

# Integrating QRM & Reliability to enhance our P's (*P*revention, *P*rediction, *P*roactivity, im*P*rovement, within *P*rojects/*P*rograms and o*P*erations)

Hosted by:

**Gary Power**, Director of Engineering, Global Asset & Reliability Management, MSD  
**Marcus O' Mahony**, Senior Research Fellow in Pharma Manufacturing at the PMTC, UL

## “Delivering Value and Resilience using QRM”



PDA CHAPTER OF THE YEAR



# GARY POWER

Gary Power is a Director of Engineering and is leading MSD's Global Asset & Reliability Management Centre of Excellence (CoE) Team for capital projects within the EMEA/AP region and sustaining asset management CoE activities for several MSD biopharmaceutical facilities in Ireland. He is a subject matter expert providing leadership and support in the areas of asset management, risk management, maintenance, and reliability for MSD's manufacturing facilities across the EMEA/AP region. Gary has held various positions in engineering, project management, network risk assessment, reliability, and process engineering with several pharmaceutical companies prior to joining MSD, including Sanofi (formerly Genzyme) and Pfizer (formerly Wyeth).

Gary's current responsibilities include supporting the linkages between quality risk management (QRM) and equipment reliability, working with global teams across MSD to ensure equipment performance is contributing to product supply. He is also interested in the strategic approaches within organizations in the transition to becoming high performing organisations (HPOs), through the application of established best practices, change methodologies and practical experiences. Gary is currently pursuing part-time doctoral studies at Dublin City University Business School in organisational behaviour and has presented his research to date in universities and conferences in Ireland, the U.S., Belgium, the Netherlands, Denmark, and the UK.



## **QRM and Reliability**

**Gary Power**  
**Director, Engineering**  
**EMEA/AP CapEx & Ireland OpEx Lead**  
**Asset & Reliability Management Centre of Excellence**  
**Global Engineering Solutions**  
**MSD**



## QRM and Predictive Approaches

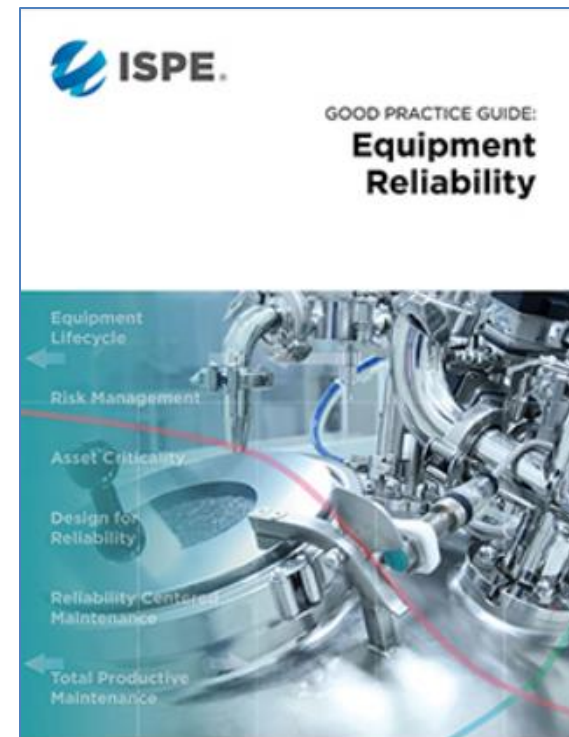
Marcus O'Mahony, PhD  
Senior Research Fellow,  
PMTC  
University of Limerick

# Objective of this session:

- Align ourselves on Equipment Reliability and Reliability Programs.
- Discuss Equipment Reliability and its connection to QRM.
- Open discussion on integrating QRM & Reliability to enhance our P's (**P**revention, **P**rediction, **P**roactivity, im**P**rovement, within **P**rojects/**P**rograms and o**P**erations)
  - Capturing:
    - *Challenges*
    - *Current State*
    - *Future Work*

# What is Equipment Reliability?

Equipment reliability is **concerned with the risk of failures in equipment and processes, providing focus on equipment availability, fitness for purpose, and cost.** The strategy and tactics of reliability contribute to realizing the value of equipment throughout its useful life and mission.



ISPE (2020). Good Practice Guide: Equipment Reliability. [Good Practice Guide: Equipment Reliability | ISPE | International Society for Pharmaceutical Engineering](#)

# How Equipment Reliability contributes to goals & objectives of various groups

**Operator** – Works like it's supposed to and doesn't break down.....

**Engineer** – Remains within process parameters during operations.....

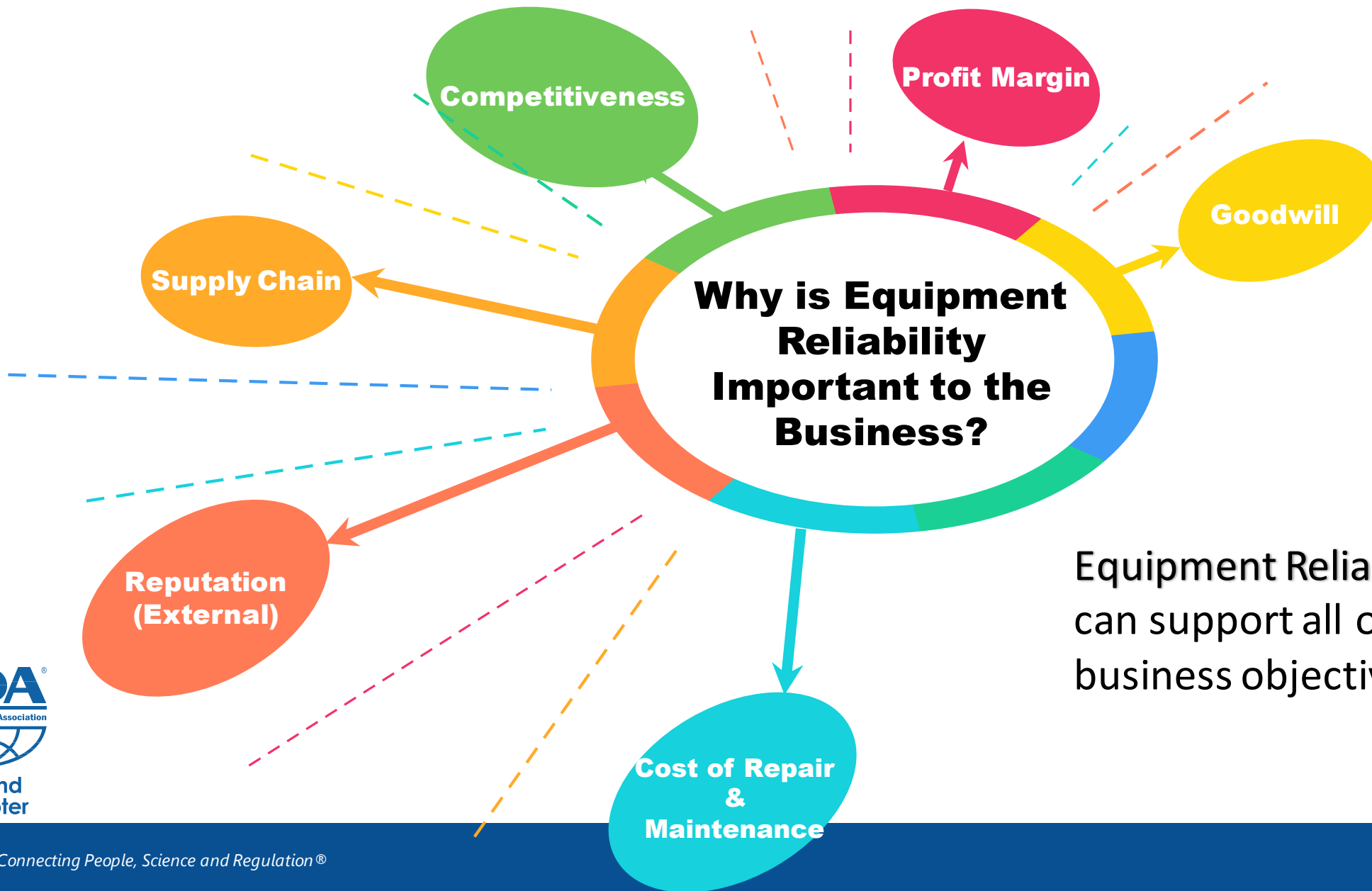
**Equipment Reliability** describes the likelihood of equipment to **continue to do what its users require in its present operating context....**

**EHS** – A reliable site is an enabler for a safe site....

**Quality** – Provides product of consistent and acceptable quality...

**Manager** – Doesn't cost a lot and will contribute to business objectives...

**Maintenance** – Doesn't require a lot of repairs....



Equipment Reliability Programs can support all of these business objectives

# Risk activities at organisations

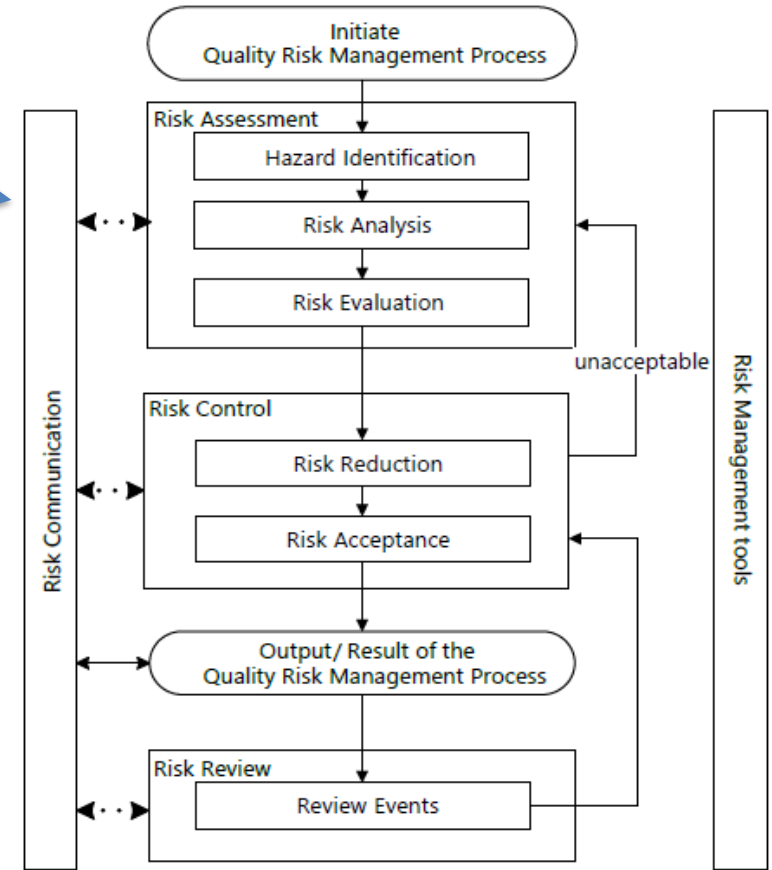
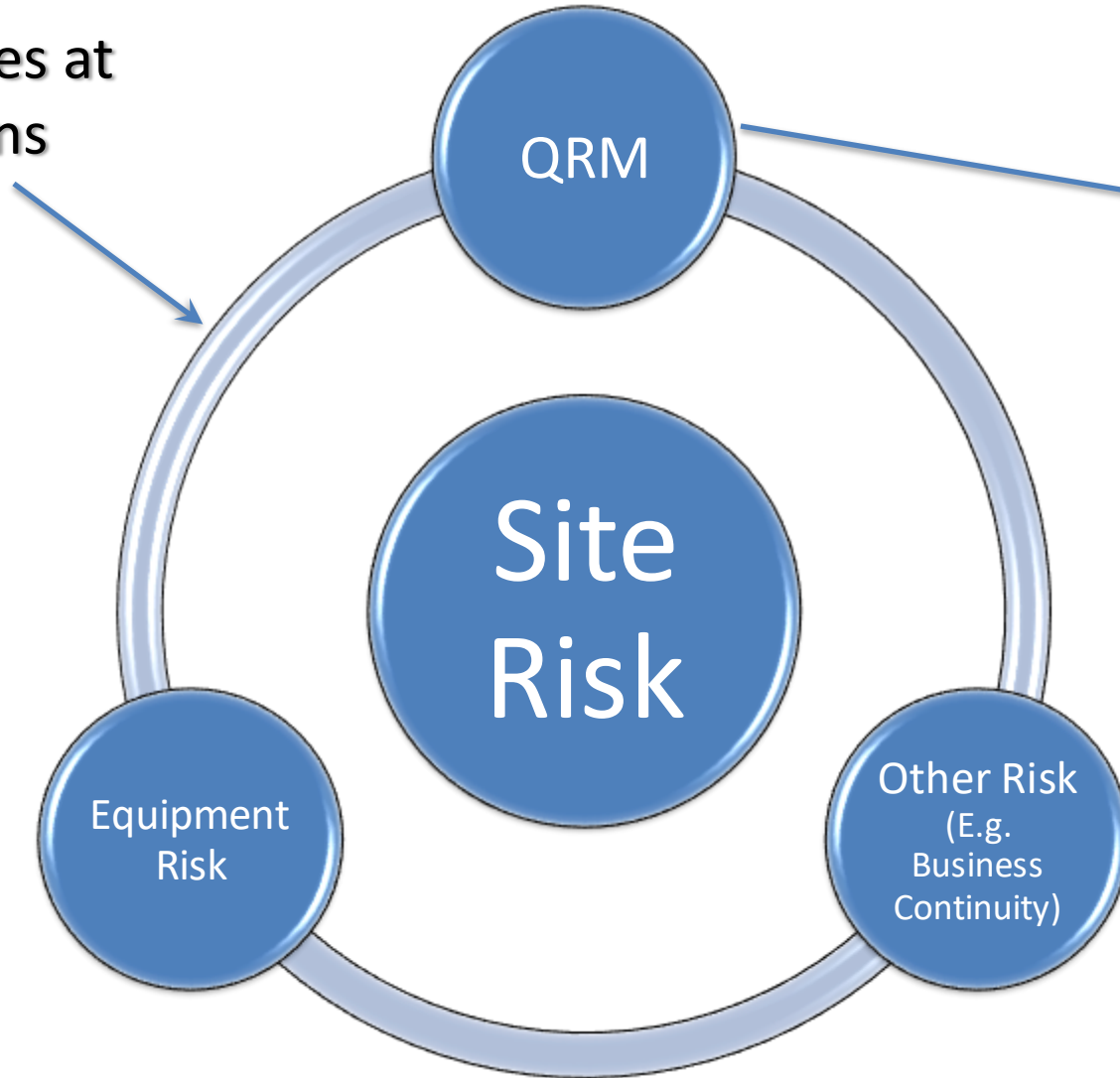


Figure 1: Overview of a typical quality risk management process. ICH Quality Risk Management, Q9.



Are there opportunities for connecting these in a more streamlined manner?



# Risk activities at organisations

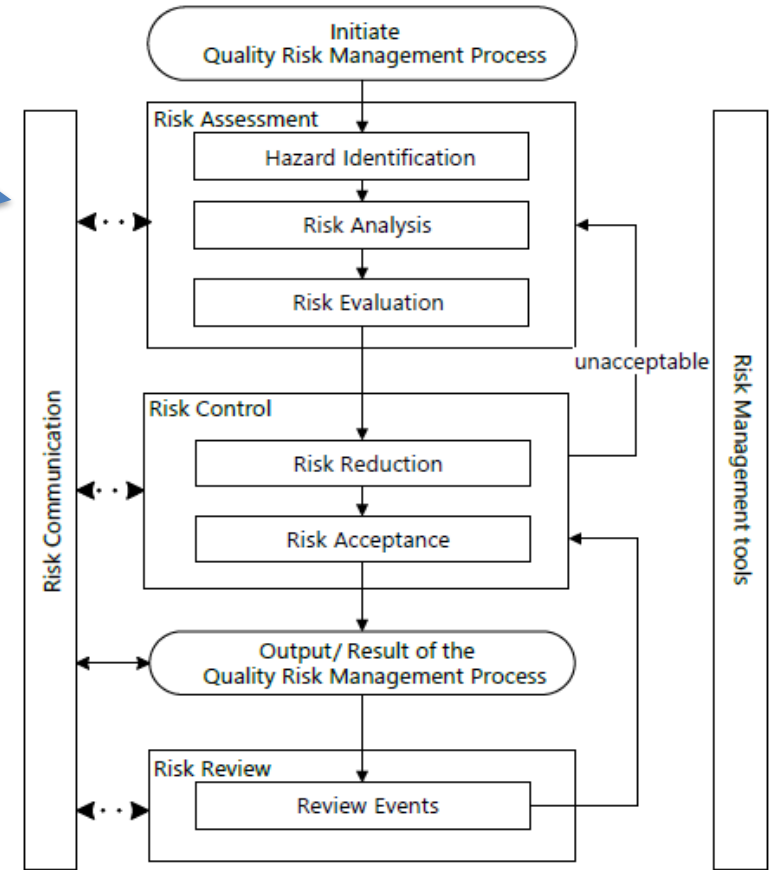
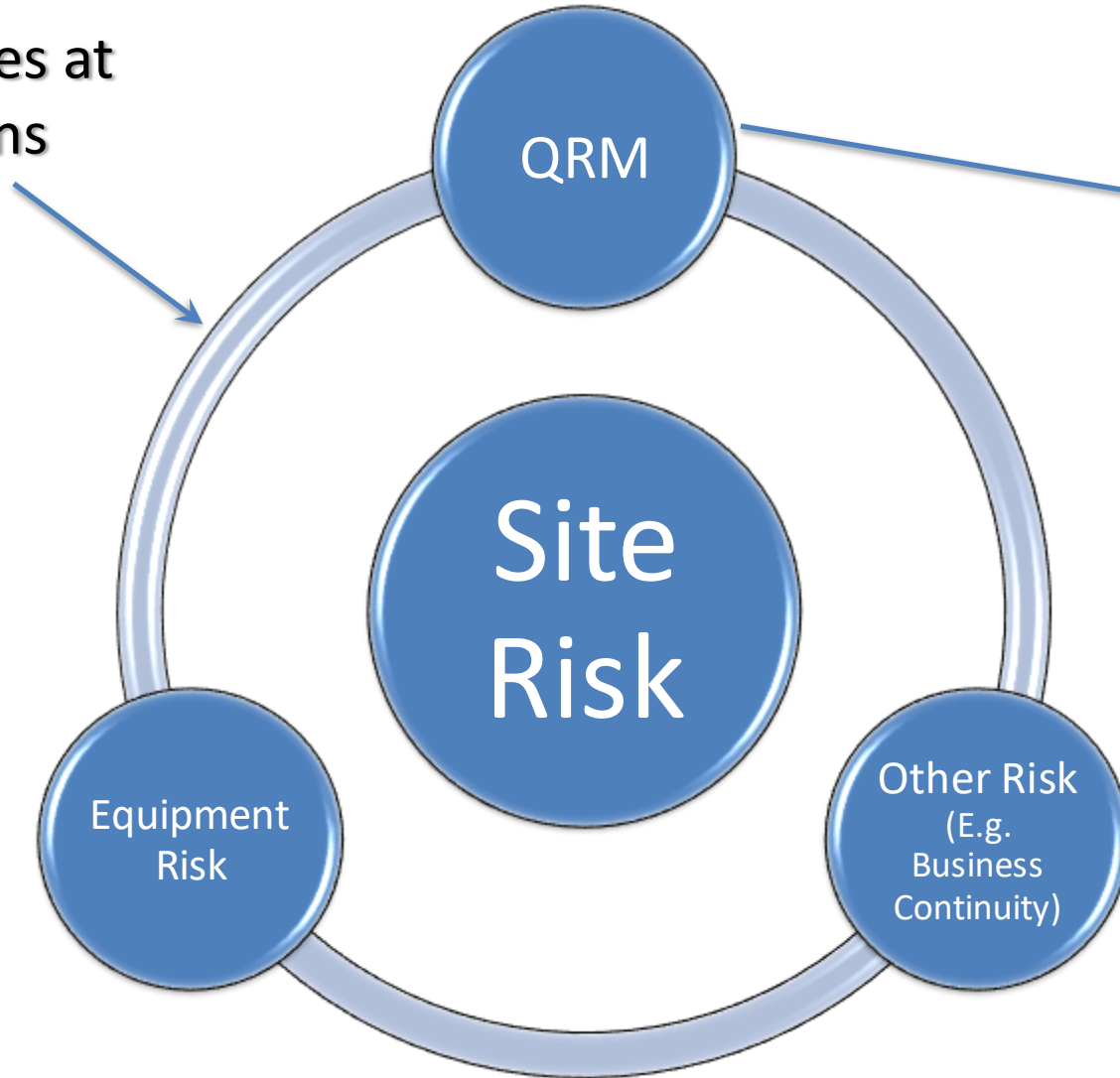


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## QRM and Reliability

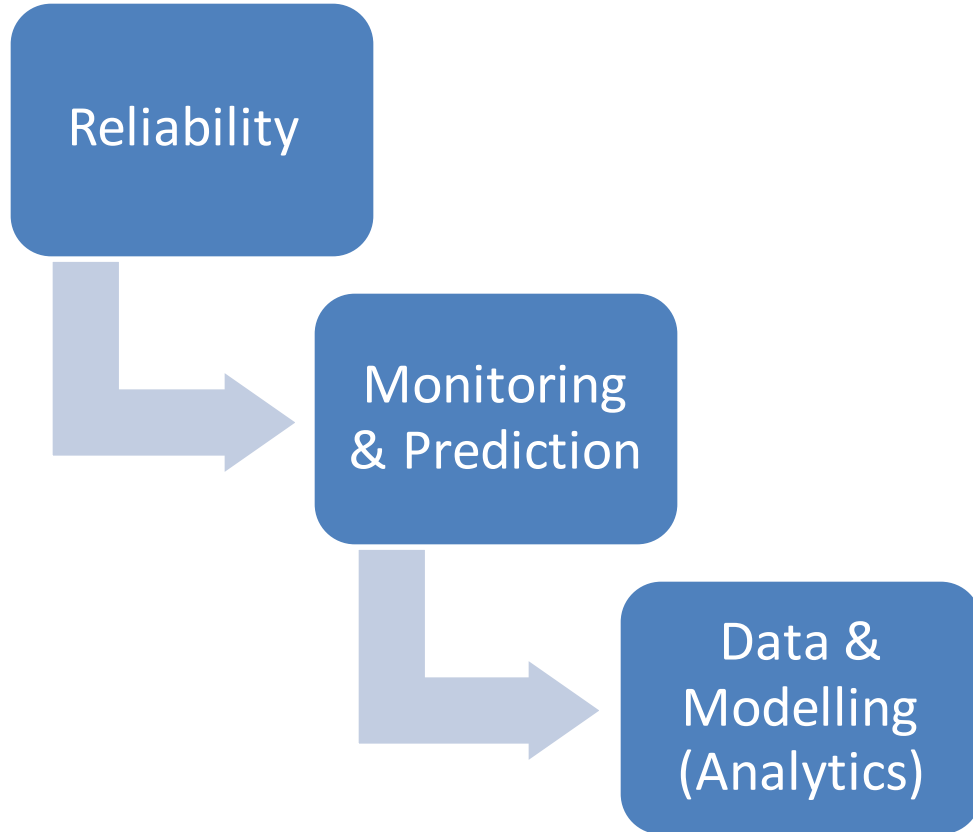
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## QRM and Predictive Approaches

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# QRM & Reliability engineering



How can monitoring & predictive analytics support the delivery of QRM system objectives ?

Or.....

How does QRM support the implementation of more monitoring & predictive technologies?

***Session Objective:***

***How to deliver value and resilience using predictive or data-leveraging approaches within QRM ?***

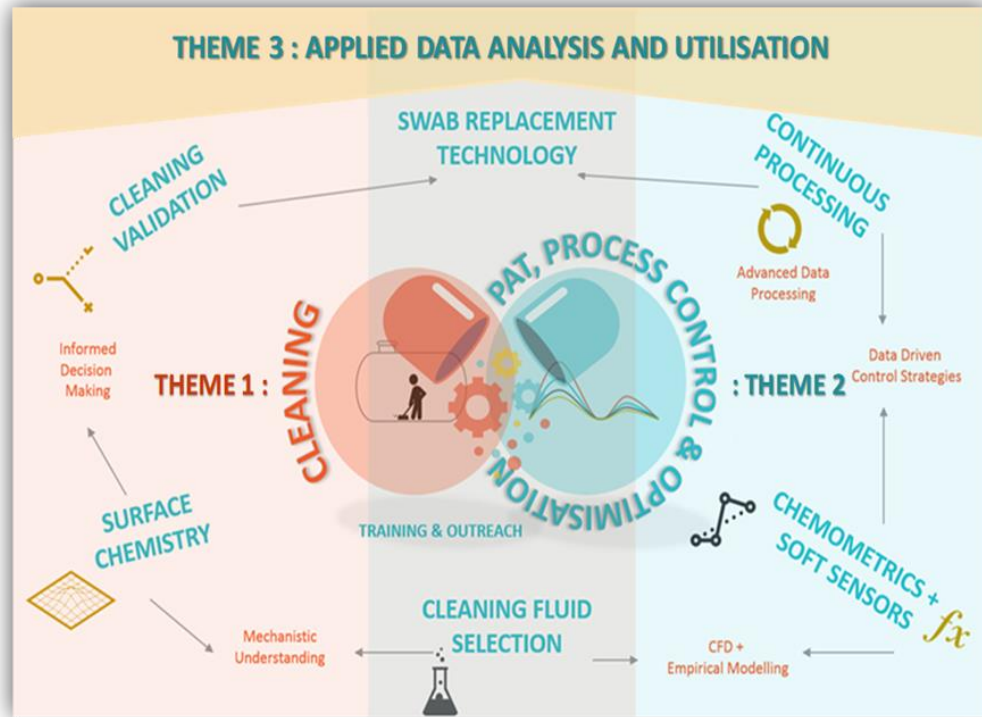
# Research @PMTc

- academia  $\cap$  Industry = PMTC
- Innovative



- Serve Industry needs
- Economic Impact

## Analytics and Risk Mgmt @PMTc



Small Molecule and Large Molecule Applications  
[www.pmtc.ie](http://www.pmtc.ie)


<https://www.pmtc.ie/resource-centre/publications/data-analytics-good-practice-guide>

Home > Journals > Arrow > current > Level3 > Vol. 16 > Iss. 1 (2021)


## Steps Towards Digital Transformation in the Pharmaceutical Manufacturing Landscape Linking Data, Analytics, Knowledge and Risk

<https://arrow.tudublin.ie/level3/vol16/iss1/>


### Foreword


 PDF "Connecting the dots to a Digital Future, Transitioning from Data to Informed Decisions"  
*Marcus O'Mahony and Anne Greene*


### Knowledge, Risk and Data


 PDF Steps Beyond Risk Assessment in QRM: RBDM, The next horizon  
*Valerie Mulholland, Anne Greene, and Martin J. Lipa*


### Deploying Analytics Solutions

 PDF "Deployment of Data Analytics to Support Manufacturing at Janssen"  
*Patrick T. O'Sullivan and Marcus O'Mahony*

 PDF "Gaining Organisational Acceptance of a Data Analytics Programme in Eli Lilly"  
*Anthony Maguire and Marcus O'Mahony*

 PDF "Data Architecture for Pharmaceutical Product Development at Alkermes"  
*Peter Couture, Damon Warnock, and Marcus O'Mahony*

 PDF "Transitioning organisations from a data quagmire to knowledge nirvana through the digital thread"  
*David Twohig and Barry Heavey*

 PDF Eliminating paper-based processes during manufacturing with a fit-for-purpose digital tool  
*Andrius Ramanauskas*



## Analytics to support QRM

### Prediction:

- Yield optimisation (supply security)
- Tech Transfer de-risking

### Proactivity:

- Multivariate monitoring to de-risking process deviations

### imProvement:

- Data workflow for faster access to data and analysis efficiency

# Current Landscape



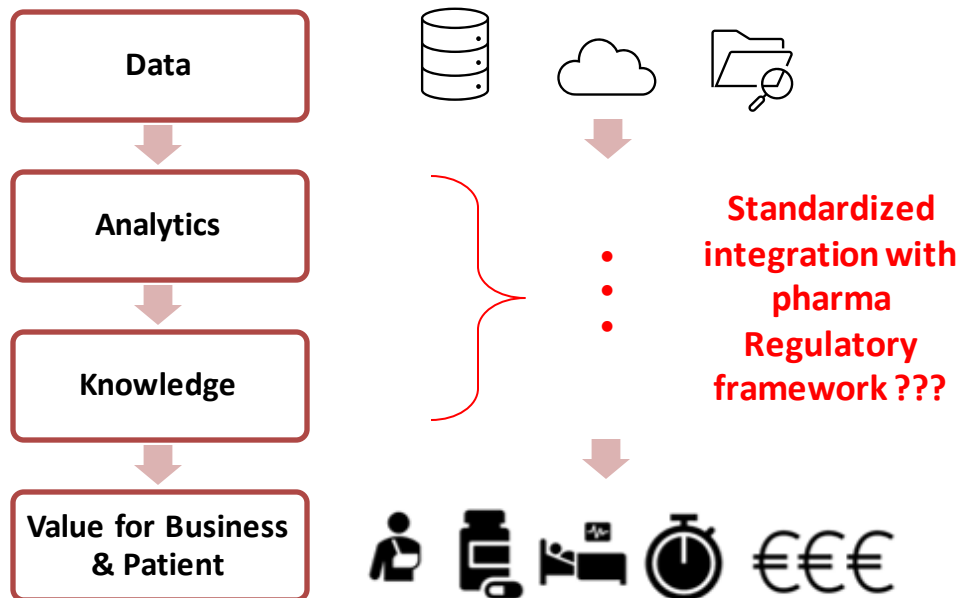
- Lack of Prioritisation
  - How to prioritise what and where advanced analytics capabilities can be utilized to enable highest impact in pharma
- No Standard Deployment Practice
  - Significant gap on integrating advanced analytics into pharmaceutical manufacturing areas and enabling continued use after deployment
- Knowledge & Risk Management
  - Lack of process to enable Advanced Analytics to be used to increase process and product knowledge on commercial processes and reduce risk
- Decision Support
  - Advanced Analytics within pharmaceuticals is not widely utilized for GxP purposes due to lack of recommended processes and approach

# Trust & Data: De-risking the Analytics Lifecycle

A Framework and Risk management methodology tool for the *provenance of data transformations* to Support decision-making across pharma manufacturing

## FoReSight

(Team → 5 large Pharma Manufacturers, 2 Irish research centres)

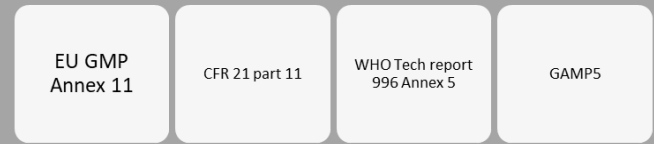


## The Data Analytics Lifecycle

**Level III:** Higher-level workup and transformation *with inheritance from level II*

**Level II:** Lower-level transformed data sets *with inheritance from Level I*

**Level I: Validated Data Source**



Data Visualisation

Statistical modelling and prediction: model development and deployment, dealing with outliers, etc.

Simulation, mechanistic modelling, digital twin development, machine learning advanced process control, etc.

Data cleaning, manipulation, wrangling munging, processing

Multi data set integration and alignment

Metadata creation

Missing data

*New risk management framework = f (Level II + Level III)*

- Case studies
- Academic-Industry-Regulatory reviews
- Benchmarking
- Interdepartmental Workshops

## OUTPUT SUMMARY:

### QRM Link to Reliability Programmes and Predictive Approaches

#### PEOPLE

- Require stronger connection between Mfg & QC to predict process issues
- Need to learn more from deviations and maintenance issues
- Persons close to operations have strong insights and the connection with QRM Control should be strengthened
- More experience needed in gaining 'insights' from trends
- Community of Practice needed in these spaces

#### GOVERNANCE

- Detailed End of Year Review required & should include:
  - Equipment
  - Maintenance
  - Deviations/CAPAs
  - Trends
  - Cumulative Effects of Change
- Reliability vs Resilience define and distinguish
- Predictive Modelling could/should be used for preventive maintenance also



## OUTPUT SUMMARY:

### QRM Link to Reliability Programmes and Predictive Approaches

#### PROCESS

- More Effectiveness Checks built in to processes
- Avoid waiting to point of failure in equipment/systems
- Include an 'APR-Like' review for Equipment – consolidate with Risk Assessments / Risk Review
- Strengthen Risk Review – who is involved?
- Effectiveness of PM - change controls relating to PM ? PM CAPAs ?
- Is cumulative effect of errors missed ?
- Lifecycle mgmt. of process risk assessments - trigger risk review e.g. calibration failures.
- Combine Knowledge from sites using similar equipment/systems
- Classify our equipment and able to leverage risks for like kit? (Bonus - access sites)
- Use Risk Based Approach to control Like-for-Like change control on equipment

## OUTPUT SUMMARY:

### QRM Link to Reliability Programmes and Predictive Approaches

