

The Avoca Quality Consortium  
**Leading Change  
Collaborative Forum**

## **Avoca Quality Consortium Leading Change Collaborative Forum**

### **Meeting Highlights**

**Topic: Beyond Study-Level Risk: Program, Portfolio, and Enterprise Risk-Based Quality Management**

**Meeting Date: September 21, 2021**

### **Background Information**

The emergence of the COVID-19 pandemic has caused the pharmaceutical industry to rapidly adapt its processes and technologies, including clinical trials. The AQC Leading Change Collaborative Forum features compelling topics designed to encourage provocative discussion. The priority is providing practical and actionable support and having immediate “peer-to-peer” benchmarking about how other organizations are managing the topic at hand, all while ensuring prioritization of patient safety, data integrity, and regulatory compliance.

How can we approach Risk-Based Quality Management (RBQM) at the enterprise level? Many companies are trying to do this, but they generally have more questions than answers. In this session, the panelists agreed that there’s no single way to make RBQM successful, but they nevertheless offered a wealth of insights.

### **Discussion Summary**

There was a general consensus that managing RBQM across the portfolio and through the enterprise makes the most significant impact. As one panelist put it, “If you’re looking study by study, you lose the learnings from study to study.”

Among the insights they offered were the following:

#### **RBQM needs to be an organizational role**

Someone has to be responsible. If you make it everybody’s job, it’s no one’s responsibility. It gets lost in the priorities of trying to get a study up and running.

#### **Decide what you want to measure**

“It can be therapeutically aligned, there can be multiple sources using data analytics and reports and those types of things to measure – but if you don’t know what you’re measuring, then it becomes very difficult,” explained a panelist. Define upfront what is most important at each level—study, portfolio, program, and enterprise.

## **Have a robust (ideally, automated) way to capture data**

That way, explained a panelist, you can “aggregate the data in such a way as to understand where you should put your time, energy, and resources. “You can better identify gaps. I think the biggest challenge comes with how you are collating the information. How are you gathering that data? And then how are you making it so that it becomes user-friendly?”

## **Focus on actionable data**

Even in a company with robust data capture, it's important the data collected be used – and that people understand how it's going to be used and why you're collecting it. Ask yourself: *Why are we collecting this data? Is the data actionable?* Otherwise, don't collect it.

## **Get everyone on the same page**

Mergers and acquisitions can result in differing approaches to risk management that need to be consolidated.

## **Risk management = continuous improvement**

“If you think about the notion of risk management being not only the intent to prevent harm...but from the standpoint of continuous improvement, when we begin to look at risk from an enterprise, it really begins to highlight to us how many risks are repeated very often in slightly different ways,” said a panelist.

## **Link issues to risks**

What happens when risks occur on a study and the team goes through the CAPA process? What are those corrective actions and preventive actions? They are risk mitigations, explained a panelist. “They're ways of controlling risk because you're trying to stop that same issue reoccurring somewhere else.” It's an approach that's been part of manufacturing, but less common in drug development.

You want people to see risk management as a way to anticipate when they'll need to make a decision to do something differently.

## **Define quality tolerance limits**

QTLs, also common in manufacturing, are now entering the drug development world. It's a level, point, or value associated with a parameter that, when a deviation is detected, should trigger an evaluation to determine whether there's a systemic issue. “We create these tolerance levels depending on the types of risks. So, it's really important to define what is most critical. What's most important? If those risks materialize, those are the ones we don't have any tolerance for. We have to take action and implement a CAPA immediately,” explained one panelist.

People may understand what data is being collected and why, but they also must understand the priority of what's collected. It gets back to a central theme of the discussion: Focus on what's most important at each level: study, portfolio, program, and the enterprise.

## Process thinking matters

The industry takes a study-to-study perspective. This lack of process thinking “really struck me when I joined this industry...from manufacturing, where it was so process focused,” said one of the panelists. It’s a matter of looking at cause and effect. “Understanding our processes better helps us to understand the cause and effect and helps us to understand what the true risks really are and where they might actually lead.”

Another panelist framed it as going to the worst-case scenario. “And if you take that step where you’re going all the way to the worst-case scenario, that’s different than what we would normally do. We don’t think that far. We’re focused on first patient first visit. So, if we go beyond that and think, okay, last patient last visit and work backwards, then you start to look at risk completely differently.”

## Change the firefighting mentality

Many organizations have a hero/firefighter mentality around risk management. Several panelists noted that the industry is good at fixing things after the fact, but an anticipated risk doesn’t generate the same sense of urgency. “And we’re doing what I lovingly call cleaning up after the elephants, like with a dustpan,” one of them said.

The mindset *needs* to be: “It’s better to be more strategic and plan to build systems that eliminate problems before they arise, instead of spending your entire career as a firefighter.”

## Change mindsets, find champions

One of the recurring themes was the need to change how people think about risk. To get team buy-in, you need executive support, the panelists agreed. “Get buy-in and then get the people who are going to be your cheerleaders, those champions, to help the organization change the mindset,” said one.

## Slow down to look at the larger picture

Doing a risk assessment on every protocol would provide a different perspective on how to execute the studies, as well. And then that learning can be taken across programs, across portfolios, explained a panelist. “But part of our problem is...the rush to move a study. And so, you need to have people step back long enough to do the risk assessment. Take the learnings that we learned from last time we’ve done it and move that forward. That’s a real challenge.”

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If you are interested in learning more about the [WCG Avoca Quality Consortium \(AQC\)](#) or its Leading Change series, please contact [Dawn.Auerbach@theavocagroup.com](mailto:Dawn.Auerbach@theavocagroup.com).