

A woman with dark hair, wearing a white lab coat, is smiling and looking slightly to her right. She is wearing a lanyard with the Syneos Health logo around her neck. The background is a mix of grey and white, with large, abstract orange and grey shapes on the right side.

Best Practices for a Quality Council

Enhancing Quality beyond compliance - a best practice model for Pharmaceutical R&D and Commercial Quality Governance and Quality Councils

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Introduction

Quality Governance, at the highest level, is how a company manages compliance with applicable laws and regulations. For many, this is about having a formal, organizational structure in place to guide business operations. Operating in a well-controlled manner directly effects company profitability and viability through:

- Having a good reputation among patients, healthcare professionals, payers, and regulators
- Improved product success supported by regulatory and payer confidence in the efficacy, safety, quality, and value claims
- Reduced cost base in terms of budget and resourcing to mitigate issues and conduct 'fire-fighting'
- Reduced potential of fines, litigation, and loss of license to operate due to non-compliance with regulations or codes of conduct.

As the key Governance body tasked with protecting the company's license to operate and managing quality risks, the Quality Council is an essential forum for leadership engagement, awareness and decision-making around the quality system and process performance. The Quality Council remit must effectively cover compliance risks, quality implications, and regulatory enforcement action to provide a comprehensive picture of company vulnerability.

A recent survey of Quality leaders¹ found that:

- 1) The majority of respondent companies do not have cross-functional Quality Councils in place
- 2) There is no significant difference in QMS efficiency outcomes between companies with and those without cross-functional Quality Councils
- 3) There is a lack of defined quality governance for organizations as a whole, with each functional area allowed to tailor to their own needs.

We believe that many companies do not have an effective quality governance structure in place. As a result, their Quality Councils are ineffective.

What does a best practice quality governance model look like?

The diagram below summarises a best practice model for key core aspects of a Quality Governance model. It comprises three levels. Data and items requiring decision-making are reviewed at the lowest appropriate level, being escalated from Management Review level via a Quality Forum to the Quality Council and onward to Executive Leadership as required.

Figure 1: Best practice Quality Governance model

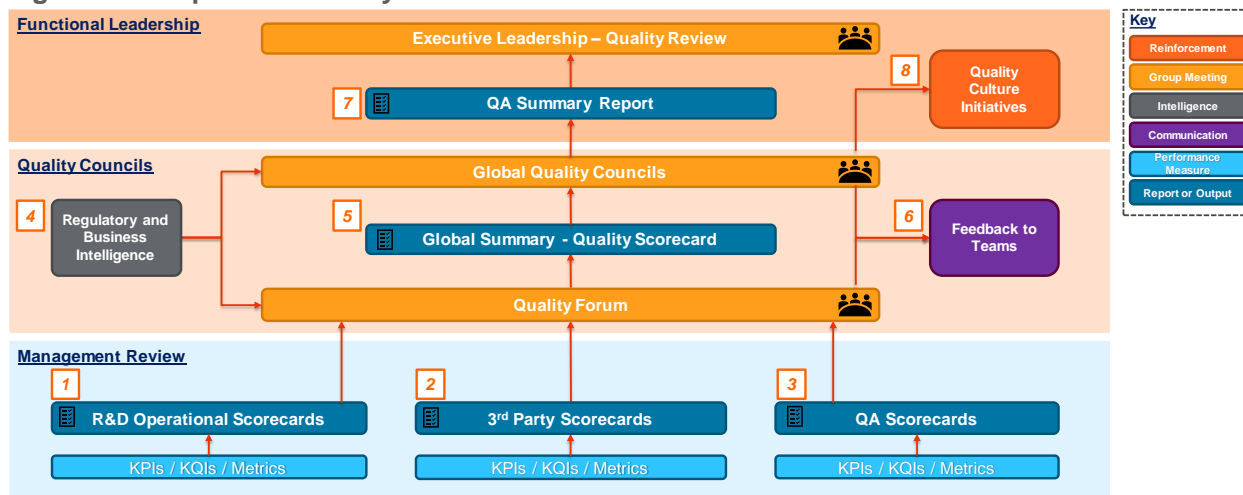


Table 1: Descriptions of Quality Governance model aspects

#	Category	Aspect	Description
1	Performance Measures	Operational Scorecards	A quality system that is data driven and is consistently focussed on the key aspects that drive ownership and accountability, the scorecards are used to predefine and monitor key target attributes
2		Third Party Scorecards	A measure of how Third Party groups perform relative to what is expected / required of them
3		QA Scorecards	A measure of how well the QA group perform
4	Intelligence	Industry wide and Global Regulatory Intelligence and Trends	The regulations that are changing, how they are changing and why they are changing; Company audit findings and other company audit findings; Conference discussions by regulators
5	Output	Global Combined Summary Quality Scorecard	A view of the regional performance and combined regional status
6	Feedback	Feedback to Teams	Feedback from regional / global governance teams and Quality Council to all hands / staff to show where they are making progress and where increased effort is required
7	Report	QA Interim / Annual Quality Reports	Entire year is evaluated in an operational review of performance, review of areas for improvement, and holistic review of risk presented by isolated incidents
8	Reinforcement	Quality Culture Initiatives	In a mature organisation the cultural aspect becomes an essential attribute and driver for quality and ensures ownership at all levels of the organisation by engaging with staff in novel ways
		Reward and Recognition	Key deliverable to all staff whereby achievements are celebrated and advertised

This model:

- Establishes an intentional and formal approach to connecting silos and domains within an organization from a quality aspect
- Facilitates information flow between all parts of the company – it promotes connectivity between functions and shared learnings with end-users
- Allows issues to be resolved at the lowest possible level and trends easily noticed and addressed
- Utilises a clear data driven, goal-orientated culture, which means that management oversight and best practice adoption are optimal.

Purpose of Quality Councils in this model

Quality Councils make up the key layer in the Quality Governance model. They:

- 1) Govern global quality topics by determining actions around risks (including risk mitigation status), underperforming KPIs, new legislation and regulatory guidance, and items escalated from the regional or operating unit Quality Forums
- 2) Recognize positive quality outcomes and initiates Quality Culture initiatives (including Reward and Recognition for positive contributions to quality management).
- 3) Assign topics, risks or issues that have the potential to impact other functions across the company to the relevant functional Quality Council or Risk Owner.

Quality Forum Meetings

Quality Forum meetings should be set up to enable functional leaders to meet and review the quality status of the organization, using Scorecards and KPIs to input into discussions. A global combined summary Quality scorecard allows regional performances to be compared and combined to give a high-level performance evaluation. Positives, negatives, gaps, issues, and risks should be reviewed in an action orientated approach, with clear agenda items that link objectives to outputs. A clear escalation approach should be put in place, to enable areas that require additional oversight to be escalated as required. Depending on the size of the organization, and the global footprint, Global or Regional Forums should be considered to accommodate an effective review of the quality status, at a suitable cadence.

Outputs of Quality Forum meetings should be cascaded appropriately, to share relevant information and communicate meeting outputs to ensure learnings are shared to all relevant functions. A simple one-page feedback newsletter to all hands / all staff following meetings, including rolled-up scorecards is a recommended approach. Positives should be rewarded to celebrate achievements of individuals / groups making an impact to the Quality performance, with an appropriate form of recognition e.g., gifts, newsletter report, recognition systems etc. Issues should be acted on accordingly to resolve underperforming areas.

Quality Council Meetings

Quality Councils should review a holistic view of the data, rolled up and aggregated globally to give the “bigger picture” of quality performance and status and identifying areas to focus while avoiding blame. Outputs of the Quality Forum(s) should be escalated to the Quality Council efficiently, to enable increased oversight for areas of increased concern, and appropriate actions to be determined.

In a model where often only negatives are of focus, it is important not to forget to reward and recognize the positives. Governance models should allow for celebration of the positive achievements of individuals and groups making a positive impact to the Quality performance. Achievements should be added as a standard agenda item at Forum and Council meetings, and an appropriate form of recognition determined. There is power in honoring and championing people for doing the right things the right way and influences collective behavior and habits.

Outputs of the Quality Council and Forum meetings should be consolidated to enable concise, and data driven reporting to staff and the wider company. Local performance should be shared with staff to promote understanding of how performance calibrates to the collective, promoting positives, and addressing

negatives as appropriate. Fostering shared ownership and an understanding of the collective performance are critical in establishing a quality culture.

Summary

Quality Councils and the associated information flow is integral for ensuring high quality within an organization. Inputs such as scorecards and KPIs, and outputs of Quality Forum and Quality Council meetings should be shared within organizations to increase awareness of the quality status broadly, and within functions, whilst also promoting knowledge sharing and management. This should focus on addressing areas for improvement, whilst also ensuring positive achievements are recognized and rewarded.

For more information on how Syneos Health R&D Consulting can support quality governance and quality council design at your organization, please contact james.man@syneoshealth.com and richard.fautley@syneoshealth.com.

References:

1. Gens Associates. 2021 Enhancing Quality Beyond Compliance Whitepaper. January 2022. Available at: <http://gens-associates.com/2022/01/14/2021-enhancing-quality-beyond-compliance-whitepaper-kts/>. Accessed February 16, 2022

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