QMM – A NATURAL DEVELOPMENT OF PHARMACEUTICAL REGULATION?

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Exec Vice President, NSF Health Sciences

- Former Chief Quality & Access Officer, UK MHRA.
- 20+ years experience of pharmaceutical industry, 16 years experience of which at the MHRA (Inspectorate through to Board level)
- Regulatory Compliance Strategy
- Business Strategy & Transformation
- Emergency Response & Incident Management
- Leadership Development
- Quality & Risk System Optimisation
NSF IS A GLOBAL LEADER IN PUBLIC HEALTH AND SAFETY

Developer of 85 currently active national consensus standards and 95 published protocols

Steadfast ties with key associations and government agencies — including FDA, EPA, and USDA

2,800+ experienced professionals, including microbiologists, toxicologists, chemists, engineers and public health experts

75+ years of public health expertise

> NSF offers services in 180 countries. We have 61 locations, in 30 countries, including 12 labs

> 119,000+ companies served BUSINESS-TO-BUSINESS

> 220,000+ audits are conducted annually with 1,500 field auditors working worldwide

> 75+ unique accreditations, licenses and certifications including ANSI, IAS, and UKAS
NSF provides services in 175+ countries with 57 office and laboratory locations. Includes CRO Taiwan and resources (with FDA knowledge) in Australia.
AGENDA

● History – learnings from the past
● Influencing trends
● Regulatory Focus and Current Initiatives
● Focus on QMM and DI
HISTORY - LEARNINGS FROM REGULATORY CITATIONS

Frequency of FDA findings for FY2021 and FY2022 for the Subparts of 21 CFR part 211

Highest Frequency:
- Records and Reports
- Laboratory Controls
- Equipment
- Organisation and Personnel

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/inspection-observations
HISTORY - LEARNINGS FROM REGULATORY CITATIONS

Top 10 MHRA Citations 2019 (By Chapter Reference)
(Source: MHRA 2019 Deficiency Data)

Quality System (Standard Operating Procedures), Deviations Management and Investigations emerge as the areas with the most deficiencies
WHAT HAS INFLUENCED THIS NEW DIRECTION IN REGULATORY APPROACH?

- From the desire to ensure a robust and effective Quality System?
- From historical deficiencies?
- From the increased knowledge and awareness of culture?
- From the global nature of our supply chains?
- From the overarching drive for high quality, safe and effective medicines?
- Continued issues with Data Governance?

- Most likely, all of these and more...
“Compliance is a behaviour”

Laura Squire, Chief Quality & Access Officer, MHRA
TRENDS OF TODAY

- Pharma 4.0
- Outcome Based Co-operative Regulation
- Cultural Excellence and Quality Culture/Climate
- Sustained Quality Management Maturity
- Quality Management & Data Integrity Maturity Assessment Models
**TRENDS – PHARMA 4.0**

- Pharma 4.0
  - Digital Maturity
  - Data Integrity

- Culture incorporated into the Op Model
TRENDS – OUTCOME BASED CO-OPERATIVE REGULATION

Professor Christopher Hodges describes the key elements as:

- Supporting people
- Intrinsic motivations with supportive interventions
- Building trust
- Involving everyone

Christopher Hodges
Emeritus Professor of Justice Systems
Christopher Hodges | Faculty of Law (ox.ac.uk)
TRENDS – CULTURAL EXCELLENCE & CLIMATE

ISPE Cultural Excellence

- Advancing Pharmaceutical Quality (APQ) Program builds on the ICH Q10 PQS model to incorporate cultural excellence.

- Working through 6 Dimensions of Cultural Excellence to deliver sustained quality management performance.

- Integration of Operational Excellence with Cultural Excellence

- Supported by industry led approach for assessing and improving Quality Management Maturity
  - Assess->Aspire->Act->Advance
TRENDS – CULTURAL EXCELLENCE & CLIMATE

CIPD’s Quality Culture

- Organisational climate – “the way an individual understands their workplace guides their behaviour”
- Strong links and overlap between climate and culture
- Defined and considered through a number of dimensions
  - Safety climate
  - Innovation climate
  - Learning climate
  - Ethical climate
  - Inclusion climate
- Recognises importance of leaders in influencing climate
TRENDS – SUSTAINED MATURITY

How do you sustain the maturity level of your QMS/PQS within an ever evolving regulatory landscape?

- Focus on continuous improvement, innovation and (some level of) investment
- There is a need to understand and measure maturity.
- Development of enhanced KPIs and metrics for better decision making.

- Reduces risk of non-compliances or recalls
- Could lead to reduced regulatory burden via risk based inspection approaches (and OBCR)
TRENDS – QUALITY MANAGEMENT MATURITY

WHY QMM?

<table>
<thead>
<tr>
<th>Current</th>
<th>Understand the current state of the Quality System beyond just metrics and audits. The model aligns to the latest thinking and strategies of global regulatory authorities.</th>
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<tbody>
<tr>
<td>Future-Proofing</td>
<td>It supports proactive continuous improvement of an organisation’s QMS.</td>
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<td>Strategic</td>
<td>It examines the robustness and effectiveness of the QMS. It looks beyond the immediate environment (i.e., what is in place/in use) and considers the wider influencing factors.</td>
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<tr>
<td>Quality Culture</td>
<td>Critically, it also considers the organisational culture and the impact on the effectiveness of the QMS.</td>
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<td>Flexible</td>
<td>The model can be used in order to undertake an organisational/site health check, or to consider QMS maturity improvements following a regulatory inspection, for example.</td>
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<tr>
<td>Client Focused</td>
<td>The model can be tailored to suit a client’s need and focus in on key areas of concern/risk. The subsequent report can provide recommendations for those highlighted areas.</td>
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TRENDS – QUALITY MANAGEMENT MATURITY

Quality management maturity is the state attained when drug manufacturers have consistent, reliable, and robust business processes to achieve quality objectives and promote continual improvement.

CDER has proposed the development of a rating system that will help encourage drug manufacturers to achieve QMM at their facilities.

Source: CDER Quality Management Maturity
TRENDS – QUALITY MANAGEMENT MATURITY
TRENDS – QUALITY MANAGEMENT MATURITY

NSF's QMM Process

Phase 1: Define / Understand the value of QMM
- NSF can help your organization sift through the complexities and dynamic challenges of the QMM framework.
  - Strategic discussions with leadership on QMM and how to plan for the potential rating ecosystem.
  - Communicate objectives and custom roadmap to operational leadership.

Phase 2: Identify the Focus Areas and Processes
- Identify Assessment target areas and processes.
  - Focus areas and process identification.
  - Document and define assessment criteria/scoring mechanism.

Phase 3: Perform Assessment
- Perform the Assessment and establish performance measurement.
  - Experienced Assessors perform the assessment.
  - Assessment report with detailed analysis on deficiencies and opportunities.

Phase 4: Improvement Roadmap
- Provide a comprehensive roadmap (Strategic & Operational) to enhance processes.
  - Strategic roadmap development with leadership feedback.
  - Operational implementation/oversight to enable improvements.

Phase 5: Continuous Improvement
- Create a culture of continuous improvement to ensure new opportunities for automation & process improvement are identified.
  - Measure processes to ensure they continue to meet business requirements.
  - Enable a sustainable QMM ecosystem through trained self-directing teams.
TRENDS – QUALITY MANAGEMENT MATURITY

Quality Management – Maturity Evolution

- Target Stage – Industry benchmark for Quality Excellence
- Proactive Stage
  - Low levels of unplanned events and institutionalization of improvement activities
  - Advanced Analytics
  - Method Reviews
  - Continuous Improvement
- Intermediate Stage
  - Equal ratio of planned and unplanned events
  - Deviations
  - Basic Metrics
- Reactive Stage
  - Basic compliance with high levels of unplanned events
  - Deviations
  - No Metrics
- Regressive Stage – Non-compliance to basic GxPs

Timeline

- Unplanned Events
- Planned Events
- Quality Excellence/Sustainability Initiatives

- Sites at this stage are ahead of the curve
- Higher probability of adopting best practices such as automation
- Attract the best talent due to learning opportunities

- Most sites fall under these categories
- High levels of firefighting leading to undue stress on Systems and Manpower
- Negligible or minimal room for Systems or Competency improvement initiatives

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ISPE GAMP® MATURITY MODEL

• Repetitive process to demonstrate improvements
• Key Topic Areas
  • Culture
  • Governance and Organisation
  • Strategic Planning and Data Integrity Project
  • Regulatory
  • Data Life Cycle
  • Data Life Cycle and Supporting Processes
• 5 Levels (1-5)
• 38 Questions

High Level Data Integrity Maturity Level

Level 1
- Undefined
- Uncontrolled
- Not monitored
- No evidence

Level 2
- Partially defined
- Not formally controlled
- Not formally monitored
- Person dependant

Level 3
- Defined policy and established processes
- Inconsistent application
- Inconsistent monitoring

Level 4
- Defined policy and established processes
- Routine application
- Routine monitoring

Level 5
- Defined policy and established processes
- Proactive
- Continuous improvement

Red
Amber
Green

Data Integrity Maturity Level
**DIMA PROCESS**

- **Design**: Size, structure, coverage, analysis, timing etc
- **Delivery**: Facilitation, execution and delivery
- **Analysis**: Collation and independent analysis of results
- **Report**: Independent report generation and industry benchmarking
- **Action Planning**: Facilitated client actions workshop
- **Action Monitoring**: Client progress monitoring

Define next DI Maturity Assessment cycle e.g. 6 months / annual
RAPID & INFORMATIVE
DEMONSTRATING IMPROVEMENT

• Comparing to previous DIMA
  • DI Improvement
  • Learn and apply
  • DI Reduction
  • Provide attention

• Rehearse for Inspections
  • Show you take DI seriously
  • Show you are improving
  • Show your Data Governance system is comprehensive
  • Show you are on top of DI
FINAL THOUGHTS...

“It is not the strongest of the species that survive, nor the most intelligent, but the one most responsive to change”

- Charles Darwin
THANK YOU!
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If you would like to know more about the QMM or DIMA services, and how we can help you, please contact:

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