

QMS Agility Model

A Pathway Chief Quality Officer Initiative

Discussion Leaders:

- Ingrid Cabalza, illumina
- David Murray, illumina
- Marla Phillips, Pathway



Today's Agenda

1.

Introduce Pathway

2.

Introduce the QMS Agility Initiative

3.

Walk through the QMS Agility Model

Be ready to engage with your peers!



Pathway's Mission:

- To help the industry achieve a quality breakthrough
- So companies can scale quality across their entire organization
- Because the next catastrophic defect could happen today
- And we believe every patient's life matters
- So the time to take action is **NOW!**



The Chief Quality & Operations Team



Beverly Bates
P&G



Tracy Founds
Glaukos



Tony Mire-Sluis
AstraZeneca



Brian Molloy
Alexion/AZ



Karen Netherton
Seqirus/CSL



Johna Norton
Eli Lilly



Maire O'Reilly
Elanco



Anil Sawant
Merck



Brian Schultz
Fisher & Paykel
Healthcare



Peter Shearstone
Thermo Fisher



Andrew Wirths
AstraZeneca



Gary Workman
Illumina

Pathway CQO Forum

A Team
in Action!



First Ever!

Quality Operations Forum

PURPOSE



To support site and corporate quality professionals in proactively implementing successful practices gained through a vibrant network of global peers collaboratively addressing contemporary and complex challenges.

Join Today!



<https://www.pathway4ph.org/site-quality-officer-forum>

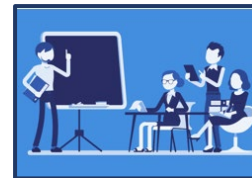


Live External Intel



- Quarterly live meetings
- Trends, insights and intel
- Regulator activity and expectations
- Global resources to improve your operations

Live World Cafe



- Weekly live meetings with forum members
- Challenging topics for site operations
- Realtime collaboration to gain insights
- Successful practices shared

60+
Live Meetings
Each Year

Live Network



- 24/7 access to your global peers
- Engage in online dialog
- Invite your peers to join initiatives that matter to you

Save the Date!

QMS Agility Model: In-depth “How to” Workshop

September 14, 2023
10:00am – 2:00pm Eastern



Today's Agenda

1. Introduce Pathway
2. Introduce the QMS Agility Initiative
3. Walk through the QMS Agility Model



Initiative Members

Ingrid Cabalza

Mark Frankenberg

Alan Johnson

Shirley Murphy

David Murray

Marla Phillips

Melissa Smith

Eva Urban

Illumina

P&G

AstraZeneca

Takeda

Illumina

Pathway

P&G

CSL Behring



Thank you TEAM for your incredible passion, and dedication to such a meaningful outcome!

CQO QMS Agility - Project Goals

1. Is it possible to have one QMS that spans the range of regulatory rigor across the various commodities?
2. Is it possible give our personnel the business acumen to make decisions that are compliant and business-smart?
3. Is it possible to pivot, instead of always defaulting to the highest standard?



Yes!

The image features a dark blue background filled with a bokeh effect of out-of-focus light spots in various shades of blue. A prominent horizontal band of bright, shimmering particles, resembling a spray or a trail of light, stretches across the lower half of the frame. The word "Yes!" is centered in the upper half in a large, bold, white sans-serif font.

But Wait!

“Is it possible to pivot, instead of always defaulting to the highest standard?”

Isn't standardization good, and don't we want to achieve the highest standard?

Chat Box: give examples of how standardization is helpful to your organization

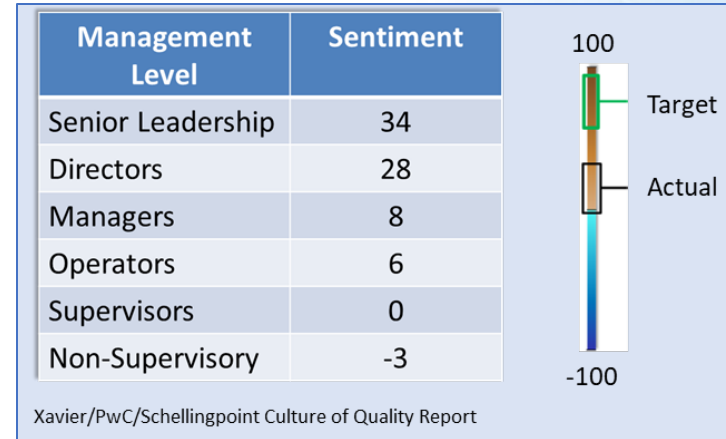
So then what's the problem?



What are your thoughts?

1. What did you have to do differently to release product during the Covid shutdown?

2. How do you think your employees felt about the decisions that were being made?



3. What would you pull out today to guide your employees through the next pandemic shutdown?

Let's Breakout

Breakout

What would you pull out today to guide your employees through the next pandemic shutdown?

Group Notetaker:
First Name closest to "A"



Today's Agenda

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Introduce Pathway

2.

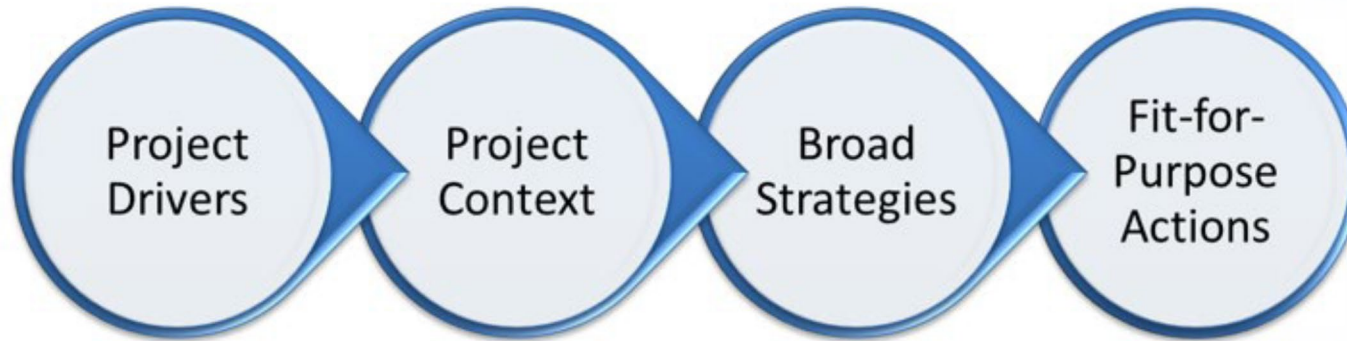
Introduce the QMS Agility Initiative

3.

Walk through the QMS Agility Model



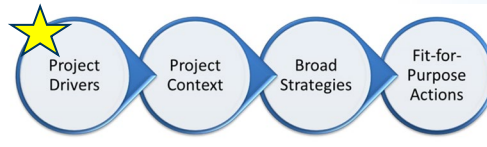
QMS Agility – A Fit for Purpose Model



Key Differentiators:

1. This is a pre-planned model that can be incorporated into your existing Risk Management Process for how you operate YOUR quality management system
2. Guides employees to proactively identify business pressures (such as time, short term cost, and long term ROI) that could impact their ability to effectively manage projects
3. Provides comparative strategies on how to lead projects differently based on the identified business drivers

Project Drivers - Tension



• Time Pressure

- Examples of what R&D could say to Quality that could cause tension?
- Examples of what Quality could say to R&D that could cause tension?

Different than having a timeline

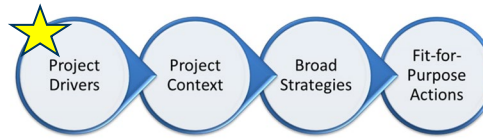
• Budget Pressure

- Can you think of 2 different kinds of budget pressure
- Are these drivers synergistic or conflicting?

Different than having a budget

Let's See How

Time Pressure Questions



Is the project (product or system) being driven by the need to meet a **customer-driven timeline**?

Is there a **Potential Market Opportunity** or **Patient Need** that needs to hit an accelerated timeline (e.g. Covid vaccine development)?

Has there been an **External Time Commitment** Made or Expectation (Investors, Clients, Customers, Regulators)?

Is there an accelerated time needed due to **social responsibility drivers** (e.g. the need to stop sourcing from the rain forest by x date, etc.)

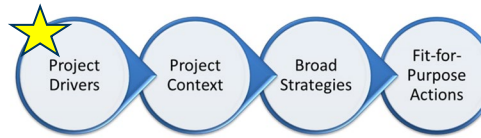
Is there a critical timeline driven by mfg. demands that could lead to inability to supply market (**stockout**)?

Is there an accelerated timeline driven **by Regulatory/gov't requirements** (e.g. the need to add serialization to packages by x date, etc.)?

Is the timeline tied to an accelerated critical **business domino effect** (e.g. moving manufacturing inhouse from a CMO, but internal capacity needs to be created by an accelerated date, or all the dominoes involved will be stopped)

Did Covid have any time pressures?

Cost Pressure Questions



Are **sales** dependent on cost containment? (could be out-priced)

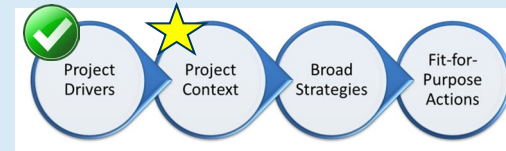
Is there **high intrinsic product or process risk** that could lead to significant cost/loss if there is a failure - keeping in mind phase of development? This could lead to investment to protect long-term ROI.

There is no significant business driver for the project, but is one that **"just needs to be done"**. Therefore, cost containment is key (no real ROI)

Is there a **lack of budgeted money** for the project (product or system) that could lead to business threat if costs are not contained?

Did Covid have any cost pressures?

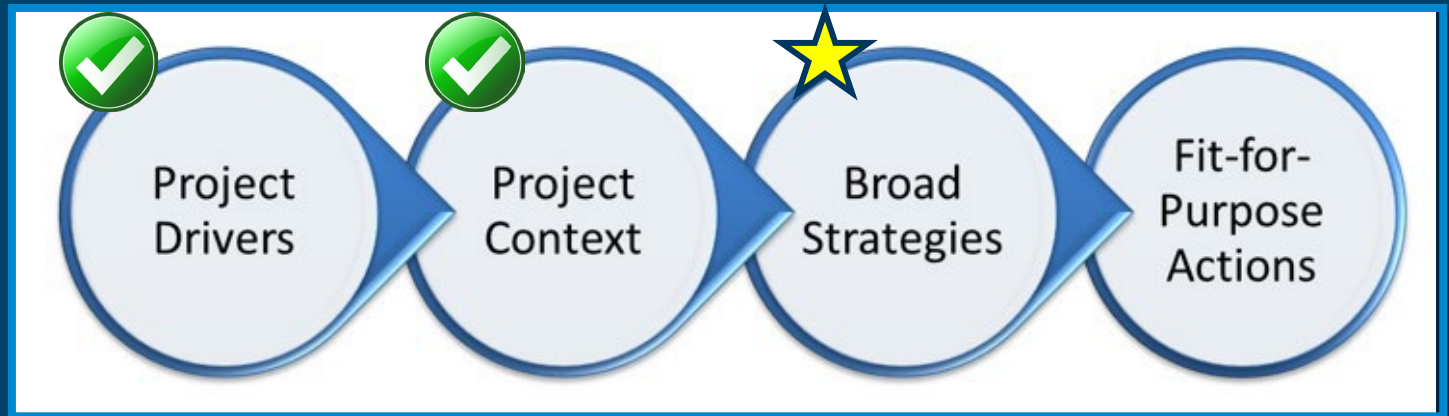
What about the Voice of the Customer?



- Why is this important when you are just trying to get product out the door, or resolve a failure, or implement a new system?
- Well...
 - Who is your customer?
 - When is too much, too much?
 - When is more needed?

*And fold-in the Pressures
You Identified!*

Project Context: take the time to understand what is needed, before you start!



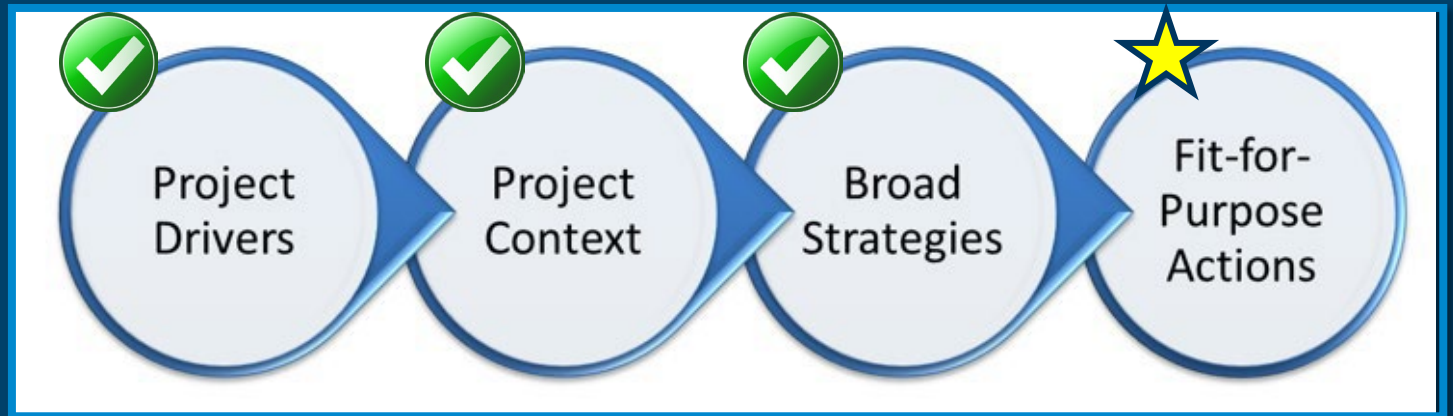
**Now, how would you
operate Differently?**

Examples of Strategy Differences



- Non-Negotiable: Must deliver a compliant product that is safe, effective, and meets intended use
- “Normal State” Strategy is provided in the report for foundation

	Time Pressure	Short-Term Cost Containment	Long-Term ROI
Resources	<ul style="list-style-type: none"> • 100% Dedicated SWAT teams with authority to make decisions and spend money. • Use experts and accumulated knowledge to cut design time - stay with proven design elements where possible • Look for external support to reduce/meet timelines (outsourcing, contractors, etc.) 	<ul style="list-style-type: none"> • Lean Teams - small number of experts (Time is not a factor). • Use shared resources (not charged to project) where possible. • Identify if external partners can result in reduced costs. 	<ul style="list-style-type: none"> • Team to include diverse, experienced team members who can assess future state and needs. • Heavy time spent in planning and optimizing options. • Experienced decision-makers to ensure patience is employed to assess multiple alternatives.
Product Development	<ul style="list-style-type: none"> • Design the product/process such that it is "good enough" for manufacturing suitability and avoidance of risk to the end user. • Post-launch, increase the studies needed to handle larger variability and further understand end user variability. • Start tasks as early as possible, and in parallel 	<ul style="list-style-type: none"> • Design the product/process such that it is "good enough" for manufacturing suitability and avoidance of risk to the end user. • Maximize as much efficiency as possible from company and industry-wide knowledge. • Do as much sequentially as possible to reduce risk of failure/rework/ cost. 	<ul style="list-style-type: none"> • Upfront research to increase input from end user - internal and external (voice of customer) • Research new industry capabilities for line efficiencies, testing efficiencies and waste reduction, etc. • Work is often run in parallel to research all relevant aspects simultaneously, to gain the most long term benefit.



**But what actions
do we take?**

Fit for Purpose Actions



- Actions are available across the Total Product Lifecycle
- Separated actions for product development and system deployment

	Time Pressure	Short-Term Cost Containment	Long-Term ROI
Product Specifications	<ul style="list-style-type: none"> • Key Concept: Determine the "basic" product specifications for teams to just start their work. • Make specs accurate enough to enable intended product functionality [minimum viable product/customer need] and in line with desired Brand <ul style="list-style-type: none"> o Specifications do not get fully approved = iterative process o Mature as you go – make improvements w/each batch/run o Design Space is smaller, since we do not need to study the world of possibilities • Leverage existing product data/studies, established parameters (e.g. shipping conditions, packaging) • Use risk analysis and risk control measures to support more parallel activities while process is evolving 	<p>Key Concept: Avoid Rework; Budget constraints drive all decisions and actions</p> <ul style="list-style-type: none"> • Leverage existing specs, but determine if new studies are needed to support cost containment <ul style="list-style-type: none"> o Focus on the critical only – no unneeded features or future scalability. o Maximize support from the business • Team works to define minimum data requirements based on intended use and to result in process/product success <ul style="list-style-type: none"> o Strip out non-critical elements ("waste"). • Review and approve iteratively to catch any failures fast 	<p>Key Concept: Maximize reduction in long term costs</p> <ul style="list-style-type: none"> • Intensive planning, voice of customer to identify ALL current design constrictions and areas of opportunity and value to invest in long-term cost reduction. Work to increase design space to allow for on-going flexibility without failure. <ul style="list-style-type: none"> o Process mapping to identify ALL current waste, constrictions and areas of opportunity, and value o Clean slate look for innovation/creativity/ blue sky thinking - think E2E solutions that optimize value and return • The innovation is in what is required!! After that, the project should follow normal processes - or may follow Time Critical to shorten the time taken to get to Future state and start enjoying the benefits <ul style="list-style-type: none"> o Consider the future - sustainability, cutting use of resources/materials, protecting the planet, energy use etc. Incorporate some future elements to avoid constant catch up. There is real value in sustainable solutions.

Fit for Purpose Actions



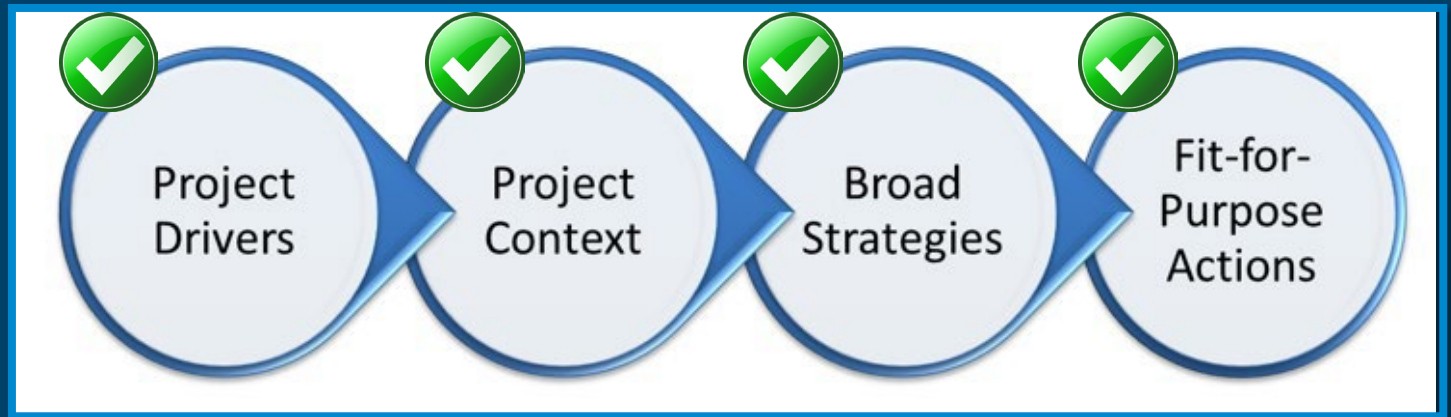
	Time Pressure	Short-Term Cost Containment	Long-Term ROI
Facility/ Equipment Calibration Requirements	<ul style="list-style-type: none"> Facility redesign and new equipment are typically not possible, unless done in advance of this project. Do heavy upfront planning to determine where in the facility (or even which plant site) and which equipment will maximize speed while maintaining regulatory requirements. Stay (where possible) within validated equipment limits/ranges. Pre and Post checks (may not worry about drift over time). <ul style="list-style-type: none"> IQ/OQ – if existing: use as is. If new: do enough in IQ and OQ to support the need. PQ = test at the end (at risk, since failure could result in major project impact. Collect data and evidence over time to make a good risk-based decision, and use prior knowledge to guide input). Maybe check a couple of critical tests to support risk decisions. Keep report writing out of the project timeline. Run in parallel, and/or have non-project team writing the results. 	<ul style="list-style-type: none"> Heavy upfront planning is needed to streamline activities and identify the most effective use of facility and equipment. Determine if current facility is the best option, or perhaps a different plant site or contract manufacturer. Typically not able to purchase new equipment, due to cost constraints. Leverage existing IQ/OQ data/studies and reports. Determine what MUST be studied for PQ. Might need to conduct work more sequentially to minimize risk of failure and rework/discards. Conduct research upfront to assess equipment failure trend analyses to use most consistent equipment possible. 	<ul style="list-style-type: none"> Spend time researching innovative equipment that could introduce automation that reduces manufacturing time long term. <ul style="list-style-type: none"> Identify equipment with faster processing speeds, larger tolerability ranges for component variability, automation, in-line testing, modularity that could make replacement parts less expensive, etc. Potentially need new equipment for larger batch sizes, and possibly additional space for the larger equipment. This would require facility design studies, air flow patterns, workflow studies, etc. Consider impact to Site Master Validation Plan and preventative maintenance program. Does innovative equipment have more expensive consumable parts, need more preventative maintenance, etc.

Fit for Purpose Actions



	Time Pressure	Short-Term Cost Containment	Long-Term ROI
Supplier Qualification	<ul style="list-style-type: none"> • Use existing suppliers even if not qualified on the desired material. Might not have time to research the best supplier that meets time, cost, capacity, experience and quality (and location, etc.). Allow for single source. No time for supplier development - take them as they are. <ul style="list-style-type: none"> o Supplier could go through qualification later as project progresses (for example, might go beyond research-use only) o Could forego a Quality Agreement to get started (especially if there is experience with this supplier), but move forward with PO indicating the desired attributes. Develop the Quality Agreement in parallel. o Build aspects into the contract that result in penalties for delayed shipments. Work to understand how much material is needed, and by when. Have a thought-out inventory/ordering plan to ensure lack of material does not delay the project. Insist on team providing a steady forecast to increase assurance of supply. 	<ul style="list-style-type: none"> • Time to explore which supplier is the best supplier for the work in question. <ul style="list-style-type: none"> • Identifying a new supplier could add cost, unless the new supplier can be used for multiple products, and the cost be shared across multiple projects. • Could have an opportunity to negotiate a better contract. • Ensure the supplier has the capability to deliver what is needed (in spec), at scale, and on-time. Provide long lead times to ensure the material is received before needed. Could work to scale order to receive discounts based on bulk, or ordering same material for other products as well. • Study the material variability and the process capability of the supplier to minimize the impact of the material performance on the final product • If an existing supplier, assess supplier performance upfront to reduce the amount of failures (returning received materials, etc.). Work with supplier to address previously experienced issues/trends. 	<p>Research new suppliers and innovations to identify long term cost savings. New suppliers will need to be qualified, requiring upfront investment.</p> <ul style="list-style-type: none"> • Avoid having a single source to increase leverage and protect the supply chain. • Optimize inventory requirements with the supplier (small lots as needed, versus having to store large amounts). Negotiate options that reduce costs (including having the supplier store in their warehouse, etc.) • Map the entire supply chain to reduce shipping expenses and time - need to assess how many plant sites could use this same supplier. • Identify suppliers that might have innovative packaging that reduces waste, storage space, impact to stability, and even employee time to manage (previous packaging might have required lifting equipment, or was difficult to open, etc.) • Consider suppliers that have cloud access to their manufacturing data that will notify plant sites of issues affecting supply, etc.

Want More?



Register Today!



QMS Agility Model: In-depth “How to” Workshop

September 14, 2023
10:00am – 2:00pm Eastern



QMS Agility Workshop

1. Understand how to adjust your QMS across the Total Product Lifecycle
2. Use the model as a guide to address non-conformances
3. Learn how to use the “Systems” Model for computer system and quality management system deployment
4. And much more...

Case Study examples to prepare you to lead successful deployment in your organization!



Working Time and Discussion

First Ever!

Quality Operations Forum

PURPOSE



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Each Year

Live Network



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- Invite your peers to join initiatives that matter to you



Thank You!

Marla A. Phillips
CEO and President
Pathway for Patient Health
Marla.Phillips@Pathway4PH.org

www.Pathway4PH.org

