

QP Forum 2017

Quality Risk Management & Quality Metrics

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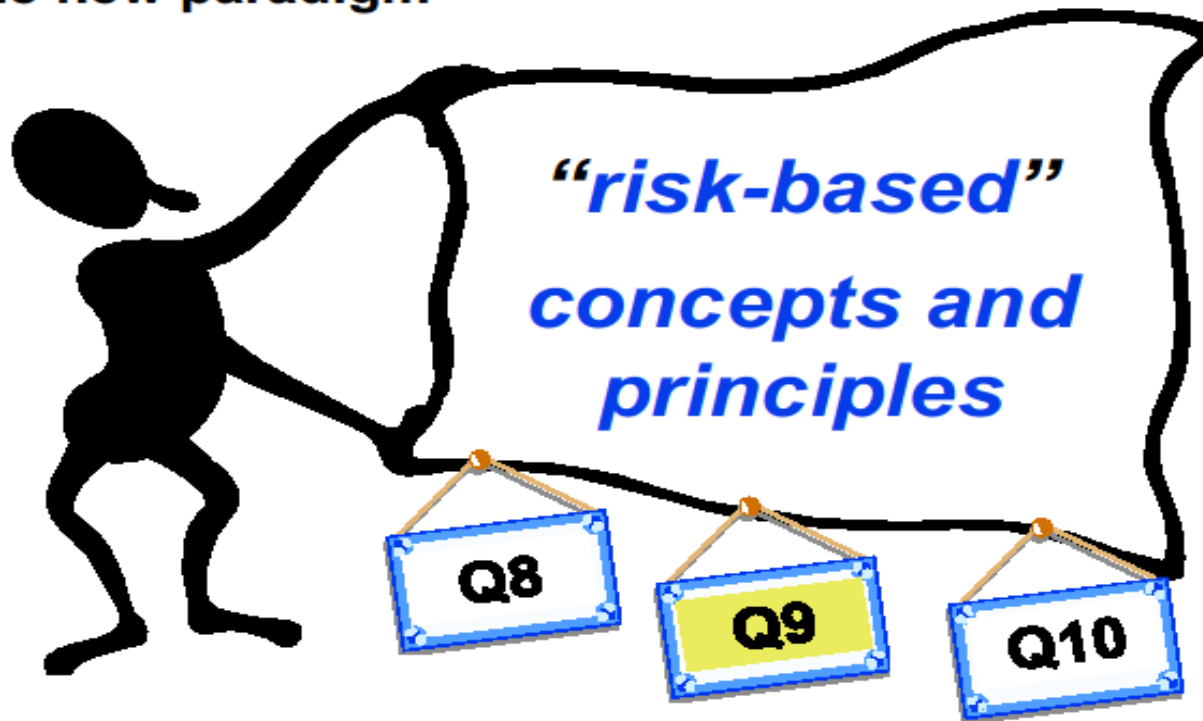
Workshop Content

- Background to QRM & expectations
- Current Expectations of Regulators for Metrics
- Typical Current Metrics?
 - What metrics do we see now?
 - Limitations on current metrics?
 - How to interpret metrics?
- Considerations when designing a Quality Metrics Programme
- Xavier University / PwC Quality Metrics
- Questions received from participants
- Conclusion- What the Future Holds

Executive summary

ICH Q9 QUALITY RISK MANAGEMENT

The new paradigm



Executive summary

ICH Q9 QUALITY RISK MANAGEMENT

Keep always in mind the

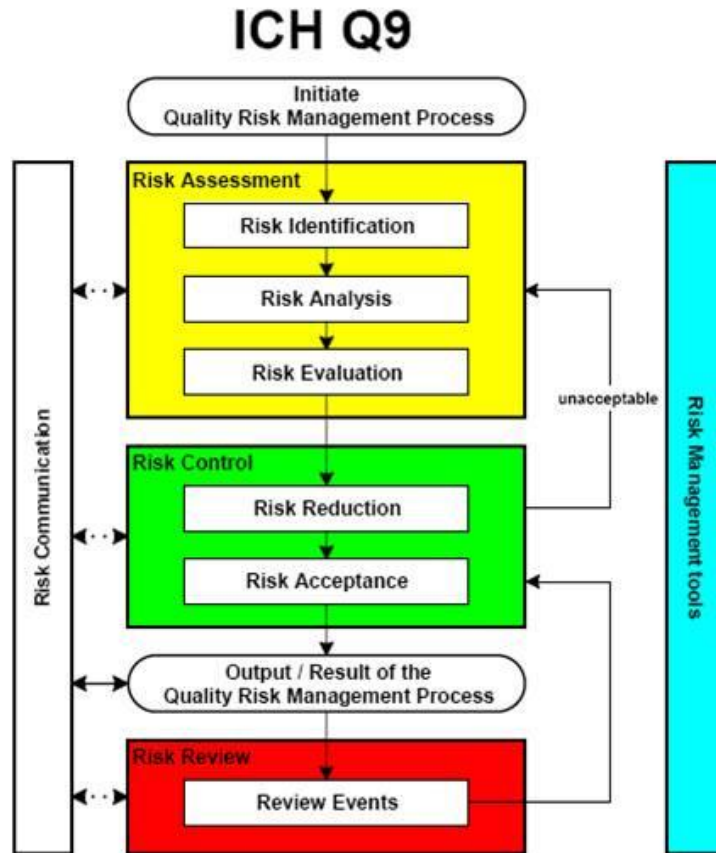
Principles of Quality Risk Management

The evaluation of the risk to quality should be based on scientific knowledge and ultimately link to the protection of the patient

The level of effort, formality and documentation of the quality risk management process should be commensurate with the level of risk

ICH Q9

Quality Risk Management



“A process (includes assessment, control, communication, and review of risk), consisting of well defined steps which, when taken in sequence, support better decision making by contributing to a greater insight into risks and their impacts”

Annex 16- Certification by a QP & Batch Release

QRM Refs

Section 1.5.6: Where sampling is performed at a third country manufacturing site, the technical justification should include a formal **Quality Risk Management** process to identify and manage any risks

Section 1.5.7: Different imported finished product batches may originate from the same bulk batch. The QPs certifying the different finished product batches may base their decision on the QC testing of the first imported finished product batch provided that a justification has been documented based on **Quality Risk Management** principles.

Section 2.2 v: Outsourced activities with critical impact on product quality should be defined in accordance with the principles of **Quality Risk Management**

Section 2.2 vi: Repeated audits should be performed in accordance with the principles of **Quality Risk Management**

Section 3.1: The impact of the deviation should be assessed in accordance with a **Quality Risk Management** process

EU - Quality Metrics

Chapter 1, Eudralex Vol IV (Jan 2013) updated to align with ICH Q10 PQS

- Use of QRM in establishing a **control strategy** for process control & product quality
- Use of tools for **measurement & analysis** of parameters
- Part of **knowledge management**
- Identification of opportunities for potential **continuous improvement**
- EU GMP Chapter 1.4 (viii)
- *“A state of control is established & maintained by developing & using effective monitoring & control systems for process performance & product quality”*

Review by management on a periodic basis:

- Measurement of QMS/PQS objectives
- Assess KPI's to monitor effectiveness of processes such as:
 - Manufacturing processes- SPC
 - Complaints, Deviation, CAPA, Change Management processes
 - Feedback on outsourced activities
 - Self-assessment processes including risk-assessments & trending
 - External audits such as regulatory inspections & customer audits

FDA Quality Metrics

Food and Drug Administration Safety and Innovation Act (FDASIA) 2012

- Gave FDA authority to request data and information from the industry in advance of or in lieu of an inspection to:
 - Identify potential risk for drug supply disruption
 - Improve the efficiency and effectiveness of establishment inspections
 - Improve FDA's evaluation of drug manufacturing and control operations
- Allows FDA to develop a process for resource allocation based on operations of greatest risk
- FDA announced its Quality Metrics Initiative in February 2013 to ascertain data the industry could submit to FDA that would provide an indication of risk to product quality

FDA Request(s) for Quality Metrics

DRAFT Guidance Document – Nov 2016

Voluntary submission by industry of metrics for each product or establishment to allow FDA calculate:

- Lot acceptance rate
- Product quality complaint rate
- Invalidated out-of-specification rate

EU - as yet no formal position on the FDA approach but EMA are very interested in starting a healthy international debate on metrics

- Eudralex Vol. 4 part 1 Chp.II: “the correct manufacture of medicinal products relies upon people” - again linking to Quality Culture and assessment (e.g., detecting problems, ensuring ownership, ability to adapt, investing in quality....)

*Ref. presentation by Judith Fernandez , EMA, 26 Nov 2015, Berlin, Germany
Title: EMA Perspective on Quality Metrics – Risk Based Inspections*

ISPE Quality Metrics Initiative: Pilot Program (Wave 2) – June 2016

ISPE is supportive of starting with 3 of the proposed metrics

- Lot Acceptance Rate (report by site, differentiated by product)
- Product Quality Complaints (report by product only)
- Invalidated OOS (report by site)

ISPE recommends to defer as potential future metrics or data points

- APR on Time Rate and Optional Metrics
- “lots pending disposition for over 30 days”

Start with reporting consistent with current industry practice

- May reduce burden for start up of program

Preliminary results from ISPE Pilot Wave 2 included in response to FDA

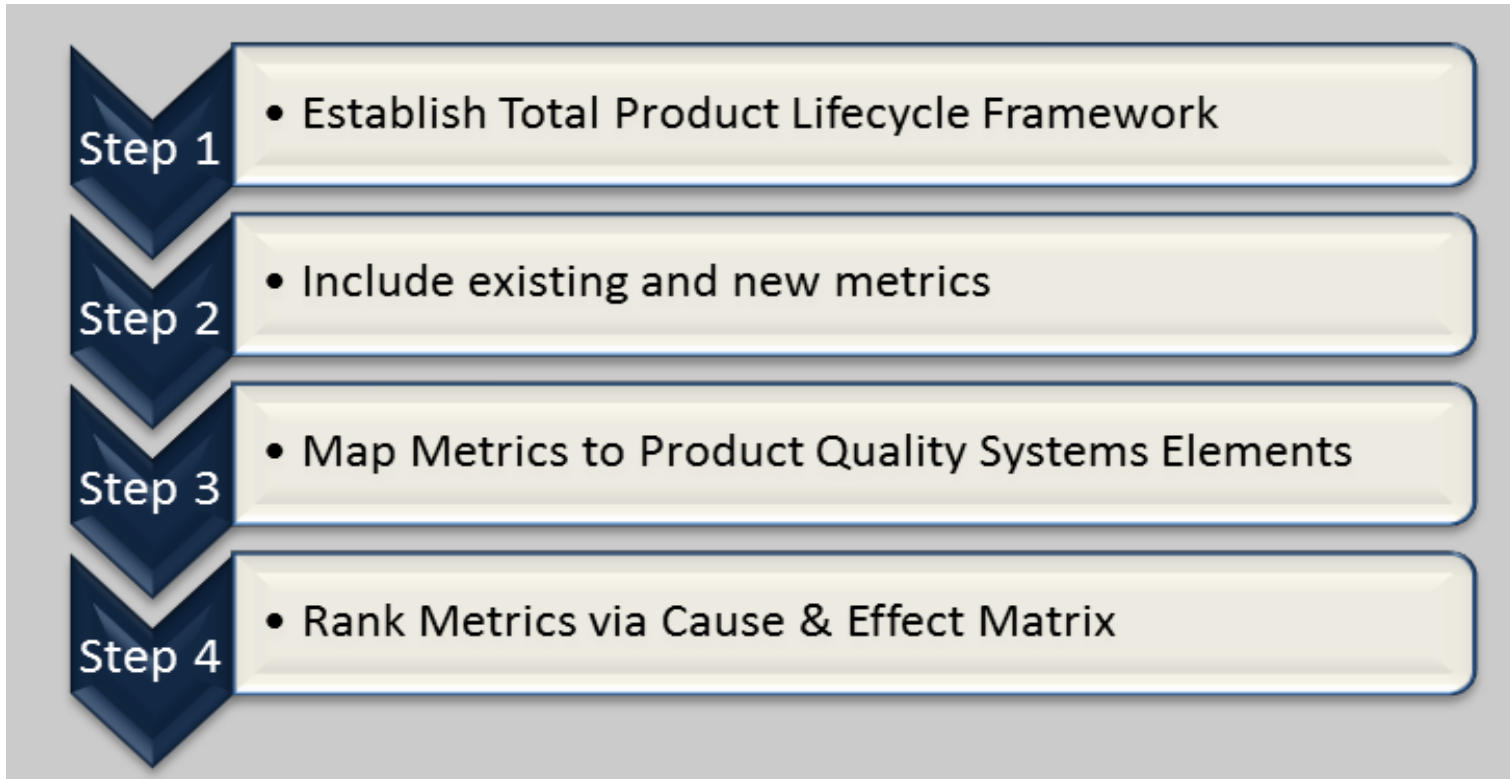
Anticipate costs for firms

Xavier University/PwC Quality Metrics

1. To identify metrics that would enable the industry and FDA to understand proactively the risk to product quality
2. To assess risk to product quality across the total product lifecycle to drive a mindset of designing quality in products at the source
3. To provide FDA information to assess during an inspection and, therefore, review in context.

Reference Xavier University/PwC Pharmaceutical Quality Metrics White Paper (January 2016)

Xavier University/PwC Metrics Initiative



Ref: Xavier University/PwC Pharmaceutical Quality Metrics White Paper, Jan 31 2016

Xavier University/PwC Final List of Proposed Metrics

Total Product Lifecycle Phases	Proposed Metrics
Pre-Production	1. Design Space
Technology and Knowledge Transfer	2. Supply Chain Assurance
Production	3. RFT of Analytical Method Transfer
Production	4. RFT of Process Validation
Production	5. RFT for Production
Production	6. CAPA Effectiveness Rate
Production	7. Commitment Index
Production	8. Supplier Risk Index
Post Production	9. Market Reliability Index
Enterprise-wide Continual Improvement	10. Quality by Design Effectiveness
Enterprise-wide Continual Improvement	11. Root cause analysis of the Production RFT metric

Quality Metrics

What do we see currently?

What Quality Metrics do you see

Typical Measurements

- **Deviations:**

- Days to closure
- % overdue? (>30 days)
- Number deviations raised per month/year/area/product
- Number Major vs Minor

- **CAPA:**

- Number CAPAs
- On-time closure
- CAPA effectiveness

- **Batch Release:**

- Release time – turn around time by QP
- Number batches reviewed
- % Right First Time
- Number batches rejected

- **Change Control:**

- Number change controls
- Number change controls open > 1year

- **Customer complaints:**

- Number complaints per quantity of product released

What do metrics like these tell us?

Do they help to :

“monitor quality control systems and process and drive continuous improvement” ?

Request for Quality Metrics – Draft Guidance for industry FDA

If so – how???

Example:

Deviations:

What does the number of deviations tell us?

When is ‘how many’ a useful measure?

What about the context?

Pitfalls with Metrics

Focus on numbers e.g. number deviations opened/ closed in a given time period

- Don't focus on risk across product lifecycle to drive Quality by Design

Focus on lagging metrics and less on leading metrics

- e.g. Right-First-Time

Non-standard & non-transparent metric calculations makes interpretation challenging

Don't provide framework for regulators to assess data

Currently don't measure quality culture!

A/PQR – a QRM tool, if embraced from this perspective!

- Compiled annually for purpose of Quality Management Review
- PQR reviewed up front in EU inspection

What KPI's drive Quality

Example of typical metric: [Deviations Closure Time](#)

Industry Standard and expectation is 30 days from date of initiation

How does meeting this KPI impact quality? Positive or Negative?

Positive:

- Timely investigations to allow people to remember the issue accurately
- Eliminates resource requirement in 'chasing' aging records

Negative:

- Rushed investigation to meet the deadline and as a consequence, not getting to true root cause
- Risk of repeat deviations

Number of Deviations

What does a 'high' number tell us?

Positives

- Good culture of reporting issues
- Root causes can be identified, trended and CAPAs can be put in place
- Trending of root cause can help identify CI initiatives

Negatives

- Systems out of control
- Culture of 'asking forgiveness' rather than permission (planned deviations)
- Low threshold for raising 'issues'
- Complex systems – difficult to follow

Change Control

What does a 'high' number raised tell us?

Positives

- All changes are properly assessed
- Progressive company embracing change
- High level of control

Negatives

- Lack of control – constant change
- No steady state
- Lack of decision making – goalposts keep moving

QP Turnaround Time

What does it tell us?

Positives

Short review time:

- Controlled system
- Only key areas being examined

Long review time:

- QP doing very thorough review

Negatives

Short review time:

- QP not looking deep enough

Long review time:

- QP finding 'issues'
- Uncontrolled system – loss of trust

So what does this tell us about metrics?

- Metrics are just numbers until they are interpreted
- They are statements of FACT
- However, the FACTS around the FACTS are that they are open to interpretation depending on what story you want to tell

Example:

2015: 1020 deviations raised

2016: 848 deviations raised

Is this a 20% improved performance? Maybe!

The 'NUMBER' can raise more questions than it answers

- Was there an intervention to deliver the 20% 'improvement' or was it just 'luck'?
- Was there a change in the reporting criteria – e.g. was an event that was considered a deviation last year 're-categorised' – i.e. is it now called something else?
- Is the improvement reflected in other indicators? – faster batch release for example?
- How a number is interpreted can depend on the audience.....

Essentially – metrics as we typically see them in the pharma industry are

BUSINESS METRICS

- They can be useful in a Quality context when they are **TRENDED**
- For trending to be useful – the measurements must be consistent – i.e. don't change the goalposts mid trend!

How will FDA expectations impact Metrics

- FDA want to use “quality metrics” for risk based inspection scheduling and predications of drug shortages
- Is this a realistic aspiration? It looks logical on the face of it – but where are the pitfalls?
- FDA are depending on corporate reporting of company ‘quality metrics’ –
 - Do all companies measure the same thing?
 - Even within any one company there may be several sites with different complexity so are metrics comparable INTER company – not to mention INTRA company?
- Will sites submit metrics individually – or at a corporate level?
- When is more appropriate to report metrics per site vs per product?
- Are the FDA prepared for the flood of ‘numbers’ they are likely to get?
- How will they be interpreted?
- The draft guideline states that “*The information collected should verify that the quality attributes are being appropriately controlled throughout the process and determine if the specifications, manufacturing or control procedures should be updated or improved*”
 - Are these the metrics you measure? Is this what they tell you?

Designing an Effective Quality Metrics Programme

Some Considerations!



The Big Picture of Metrics

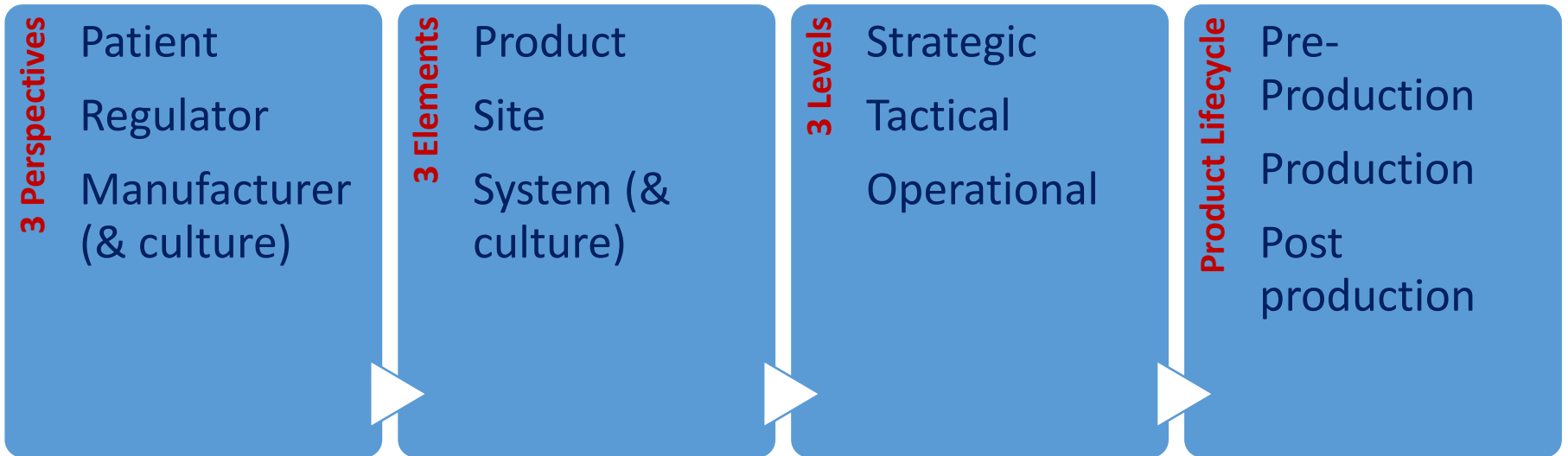
Metrics are hierarchical, should be structured, cascaded, aligned and interlinked with the end-to-end product life cycle processes

Incorrect measuring will lead to undesired behaviour

- **Leading Metrics (process indicators) for targeting of strategic goals and objectives:**
 - Objective: Measure process improvements as indication of achievable business goals
 - Enablers: Risk Management and Knowledge Management
- **Lagging Metrics (results indicators) for continuous performance measurement:**
 - Objective: Tactical tool for quality planning and management review.
 - Reveal opportunities for improvement
- **Problem metrics for reactive operational use:**
 - Objective: Compliance/safety critical, CAPA initiation

Henny Koch; 'Assignment of Metrics and Correlation with Process Controls'

Points to consider when developing Transformative Metrics and KPI's



Development of Metrics – Some considerations!

Select right Metrics

- Based on organisational goals and objectives for quality

Define Metrics

- One full sentence with verb e.g. percentage of third parties CAPAs completed no later than planned completion date

Set Targets

- Aligned with goals and objectives
- Set baseline after collation of data
- Consider 'SMART - A' targets: Specific, Measurable, Attainable, Realistic, Time-bound, Aligned

Rolled up Metrics

- For example CAPA timeline is the sum of performance of each departments' results
- Apply weightings

Maintain Metrics

- Is it performing as intended?
- Change with caution!

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Pre-Production

Design Space

of projects completed with scientifically justified predefined ranges¹ x100

Total # of projects completed

¹for CPPs, CMAs and CQAs

Supply Chain Assurance

of Tier 1 suppliers² approved through cross-functional review x100

Total # of Tier 1 suppliers in the supply chain for the product in question

Number of Tier 1 suppliers approved through cross-functional approval to ensure internal alignment against all critical success factors.

² Tier 1 suppliers = API, Excipients, Primary Packaging Components

Transfer Metrics

Process Validation RFT

- % process validation batches without deviations related to product & process development

$$\frac{\text{\# of process validation batches without product/process related deviations}}{\text{Total \# of validation batches attempted}} \times 100$$

Analytical Method RFT

- Measure of the % of analytical methods transferred without analytical method development deviations (planned & unplanned)

- **RTF**

of analytical methods transferred with no method related deviations x100

Total # of transfer attempts per product

Production Metrics

RTF during Production

- A measure of % of batches without potentially product impacting deviations, investigations, OOS results, or unplanned rework or rejections. Recommended to calculate by product and by site.

of batches or lots without deviations x100

Total # of batches or lots attempted

CAPA Effectiveness

- A measure of whether actions taken as a result of problems/issues encountered have effectively addressed the deficiency and prevented recurrence

of successful effectiveness checks x100

Total # effectiveness checks attempted

Production Metrics ⁽²⁾

Commitment Index

- A score that measures the commitment of a company/site to a culture of quality through capture of performance related to on-time completion of requirements associated with regulatory/industry expectations.
- Includes the assessment of a core group of metrics that can be modified (including the timeframes) or removed per company/site if that activity does not apply to that company/site: e.g.
 1. **Investigations** – # closed in ≤ 30 days per month vs total # closed per month x100
 2. **Customer Complaints** – # closed in ≤ 45 days per month vs total # closed per month x 100
 3. **Regulatory Commitments** – # commitments completed on or before the original commitment due date per month vs the total #
 4. **CAPA; APQR; GMP Training; Audits; PM/Calibration**

Production Metrics (3)

Commitment Index contd

This metric also has flexibility on how to weight each term

(Investigations x 0.2) + (Customer Complaints x 0.2) + (CAPA x 0.1) +
(Stability x 0.1) + (Training x 0.05) + (Audits x 0.05) + (PM x 0.05) + (Reg.
Commitments x 0.1) + (Revalidations x 0.05)

Supplier Risk Index

- Assessment of supplier risk based on qualitative and quantitative factors, such as level of concern related to performance, audit findings, geographical risk, leverage, capacity, and status of necessary agreements
- Includes existing Tier 1 suppliers, such as:
 - API
 - Excipients
 - Primary packaging components
 - Contractors (manufacturing, laboratory, packaging, logistics)
- All to be measured using a scale: 0,5,10 (where 10 is good):
 - A. Level of confidence, as measured by complaints related to the supply in a given time period based on # of lots received
 - B. Level of confidence relative to audit/regulatory findings in a given time period
 - C. Necessary agreements are in place
 - D. Sufficient capacity and/or redundancy such that risk of a shortage is lowered
 - E. Level of confidence relative to geographical risk
 - F. Level of confidence related to company's leverage and supply stability
 - G. Level of confidence in track record of the supplier

Supplier Risk Index (2)

Formula: $A+B+C+D+E+F+G < 70$

- 60-70: No action required, assuming all responses are 5 or higher
- 40-55: Cross-functional assessment of mitigation strategies
- 20-35: Cross-functional escalation of risk awareness, assessment of supplier alternatives and mitigation strategies, heightened involvement in supplier operations and oversight.

Post-Market Metrics

- An overall product confidence score established on a roll-up of the post-market surveillance data including: complaints or unexpected trends that triggered action, adverse events, stability failures, drug shortages, field alerts, and recalls.
- $(100 - \% \text{ Customers Complaints}) \times 0.15 + (100 - \% \text{ Adverse Events}) \times 0.15 + (100 - \% \text{ Drug Shortages}) \times 0.30 + (100 - \% \text{ Field Alerts}) \times 0.20 + (100 - \% \text{ Recalls (will intentionally include those issues already captured in Field Alerts)}) \times 0.20$
- This metric takes into account double counting of certain items. For example, an Adverse Event will have a complaint associated with it.
 - By allowing Adverse Events to be double counted, it places more importance and weighting on Adverse Events, essentially weighting it more than the proposed 15%.

Enterprise-Wide Continual Improvement Metrics

Right First Time Rate for Production

- Metric taken directly from Right First Time during Production (see earlier)

Quality by Design Lifecycle Effectiveness

- An assessment of all failures related to product, process and supply chain that are attributed to development and transfer.
 - Examples include: changes, complaints, FARs, recalls, poor Cpk, poor yield, stability failures, inadequate material characterisation, product failures
- Calculation of % scores for each KPI selected
- Sum of the values of % score for each follow through score x its weight factor
$$(100 - \% \text{ Customer Complaints}) \times 0.25 + (100 - \% \text{ Process Capability}) \times 0.25 + (100 - \% \text{ Stability Failures}) \times 0.25 + (100 - \% \text{ Product Failures}) \times 0.25$$
- An assessment of the root causes and trends is critical for enterprise-wide learning, and is to feed back into R&D and Production as appropriate with triggers for action.

Quality Culture Metrics?

Planned Maintenance Rate

- (# orders planned / total orders) x100

Unplanned Maintenance Rate

- (# unplanned orders / total orders) x 100

Employee Turnover Rate

- (# / av. headcount of start & end of time period) x100

Training Metrics

- On-time
- Prioritised per role

Human Error Deviations Rate

- (# with HE as root cause / # closed) x 100

Deviations with no assigned Root Cause Rate

- (# with no assigned RC / total # closed) x 100

CAPA re Internal Audit Findings

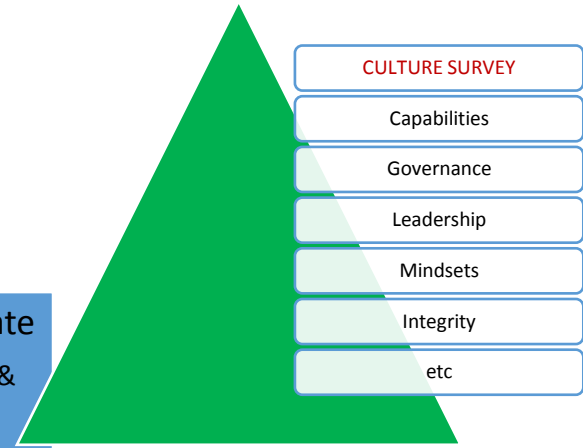
- CAs & PAs closed on time
- CAPA effectiveness

CAPA re Supplier Audits

- CAs & PAs closed on time
- CAPA effectiveness

CAPA requiring Retraining Rate

- (# CAPAs requiring retraining / total # CAPAs) x 100



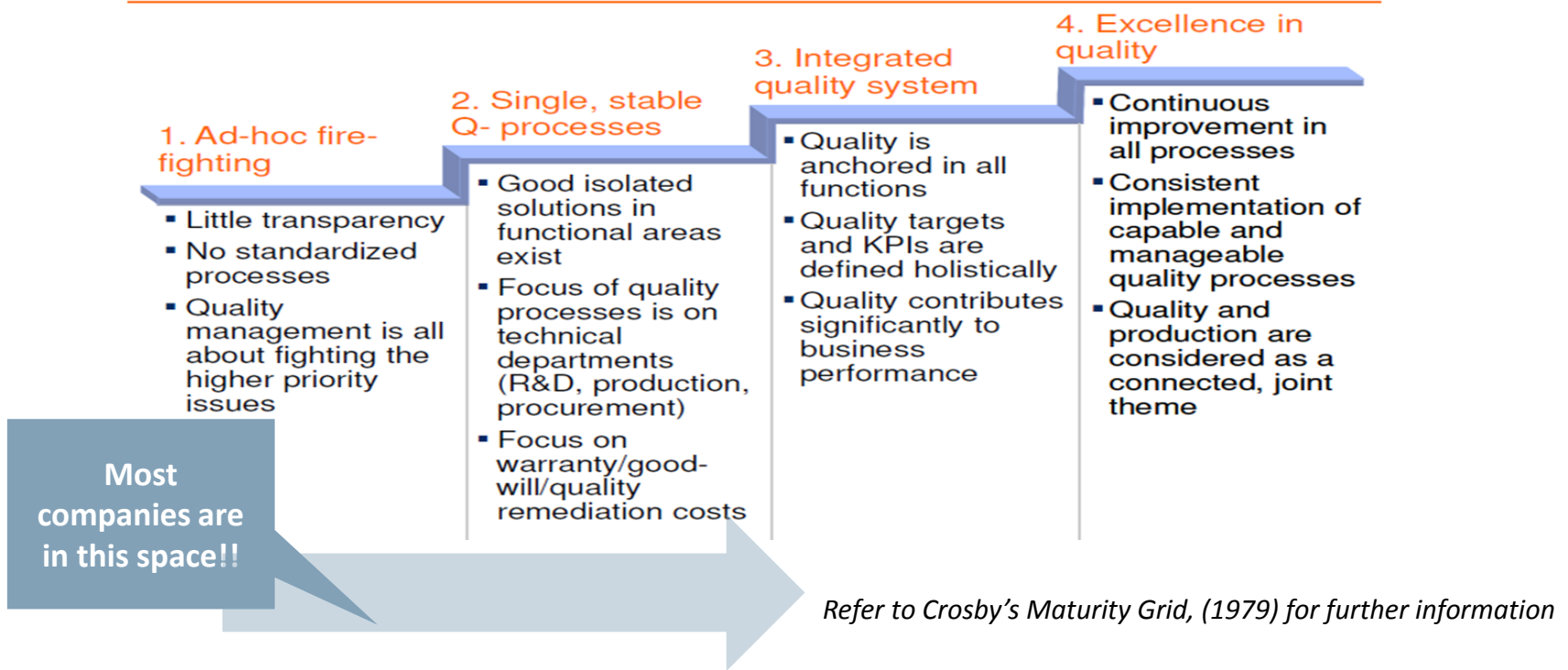
Participant Questions – Question 1

What are the expectations for Quality System integration? What does good integration look like for deviation management, change control, complaints etc?

- ‘Doing’ QRM vs managing product related risks!
- A well-defined QRM governance system
- ICH Q9 process built into each of the system elements
 - Risk/ impact assessment; risk acceptance or mitigation; risk communication; risk review;
 - Communication as a process
 - Proactive/ prospective risk evaluations of systems & processes
 - Know where risks lie & re-assess as part of issues arising, planned changes & routinely periodically
 - Know risk controls & track effectiveness of the controls
- Knowledge management
 - Identifying critical information types & sources
 - Capturing the information in a structured manner
 - Managing the information under Documentation Mgmt system

Quality Maturity – Where are you?

Quality maturity is often measured along four stages



Companies can develop roadmap(s) to outline their journey (including milestones and targets) to achieve Excellence – short, medium, long term plans

Participant Questions – Question 2

Leading metrics vs Lagging metrics. Meaningful metrics in the virtual pharma world?

- Leading vs Lagging metrics
 - Definitions - refer to slide deck
 - Examples – covered in session
- Meaningful metrics – covered in session

Participant Questions – Question 3

Closure risk assessments' appropriate to use? Should it be carried out in conjunction with a formal risk assessment or can it be used as a stand alone? Formal vs informal assessment?

- Tools to perform RA to be selected by the users
 - Appropriate to the type of RA required
 - Refer to ICH Q9 toolbox for guidance
- No clear definitions of formal vs informal RA
 - Refer to PDA Ireland website – QRM Seminar 20 March & next slides

Q3- Closure Risk Assessments

- Understand question relates to RA for NPI
- Definition?

“Closure analysis is a tool used to demonstrate that a manufacturing process and or equipment are designed to provide adequate protection from the surrounding environment.

We use process flow diagrams to break down the manufacturing process and identify key unit operations also utilising risk ranking and fault tree analysis tools to assess the closure of the system with the process requirements to determine a risk class, and this determines if mitigations are required to close the system.

We use this tool at NPI stage but as it is a very unused tool I was wondering what other tool could be used which would be more beneficial and more well known?”

Q3- Response

- Use a set of tools appropriate for the task
 - Don't use a hammer to crack a nut if you have a nutcracker!
- For NPI:
 - Perform a high level Gap Analysis against the design philosophy
 - Risk assess unit operations in the context of:
 - Facility design –HVAC, clean utilities, cleaning
 - Flows of people, materials, waste, equipment

PHA toolbox (process hazard analysis)

- HAZOP
- HAZOP/FMEA combined
- FTA (Fault Tree Analysis)
- ETA (Event Tree Analysis)
- PHR (Process Hazard Review)
- RR (Relative Ranking)
- Checklists
- What-if/ What-if Checklists
- LOPA (Layer of Protection Analysis)

Formal QRM

PDA Ireland, QRM Seminar Output 20 Mar 2017

Systems focused rather than on evaluating risk of individual events

Structured – SOP & Tools

- Risk Assessment (RA) vs Root Cause Analysis (RCA) Tools?
- Strong RCA supports RA

QRM is integral part of PQS. Key elements:

- Escalation process
- Management Review as a QRM tool
- APQR as a QRM tool

Formal QRM

PDA Ireland, QRM Seminar Output 20 Mar 2017

End-to-End process

Structured Governance

Communication element – embed into each element of QRM process

Risk outputs end up in Risk Register

Informal QRM

PDA Ireland, QRM Seminar Output 20 Mar 2017

Event focused rather than system based risk management

Stand alone risk assessments

Formal vs Informal QRM

PDA Ireland, QRM Seminar Output 20 Mar 2017

Could 'Rigour' be used as a means of differentiating formal & informal QRM?

Risk Assessment element of QRM Process

PDA Ireland, QRM Seminar Output 20 Mar 2017

Formal & Informal

- Use of a facilitator as required
- Multi-functional team as required
- Shop floor evaluations work well; don't always need meeting room events
- Documented process – different levels of formality as appropriate
- Training in the conduct of RA is key
 - Training in tools as required

What does the Future Hold?

Present and Future Expected Developments

- Traditional GMP and QA have now evolved into the overall **Pharmaceutical Quality System**
- **Lifecycle Approach** – Quality embedded from development through to post-marketing and ongoing monitoring (note upcoming ICH Q12)
- Active **CAPA** and **CAPA effectiveness** management
- Supply chain and distribution - controls and oversight
- **MA Compliance** – transparency for manufacturing sites
- **Data integrity**



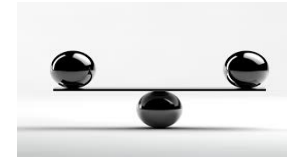
Present and Future Expected Developments

- **FDA & EMA may request quality metrics**
 - Further transitioning from a reactive to proactive quality culture
- Further use of quality metrics to ensure **reliable, consistent processes**
- More electronic systems **are now generating metrics**
- **Quality Management Review** – metrics play a key role to help identify risks and challenges and to ensure improvement planning and delivery of actions



Current Challenges within the Industry

- **Balance time to generate sufficient metrics with time for action**
 - Visual information adequate to drive action
 - Not overloading people with metrics
 - Less may be more !
- **Optimising teamwork and partnership**
 - Quality personnel interacting from development through the product lifecycle to pharmacovigilance (looping back)
- **LEAN programmes** - building in the 'pillar of Quality'
- **High business pace** – challenge to get products to market, even faster
- **Process mapping skills** – adequate to achieve the best outputs
- **Time to allow adequate QbD** during product development



Current Challenges within the Industry

- **Use of trends and statistics**
 - Trained personnel, adequate skills
 - Understanding the limitations
 - How much is enough?
- **Skills for process mapping and problem solving**
 - Not wasting too much time mapping– plan so adequate time for ‘action’
 - Ensuring the right improvement actions are identified
- **Awareness of process demands downstream and upstream from you**
 - Not just measuring process performances in isolation
 - Awareness of existing or other data, so not duplicating data
- **Adequate risk assessment skills**
 - Qualitative vs quantitative approaches
 - Knowing the limitations, ensuring the right people inputs



Current Challenges within the Industry

- **Continuous Process Verification, PQR and Quality Management Reviews – connecting data**
 - Optimising data generation and review processes so that they are action focussed and drive real improvements for the overall business

- **Establishing the best system for sharing of metrics**
 - Visual systems
 - Adequate information for internal personnel
 - Also facilitating visitors and inspectors!



Effective Quality Metrics - Benefits



- **These assist the delivery of improved performance**
 - Corporate quality goals cascading through the organisation - systemised
 - Small number of key metrics to highlight overall quality performance at corporate/senior level

- **Real risks are visible, leading to adequate improvement plans**

- **Highlight opportunities for improved resource management**
 - Metrics are established for key activities which are absorbing resources
 - Measure performance of Quality departments along with operational departments – fair is fair !

Benefits of Effective Quality Metrics

- **Help to increase personnel engagement with Quality improvement agendas**
 - Performance awareness can lead to the right behaviours and interest
 - Invite departments to Quality review sessions and ensure data speaks!
 - Promote Quality and consider running awareness campaigns
 - Ensure Quality performance is communicated within operational metrics
 - Operational departments also present Quality metrics/improvement plans

- **Can lead to reductions in test levels and other controls – cost saving**
 - Decreased frequencies/sampling levels for example

- **Can help to reduce quality defect levels – know where there is waste**
 - Some Authorities highlight that despite QA and Quality System developments, levels of quality defect are still perceived to be high

- **Help to identify business areas worthy of future investment**
 - supporting the journey towards operational excellence



Tips to Aid Effective Quality Metrics and Use

- Clear roles/responsibilities** - for metrics preparation and improvement actions. Ownership of metrics
- Review the right performance data, at agreed frequencies**
 - for example, at least weekly at operational level
 - 'stand around' meetings at visual boards, action focussed
 - enable performance discussion and dialogue
 - boardroom vs "go see" and walkabouts
- Perform data benchmarking** across sites, within industry
 - to drive and maintain momentum
- Recognition and reward**
- Ensure quality metrics are linked to business plans**
- Use metrics to build standard processes with standard times**



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Quality Metrics

Some final food for thought....!

*You get what you inspect,
not what you expect...*



Is it wise to “ass.u.me” ?



Good data speaks !

Acknowledgements

- Marie O'Callaghan, Sanofi, Waterford
- Team at MPI

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