



The Culture of Quality

Pharmaceutical Industry Association of Puerto Rico
21st Regulatory Conference

Lilly

CULTURE OF QUALITY

How is it defined?



It has been discussed for years, yet current regulations do not explicitly define it.



It is infused into the company Quality Management System.



Measuring is difficult but strongly signaled.



Tone at the top matters jointly with a sense of accountability by all.



There is no endpoint; we are never done.

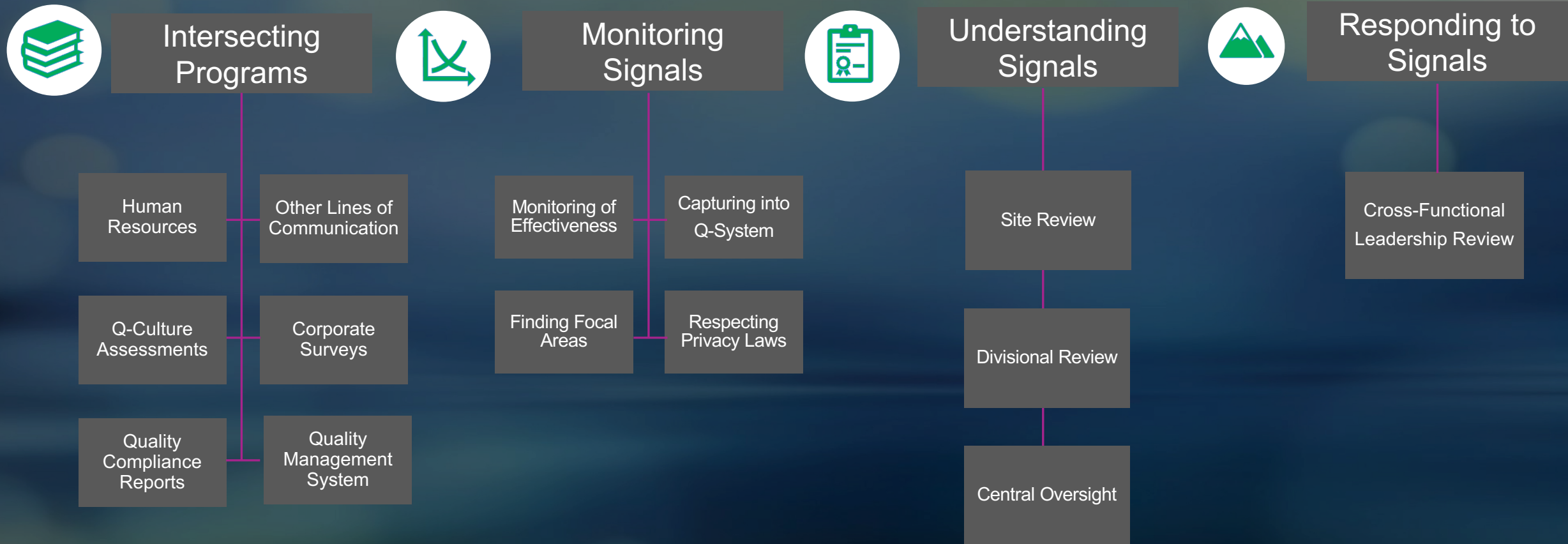


It is powered by **PURPOSE.**

Integrity, Excellence, and Respect for People inspire us to do the right things for the right reasons.

- There is a strong connection between operations performance and company practices - driven by a Quality mindset.
- Many companies promote the importance of quality—but efforts are missed if the message is not believed.
- Maintaining leadership commitment also drives employee ownership and sense of accountability.
- More than ever, ensuring the availability of medicinal products rest on Quality driven-behavior and operational models that promote a culture of excellence.

Quality Culture Excellence Framework



Intersecting human behavior components and quality performance indicators drive an enduring Culture of Quality.

The **CULTURE** of Quality is the outcome of systems and behaviors.

- Drive a culture of excellence by setting Corporate Quality Practice expectations to spend time on the floor
- Leaders and frontline resources working together for continual improvement
- Visualization boards, checks of practices against procedures, and fostering a collaborative work environment are some of the areas to keep in mind
- Culture of Quality Assessments manufacturing sites across the globe

Engagement Behaviors

- Establish constructive dialogue
- Ask questions
- Seek to understand
- Identify and help remove barriers



Lilly Conducted a Manufacturing and Quality Innovation Laboratory including line personnel

13

Lilly manufacturing sites, including US and OUS sites

- Reached thousands of Manufacturing and Quality Employees
- Over 50 global participants traveled to attend
- Corporate cross-functional executive leaders were present

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New manufacturing under construction to serve more patients

- Host conditions where everyone could fully participate and feel valued for their contributions
- Explore potential solution areas that are transformational and actionable at the organizational and/or site level



THANK YOU

“Take what you find here, and make it better and better”

Colonel Eli Lilly 1876

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