



Practical Strategies for Building Cultural Excellence to support Enhanced Quality Outcomes

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 Arnold F. Graves Scholar, TU Dublin

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Speaker

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Nuala is a 25 year veteran of the pharmaceutical industry. Her work as a consultant, academic, author and commentator is directed toward the development of practical, patient-focused excellence and has included research for FDA(USA), HPRA(Ireland) on enhancing patient safety and product quality in the manufacture and distribution of drugs.

Nuala works with organizations on transforming organizational culture, delivering more effective end-to-end risk management, implementing knowledge excellence strategies, behavior-based good data governance and enhancing performance management through people.

Nuala co-leads the ISPE Quality Culture Team and is a founding member of the ISPE/ PQLI Task Team on Knowledge Management. She is also the Arnold F. Graves Scholar with the Pharmaceutical Regulatory Science Team at TU Dublin, Ireland, where she leads a number of patient focused regulatory science research projects at Masters and PhD level.

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Opening thoughts
on

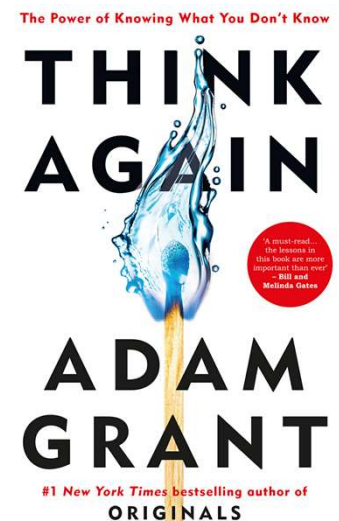
Learning and
Unlearning!

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Preachers, Prosecutors, Politicians & Scientists!

"If you're a scientist by trade, rethinking is fundamental to your profession. You're paid to be constantly aware of the limits of your understanding. You're expected to doubt what you know, be curious about what you don't know, and update your views based on new data."

Grant, Adam. Think Again (pp. 19-20). Ebury Publishing. Kindle Edition.



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Diversity, Equity, Inclusion & Belonging



Diversity of thought.
Creating a sense of belonging



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What are we talking about
when we talk about a
Culture of Excellence?

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Values & Behaviors ... & You



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Understanding the Why

Let's remind ourselves of what Patients Expect...



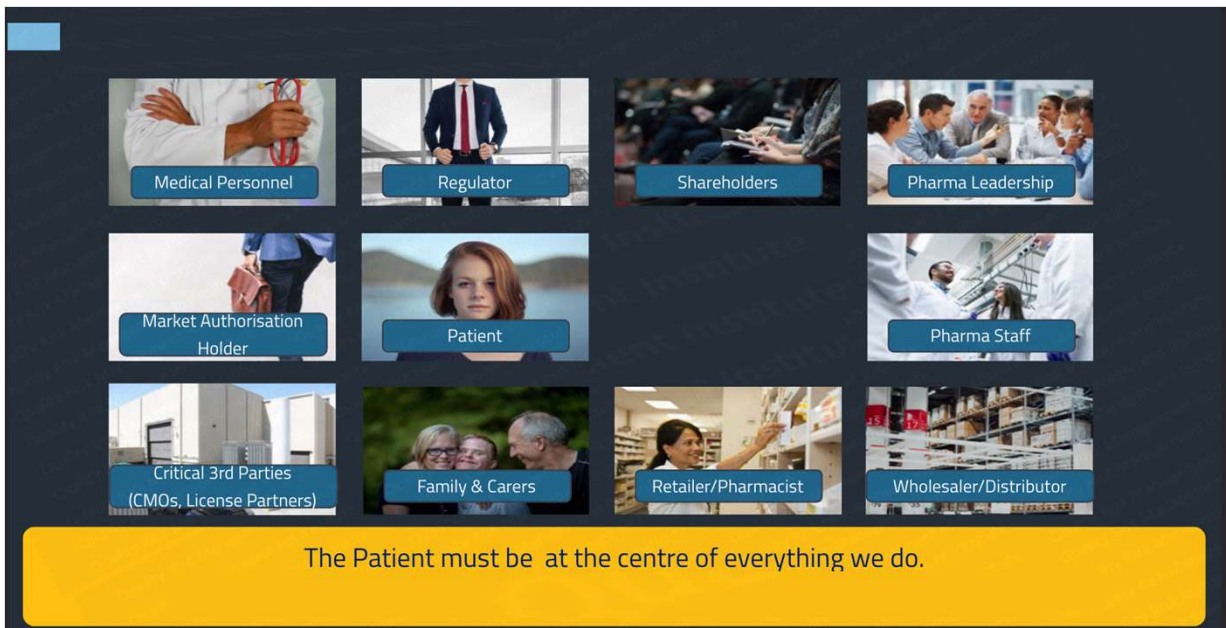
High quality, available
medicines delivered
on time, in the correct
dosage, and at an
affordable price.














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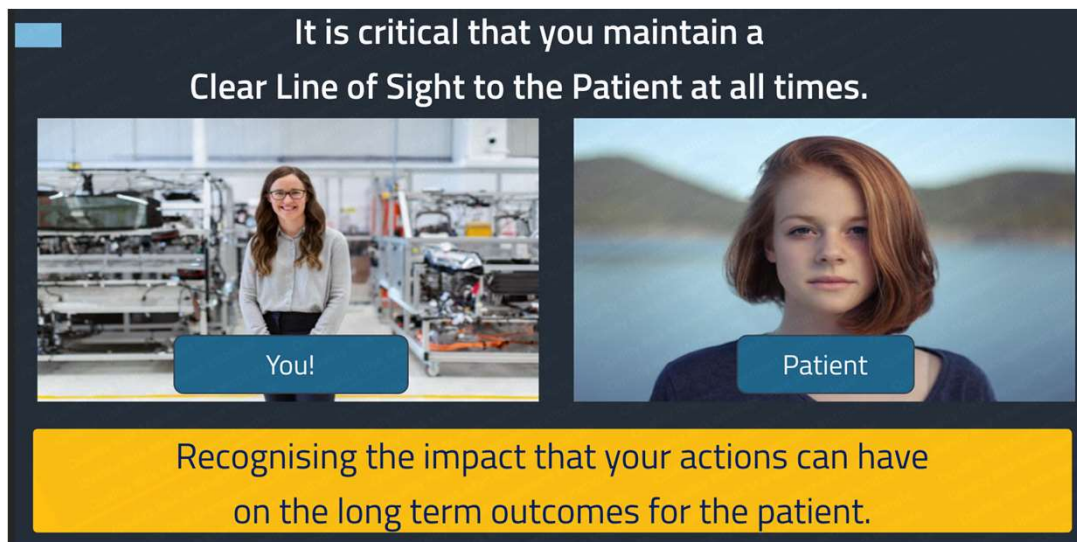
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 Medical Personnel	 Regulator	 Shareholders	 Pharma Leadership
 Market Authorisation Holder	 Patient		 Pharma Staff
 Critical 3rd Parties (CMOs, License Partners)	 Family & Carers	 Retailer/Pharmacist	 Wholesaler/Distributor

The Patient must be at the centre of everything we do.




It is critical that you maintain a
Clear Line of Sight to the Patient at all times.

You! Patient

Recognising the impact that your actions can have
on the long term outcomes for the patient.

Building a Culture of Excellence is about...

Make Sure You Start With "THE WHY".



Find ways to make
your patient real for
you and your
colleagues
EVERY BATCH,
EVERY DAY.



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Spreading the excellence from the few to the many...

The Power of Many



Mobilise the power of the entire workforce.

Excellence can't be commanded from above. It must be made contagious, individual to individual. The trick is in knowing how to transfer the right mindsets and best practices without "voltage loss" as they spread. Dr. Robert I. Sutton, Scaling Excellence



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Let's get practical!

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ISPE Cultural Excellence Report (2017)

A collection of **practical, powerful tools and cases**



International Society for Pharmaceutical Engineering.
"The Cultural Excellence Report – Six Key Dimensions", April 2017, available for download at:
<https://www.ispe.org/products/cultural-excellence-report-six-key-dimensions>, © ISPE 2017. All rights reserved.



ISPE The Six Dimensions of Cultural Excellence

17 Embedded Tools

Case Studies **3**

4 Detailed Appendices

Benefits for *your business* and *your patients*.



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5V's of Leader Influence on Culture



Why are GEMBA walks part of cultural excellence?

- ❖ Creating visible management commitment to excellence and employees
- ❖ Engaging all employee levels of the organization
- ❖ Enhancing communication of priorities, objectives and desired behaviors
- ❖ Engaging internal customers to facilitate learning about one another's processes



A Wide Range of Oversight and Review Tools



Enabling the Development of Quality Culture Capability

Low Capability KBIs

High Capability KBIs

Low Quality Capability

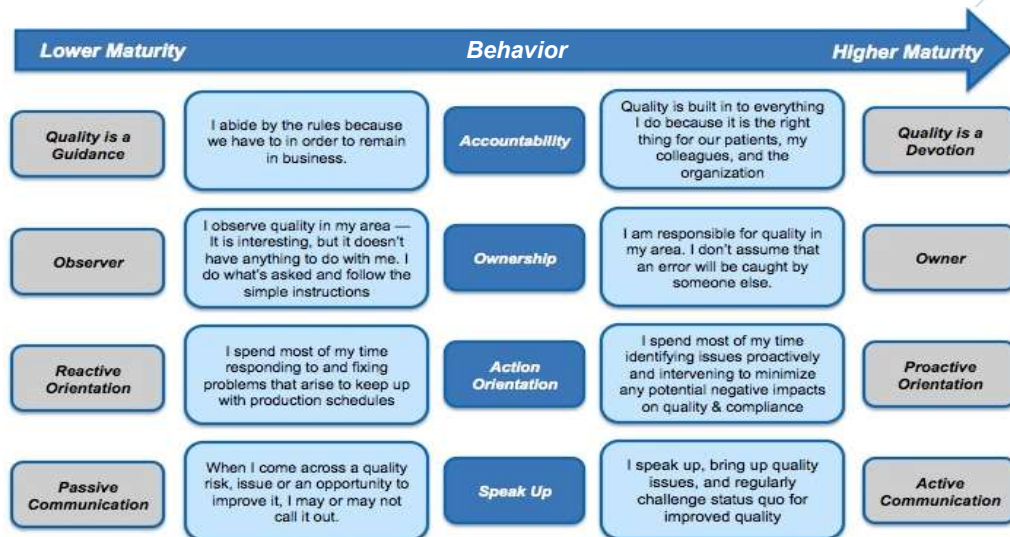
- Top/Down power
- Employees heavily reliant on management decision-making
- One-way, top-down communication
- Loyalty in highly rewarded
- Employee rights are not valued; inequality is accepted
- Individual success is more important than the teams
- "Firefighting" is the norm and is recognized. Focus on correction.
- The "right" behavior is not recognized and may even be punished
- Little or no employee training/development
- Blame culture
- Little or no root cause analyses

High Quality Capability

- Collective thinking and idea generation
- Self-reliant employees
- Open communication with feedback loops
- High Performance is highly rewarded
- Employee rights are important and fairness/equality is valued by all
- Success of team is valued over individual success
- Systems thinking and systems improvement are the norm. Focus on prevention
- The "right" behavior is recognized which encourages that behavior to continue
- Formal employee training and development systems are in place
- Peers hold each other accountable
- Strong root cause diagnostics & thinking

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Shifting Mindsets, Attitudes & Key Behaviors:



International Society for Pharmaceutical Engineering, "The Cultural Excellence Report – Six Key Dimensions", April 2017, available for download at: <https://www.ispe.org/products/cultural-excellence-report-six-key-dimensions>.

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Designing Measures for IMPACT

Table 4-A: An example of the IMPACT Tool for designing behavior-based LQIs

I IDENTIFY GOAL	Consistent delivery of high-quality medicinal products.	
M SELECT THE MEASURE TOW DELIVER GOAL	Increase the number of RFT batches to X%.	
P PINPOINT THE BEHAVIORS	<ol style="list-style-type: none"> Promote and coach for enhanced attention to detail through leadership and vision, as well as routine Gemba walks. Encourage a speak-up culture where concerns, issues, and mistakes are raised in a neutral, constructive forum. Begin proactive daily multidisciplinary interim batch reviews and resolution. 	
AC ACTIVATE THE CONSEQUENCES	<ol style="list-style-type: none"> Organize team briefings on the consequences of rejected or delayed batch approvals for the business and the patient. Review outcomes from recent rejected or delayed batches or relevant customer complaints with the team. Senior leadership and local management celebrate/acknowledge each RFT batch during Gemba walks. Use local visual management boards for motivation on progress toward goal. Acknowledge and recognize improvement efforts by team members in team/public areas/newsletters. Motivate the team through team awards, e.g., movie tickets, team lunches. 	
T TRANSFER KNOWLEDGE AND SKILLS TO SUSTAIN CHANGE	<ol style="list-style-type: none"> Learning teams use root cause analysis (RCA) tools to proactively identify and document solutions to issues raised. Lessons learned are documented and shared with wider workforce. Lunch-and-learn sessions are arranged to facilitate Q&A between different improvement teams. Create improvement case studies in a shared area on intranet. 	
LQIs/LBIs	<p>Leading</p> <ol style="list-style-type: none"> Measure and report attendance at the multidisciplinary daily meetings. Number of employee/team RFT improvement suggestions implemented (by period). Number of good catches identified at interim batch reviews (by batch). Number of successful RCA exercises completed (by period). <p>Trended Lagging</p> <ol style="list-style-type: none"> % RFT batch approvals/investigation free lots. % RFT batch records (paperwork completions). 	

International Society for Pharmaceutical Engineering, "The Cultural Excellence Report – Six Key Dimensions", April 2017, available for download at: <https://www.ispe.org/products/cultural-excellence-report-six-key-dimensions>.



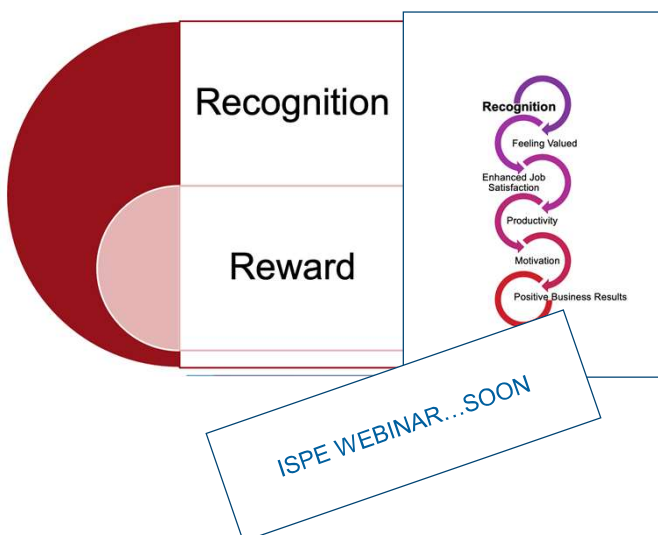
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Cultural Excellence 2.0

What are Recognition and Reward?



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People	Unfulfilled	Unfulfilled	Unfulfilled	Unfulfilled	Unfulfilled
	Level 1	Level 2	Level 3	Level 4	Level 5
1. Management	<p>Unfulfilled</p> <ul style="list-style-type: none"> Management doesn't see quality improvement as their personal responsibility. Management doesn't have authority to make decisions and drive their team to the desired state. Management doesn't identify issues that may have negative effects on quality and performance. 	<p>Unfulfilled</p> <ul style="list-style-type: none"> Management doesn't have authority to make decisions and drive their team to the desired state. Management doesn't identify issues that may have negative effects on quality and performance. 	<p>Unfulfilled</p> <ul style="list-style-type: none"> Management doesn't have authority to make decisions and drive their team to the desired state. 	<p>Unfulfilled</p> <ul style="list-style-type: none"> Management doesn't have authority to make decisions and drive their team to the desired state. 	<p>Unfulfilled</p> <ul style="list-style-type: none"> Management doesn't have authority to make decisions and drive their team to the desired state.
2. Team	<p>Unfulfilled</p> <ul style="list-style-type: none"> Team doesn't see quality improvement as their personal responsibility. Team doesn't have authority to make decisions and drive their team to the desired state. Team doesn't identify issues that may have negative effects on quality and performance. 	<p>Unfulfilled</p> <ul style="list-style-type: none"> Team doesn't have authority to make decisions and drive their team to the desired state. Team doesn't identify issues that may have negative effects on quality and performance. 	<p>Unfulfilled</p> <ul style="list-style-type: none"> Team doesn't have authority to make decisions and drive their team to the desired state. 	<p>Unfulfilled</p> <ul style="list-style-type: none"> Team doesn't have authority to make decisions and drive their team to the desired state. 	<p>Unfulfilled</p> <ul style="list-style-type: none"> Team doesn't have authority to make decisions and drive their team to the desired state.

GEMBA Companion Tool for APQ Self Assessment Teams

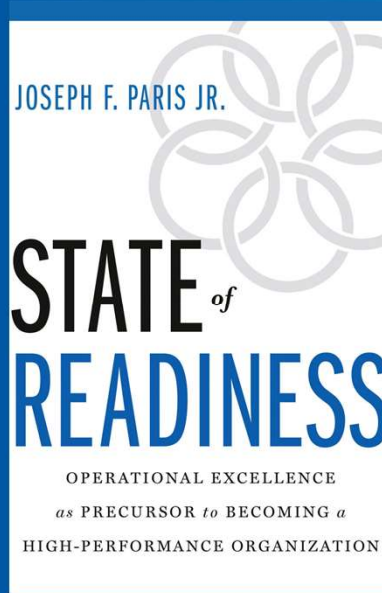
Next Up...

- Additional case studies
- Tiered Accountability Processes / employee engagement
- Human error reduction A3
- Culture building with a virtual team Building Learning organizations



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...where the corporate culture is committed to the continuous and deliberate improvement of company performance AND the circumstances of those who work there—

and is a precursor to becoming a high-performance organization.

Paris Jr., Joseph F.. State of Readiness: Operational Excellence as Precursor to Becoming a High-Performance Organization (p. 10). Greenleaf Book Group Press. Kindle Edition.

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**Thank You
for your time
today**

Thanks to the Team

ISPE Cultural Excellence 2.0	
The Team	
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