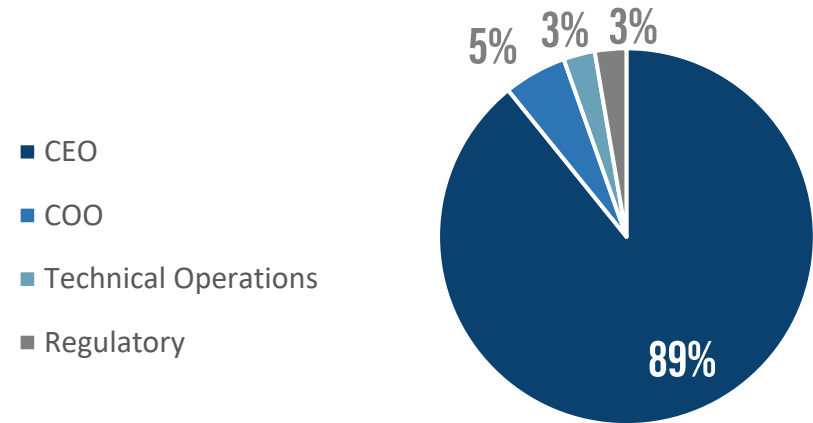
Participants were asked **what stage their company is currently in** with options of Discovery/Preclinical, Phase 1-2, Phase 3, Programs in Development and 1+ Commercial Products, and Commercial Only. Results showed that 44% of participants work at companies with programs in development and 1+ commercial products.



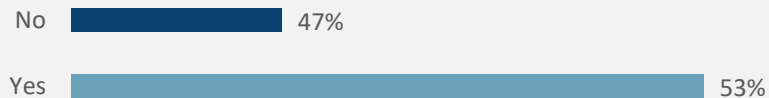
Participants were asked **what their current reporting structure is** with the options of CEO, COO, CMO, Technical Operations, Regulatory, Legal, and Other. Respondents that selected Other indicated that they reported to the Chief Quality Officer, and Strategic Operations. Results showed that 41% of participants report to the CEO, 19% report to Technical Operations, 14% report to Regulatory, 14% report to the COO, 5% report to Legal, 3% report to the CMO, 2% report to the Chief Quality Officer, and 2% report to Strategic Operations.



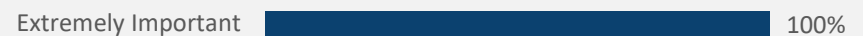
Participants were asked to **in their opinion, where should Quality report to** with the options of CEO, COO, Technical Operations, Legal, Regulatory, and Other. No respondents chose Legal or Other, so those categories were removed for the chart below. Results showed that 89% of respondents think that Quality should report to the CEO, 5% said Quality should report to the COO, 3% said Quality should report to Technical Operations, and 3% said Quality should report to Regulatory.



Participants were asked **if Quality has a seat in the leadership team in their current company**. Results showed that 53% of participants said Quality does have a seat in the leadership team, and 47% said that Quality does not have a seat in the leadership team.



Participants were then asked, **in their opinion, how important is it that Quality have access to the C-level (COO, CEO, etc.)** with the ability to rank their response from 0 (not at all important) to 10 (extremely important). 100% of respondents ranked their answer between 8 and 10, indicating that they think it is extremely important for Quality to have access to C-level leaders.





Comments About Effects of Reporting Structure on Quality



“The CEO has accountability for GxP compliance and must be aware of the quality / compliance-related issues so they can be appropriately addressed and resourced. FDA expects to see this 'connection'. FDA has seen that lack of GMP compliance is often directly attributable to lack of resources because the company (CEO) has not appropriately prioritized the Quality function.”

“Quality is where all the dangerous problems aggregate. This is the pinch point and the CEO needs to get an independent report of the issues and not a shaded report from those responsible for the issues. Best way to keep a company out of trouble.”

“High quality and a good quality culture are essential for a successful pharma company. The awareness that quality is important is essential for all levels of a company but needs to be supported and enforced by the C level.”

“Quality provides framework and escalation of risk potential. Without direct access to leadership, messages can get mixed, bias may be introduced. Independent voice of quality is critical for a culture of compliance and should not be represented through operational lens of the function(s) it supports.”



GET IN TOUCH

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