



Collective Problem-Solving With Regulatory or Compliance Partners: Three Stages

— Created by Dan Seewald, former Head of Worldwide Innovation at Pfizer

Stage 1. Alignment and Understanding of the Need

The first stage is to build deeper alignment and understanding, and properly frame the reward and risk alongside your regulatory and compliance leader. This ensures that you have a common framework of understanding and value for the innovation project.

1. **Customer Empathy:** Why might our customers get value and benefit from this innovation?
2. **Internal Stakeholders:** How could this innovation benefit our business and our team?
3. **Regulatory Barriers:** What would “keep you up at night” regarding the current state of this innovation project? (i.e., your biggest concerns)

Stage 2. Assessing the Risk of Innovation

The second stage is a way of dispassionately risk-assessing the innovation and determining the REAL risks and the underlying reasoning from a regulatory and compliance standpoint. This helps you uncover some of the regulatory landmines that you may step on if the situation is not properly unpacked from the outset.

1. **Killer Assumptions Test:** What must hold true for this innovation project to be approvable?
2. **Certainty Test:** Which of the “killer assumptions” are most uncertain, and pose the greatest risk?
3. **Impact Test:** Which of the “killer assumptions” might have the greatest negative impact if they happened? Why?

Stage 3. Problem-Solving for Innovation

The final stage invites your regulatory and compliance partner to turn the “killer assumptions” or risks into solvable propositions. We do this by gently imposing reflection and exploration questions. And we culminate with them joining forces with you to brainstorm on how they can overcome the biggest barriers.

1. **Past Performance:** What has been tried before that has been acceptable? Why?
2. **Where Else:** From your experience, where else has this problem been faced? (Probe on: other brands, other companies, other industries.) How did they overcome this hurdle?
3. **Adaptation:** What might we be able to do at our company that could overcome the biggest compliance/regulatory barriers?

In the end, you will have helped shift your internal partners from being stuck in a defensive regulatory or compliance position to working alongside you as a joint problem solver.