



Quality Assurance

Trust · Delight · Value

Quality Management Maturity Domestic Pilot Industry Perspective

Nelson Webb - Procter & Gamble

AstraZeneca 

Baxter



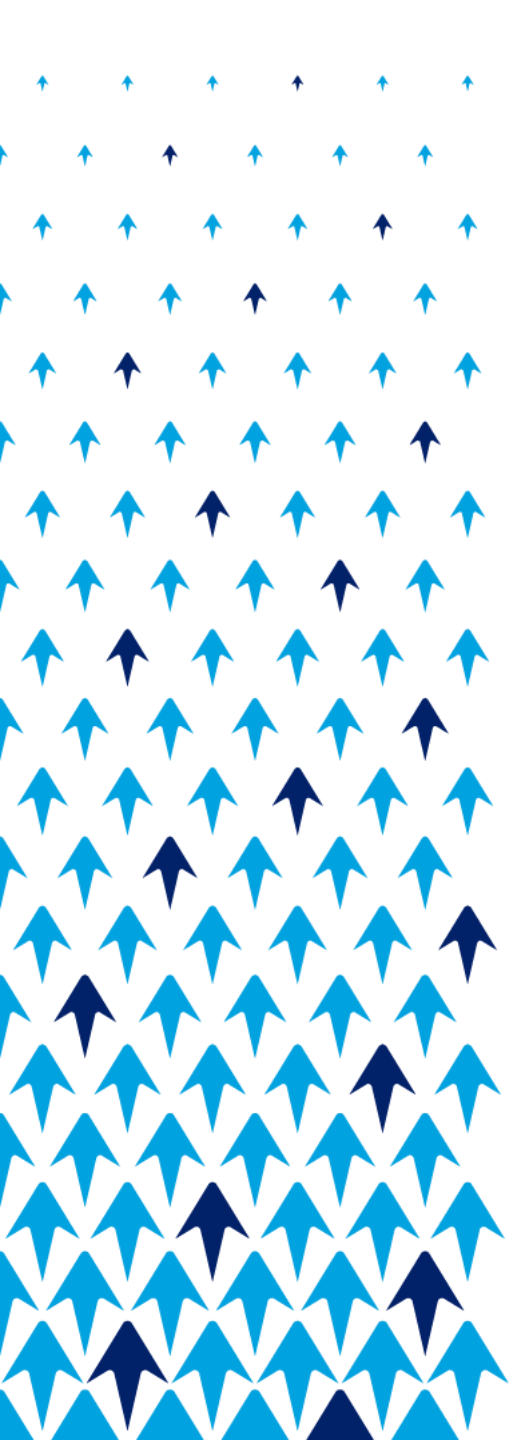
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P H A R M A S C I E N C E S



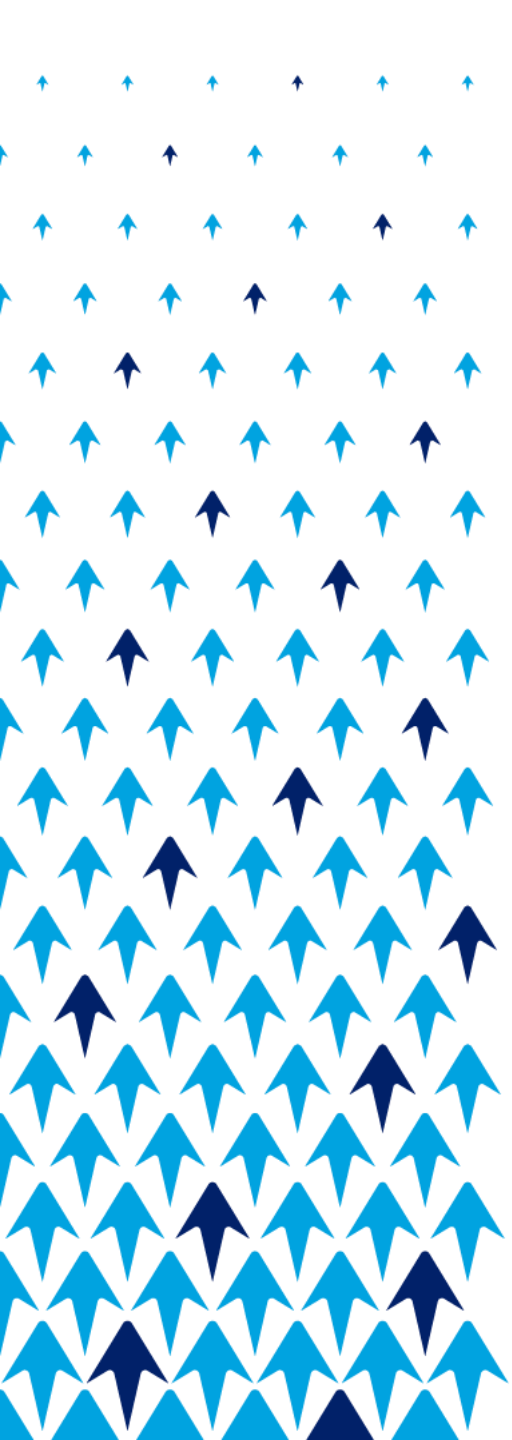
Topics We Will Discuss

- The Pacific Force Group (PFG) Assessment Tool
- Self Assessment vs. PFG Assessment
- Opportunities for Improvement
- Benefits to Participating Firms



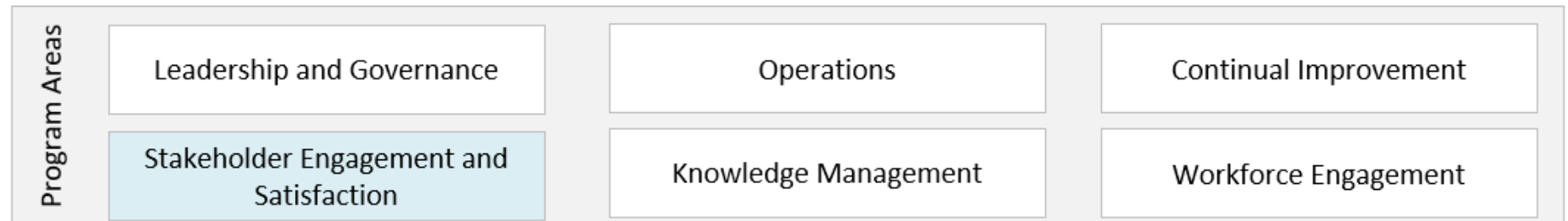
The Assessment Tool

- Easy to use
- Clear descriptions across 6 program areas
- Increased emphasis on data analytics and AI at higher levels
- Some redundancy between sections (being addressed)
- Unclear with regards to suggested evidence
- Unable to attach evidence directly adjacent to requirements...very basic upload portal



Pacific Force Group: Program Areas

While the assessment is “site” focused, many of the program areas are managed centrally.





Typical Progression of Requirements

CUSTOMER / PATIENT FOCUS

A. Which level best describes how your organization listens to the Voice of the Customer or Patient in order to serve and exceed customer/patient expectations?

1. **Level 1 (Initial):** The organization treats all customers and patients with courtesy and with the intent to meet customer needs and responds to customer complaints in a timely manner. The organization has systems and processes in place to **capture and resolve customer complaints**.
2. **Level 2 (Developmental):** The organization has one or more **listening or feedback mechanisms** in place to obtain actionable information regarding customer and patient requirements. The organization's listening/feedback mechanisms vary across the customer lifecycle.
3. **Level 3 (Defined):** The organization seeks immediate and actionable feedback from customers pertaining to product offerings and services and conducts surveys and other forms of customer contact to identify customer requirements. Customer complaints are **routinely reviewed** to determine and identify root causes and implement corrective/preventive actions.
4. **Level 4 (Managed):** In addition to Level 3 activities, the organization identifies and adapts product offerings to meet and exceed customer requirements based on feedback from customers, stakeholders, and suppliers. **Analysis of customer data** is used to inform post-delivery activities and enhance product and service design. All complaints are processed efficiently and tracked through the service delivery process to resolution, initiating customer recovery plans as needed.
5. **Level 5 (Optimized):** In addition to Level 3-4 activities, the organization incorporates **Artificial Intelligence (AI)** and **advanced analytics** to analyze/respond to trends that present risks to the consumer. Additionally, AI and advanced analytics are used to inform customer requirements and market segments to emphasize product offerings, enter new markets, attract new customers, and drive future growth. The organization has robust mechanisms in place that integrate machine learning and predictive analytics to enhance the customer experience and improve brand image.



Virtual Assessment Sessions (5 hours total)

- Collaborative and positive engagement for first-timers with “FDA” ... confidence builder / watchout
- Some new requests during sessions (example: corporate assessment program)
- Unclear how to best present evidence...wide range among participating firms

One approach to sharing...

Here's the list
you asked
for... What
questions do
you have?

SOP Index

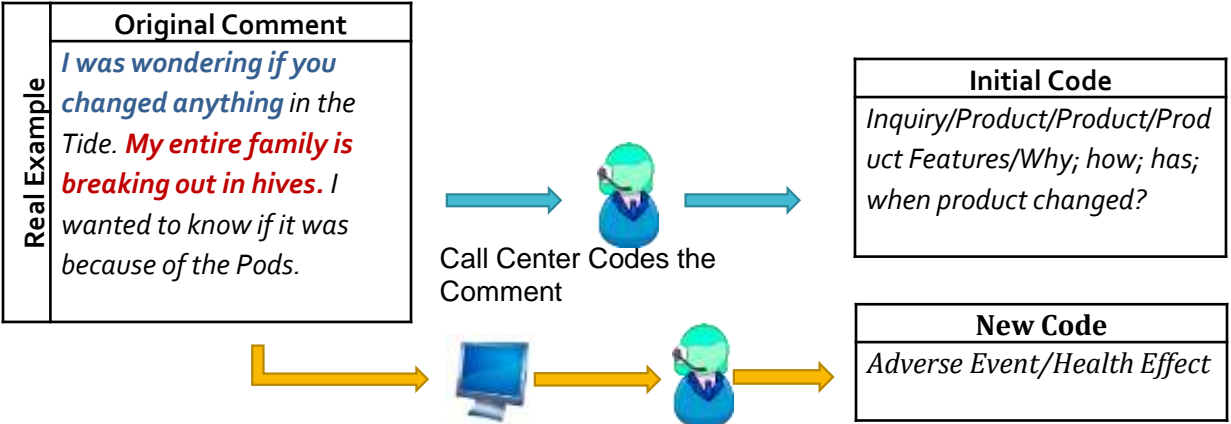
1. Xxx
2. Xxx
3. Xxx
 1. Yyy
 2. Yyy
4. .
5. .
6. .
7. .
8. .

One approach to sharing...

Consumer Comments Data Analytics

Detecting Misclassified Adverse Events with Machine Learning

- All consumer comments are coded by P&G. 100% of Adverse Events are then reviewed by our Global Safety & Surveillance (GSSA) organization to ensure our products' safety.
- Using AI, we can automatically detect consumer comments that may have been incorrectly coded



Machine Learning flags the comment, sends back for human review, comment code is corrected



Assessment Report

- Self Assessment and Pacific Force Group scores were well calibrated
- Improvement areas not consistently called out in the report for each area < 5 rating
- Some gaps were for topics not explicitly covered in assessment and not discussed during the virtual session
- Some actionable insights...but at a much higher level than typical FDA or GMP consultant feedback

“Compliance” Is Base Expectation for QMM

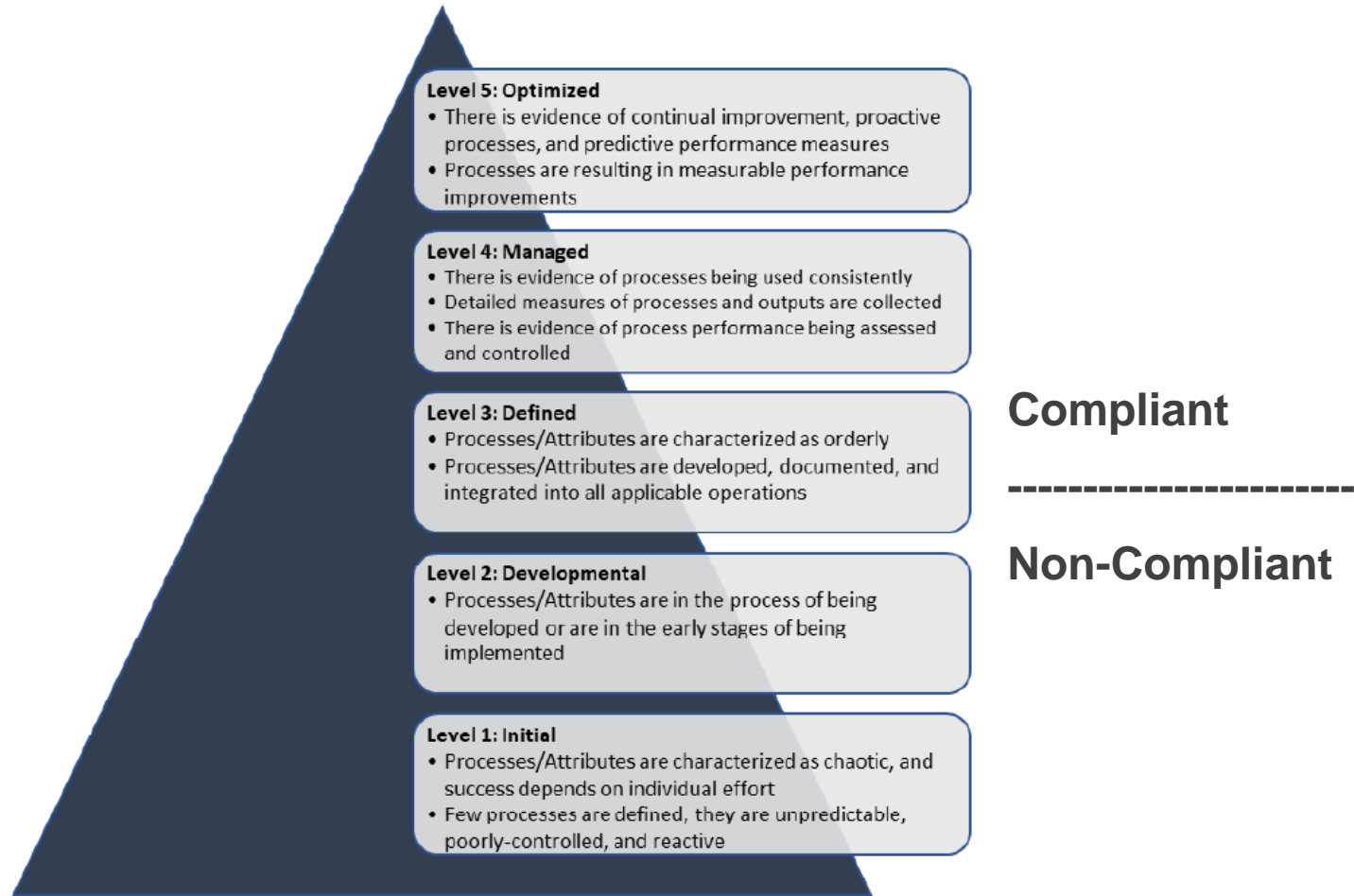


FIGURE 3: QUALITY MANAGEMENT MATURITY LEVELS

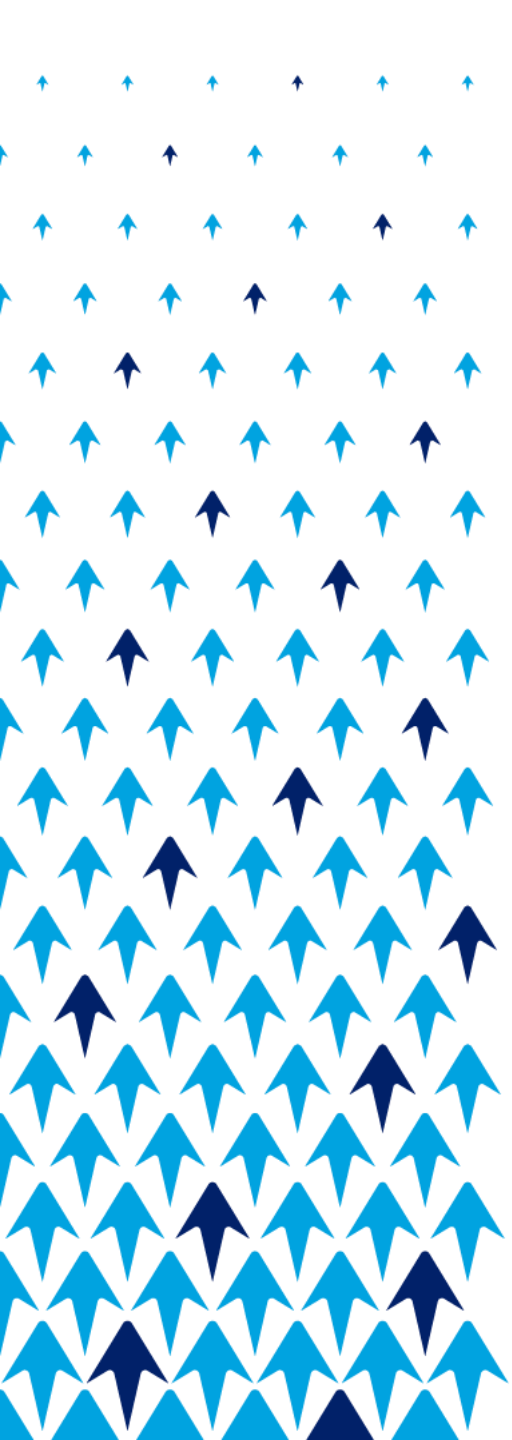


Well Calibrated Scores = Clear Assessment Tool

4.1.1 Program Area 1: Leadership and Governance

TABLE 1: PROGRAM AREA 1 ATTRIBUTE MATURITY LEVEL SCORES

Item	Attribute	P&G Self-Assessment Maturity Level	PFG Assessment Maturity Level
1.1	Management Commitment	4	4
1.2a	Management Reviews, Oversight, and Monitoring	4	4
1.2b	Management Reviews, Oversight, and Monitoring	4	4
1.3	Internal Communications	4	4
1.4	Business Excellence and Societal Contribution	5	5



Examples of Feedback



Maturity Level

Opportunities for Improvement (OFI):

- P&G may consider deploying processes to evaluate and measure communication effectiveness including **establishing associated metrics** designed to optimize continual improvement of communication modalities.
- Although P&G identified that QA representatives are available to enter quality deviations, the organization may benefit from enhancing this system to allow all employees to input deviations to include an **anonymous entry function**. This approach may identify new opportunities, enhancing P&G's ability to identify deviations and improvement initiatives.



Why Participate?

KEY TAKEAWAYS

- Easy-to-use self-assessment process engaging different parts of the organization
- Valuable discussion and feedback...even virtual
- QMM provides a different look into how organization quality culture is created and maintained
- Highlights leadership role vs. daily execution role
- More foundational than Quality Metrics?



Don't Wait!

None of us are waiting on Quality Metrics to establish a Quality Scorecard.

There are tools available today that can help you along the Quality Maturity journey:

- St Galen's University Operational Excellence
- ISPE – Advancing Pharmaceutical Quality

Thank you.

