IPA Session 3

Introduction to Quality Management Maturity (QMM): Key Expectations from the Industry

Dr Samantha Atkinson
Executive Vice President, NSF
Dr Sam Atkinson
BSc (Hons), MSc, PhD, MBA, MRSC

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 provides services in 175+ countries with ~60 office and laboratory locations.

~2800 Experienced Professionals, including ex-Regulatory and ex-Industry

80 Years of Public Health expertise
Our Clients

- We work globally with Fortune 100 and Fortune 500 companies
- We also work with smaller companies to help them establish a footprint
- 80% of our business is repeat or referral business

Our Services
**Pharma Biotech | Expertise and Experience**

Our staff of former FDA and EU officials and industry experts combines global regulatory knowledge with industry best practices to help you achieve successful regulatory strategies and execution as well as sustainable and compliant quality systems.

Our areas of expertise and experience encompass:
- Pharmaceuticals
- Biotechnology, including Biologics & Vaccines
- Medical Devices & In-Vitro Diagnostics
- Dietary Supplements
- Cosmetics

**Service & Capabilities | Product Lifecycle Approach**

Product Development  ➔  Regulatory Approval  ➔  Commercialization
## Competencies – Pharma Biotech

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<tr>
<th>Consulting</th>
<th>Quality Systems and Compliance</th>
<th>Auditing and Assessment</th>
<th>Regulatory and Clinical</th>
<th>Training and Education</th>
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<tr>
<td>GxP, Regulatory and Compliance support.</td>
<td>Compliance Assessment, Simplification, development and implementation against Industry best practice</td>
<td>GXP Audits • GMP • GLP • GCP • GVP • Data Integrity</td>
<td>Regulatory Strategy Development</td>
<td>Qualified Person Education</td>
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<td>Warning Letters and Regulatory Assistance</td>
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<td>Regulatory Affairs</td>
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<td>Consent Decrees</td>
<td>Data Integrity Analysis</td>
<td>3rd Party and Supplier Audits</td>
<td>Clinical Trial Support</td>
<td>Pharmaceutical Audit and Self Inspection (IRCA)</td>
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<td>AIP Data Integrity/Governance</td>
<td>Error proofing systems</td>
<td>Due Diligence</td>
<td>Regulatory Liaison and post approval changes)</td>
<td>Leadership development and coaching</td>
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<td>Remediation Activities (reactive and proactive)</td>
<td>Quality System Design, Redesign and optimization</td>
<td>Regulatory Inspection Readiness</td>
<td>Conduct meetings with Regulatory Authorities inc FDA, MHRA, EMA etc</td>
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<td>Quality Management Maturity Assessment</td>
<td>Quality Culture and Change Management.</td>
<td>Regulator – Incident Management</td>
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<td>Culture Change Roadmaps</td>
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<td>Technical Consulting (e.g. Sterile, Formulation, Facility Design review, Start-up, Commissioning and Qualification etc)</td>
<td>Risk Management</td>
<td>Mock Regulatory Inspections (FDA, EMEA, MHRA etc)</td>
<td>Global Submissions (eCTD)</td>
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<td>Quality Risk Management Approaches</td>
<td>Inspector Training - How to inspect.</td>
<td>Regulatory Training: - Regulations &amp; Guidance - Data evaluation &amp; assessment - Train the Regulator</td>
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<td>Customized in house programs: e.g GxP; Inspection readiness etc</td>
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Competencies - Medical Device Consulting – 6 Pillars

NSF’s world class experts provide comprehensive services and solutions to effectively navigate the complex global regulatory landscape. Offering Consulting, Training, Auditing and Technical support across the total product lifecycle.

- Regulatory Strategies & Premarket Submissions
- Clinical Support & Claims Management
- Post Market Surveillance & Vigilance
- FDA & Notified Body Inspection Readiness
- Risk Management & Quality System Improvement
- Emerging Regulations & Technical Support
Competencies - Training & Education Services

MEDICAL DEVICES AND IVDS TRAINING

PHARMACEUTICAL TRAINING

QUALITY SYSTEMS

GXP

STERILE & BIOTECH

QUALIFICATION & VALIDATION

REGULATORY

QUALIFIED PERSON

For more information, each course is hyperlinked to our website. Or if you have any questions, email nsfmdtraining@nsf.org.
Today

- Case Study – IBM
- Why is getting it right important?
- NSF Quality Management Maturity
- Road to Success
- What Success Looks Like
The turnaround of IBM

One Hundred Years of Market Value (1920–2020) by IBM Chief Executive Officer

How did Gerstner turn IBM around?

Initial Actions – Business Optimisation and Cultural Maturity

- Listened to the workforce & lived their experiences.
- Embedded new values around respect, inclusivity and safety (vs fear/blame)
- Focus on ‘customer engagement’
- Removed internal tensions and competition
- Changed expectation of Leaders & Managers from gatekeepers for decision making, communication or reporting, to be actively involved.
- Changed the compensation system so that rewards were based on total corporate performance rather than division or unit performance.
- Changed the rules for getting promotions.
- Created a new and disruptive business strategy to – “offer solutions to customers” and allow IBM products and services to integrate with competitor products.
Alignment - in Culture & in Business

Galbraith’s Star Model

Knowingly, or not, Gerstner was identifying and correcting mis-alignments…

This drove different **behaviours** across IBM…

Which in turn defined their **new culture**…

And business success.
Why is getting it right important?

US FDA

- As of December 31, 2023, FDA had identified 98 ongoing CDER- and CBER-tracked shortages.
- The number of new drug shortages per calendar year has declined from a high of 251 in 2011 to 55 in 2023.
- In 2023, FDA worked with manufacturers to successfully avoid a large number of drug shortages, helping to prevent 236 shortages.

Impacts

- Patients
- Health Service Challenges
- Financial Costs

Source: https://www.fda.gov/media/179156/download?attachment=&utm_medium=email&utm_source=govdelivery
Road to Success

Leadership, Purpose, Alignment, EDI, Trust, Communication, Recognition, Reward, Career

Processes & Technology

Environment

Culture

Positive Employee Experience

Higher Job Satisfaction
AND
Higher Employee Engagement
LEADING TO
Higher Organisational Performance
How to deliver the change

NSF’s QMM

**Executive Summary**

It’s well-recognized that the Quality Management System (QMS) — whether documentation, decision and event management or a combination of all three — is the heart of any organization. Given the requirements have been tailored to the needs of an organization, only is the QMS essential to the success of any organization, but it is also a key part of its culture. Therefore, it is important to understand the impact of the QMS on the organization’s performance. In this paper, we examine 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.

**NSF’s QMM Assessment Areas**

- **Quality Policy & Strategy**
- **Manufacturing, Strategy & Operations**
- **People Management**
- **Analytics & Metrics**
- **Risk Management**
- **Quality Excellence & Sustainability**

**Assessment Criteria**

- **Current**: 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.
- **Future-Proofing**: It supports proactive continuous improvement of an organization’s QMS.
- **Strategic**: 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.
- **Quality Culture**: Critically, it also considers the organisational culture and the impact on the effectiveness of the QMS.
- **Flexible**: 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.
- **Client Focused**: 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.
How to deliver the change
NSF’s QMM

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.

Phase 2: Identify the Focus Areas and Processes
- Strategic discussions with Leadership on QMM and how to plan for the potential rating ecosystem.

Phase 3: Perform Assessment
- Focus areas and process identification.

Phase 4: Improvement Roadmap
- Experienced Assessors perform the assessment.

Phase 5: Continuous Improvement
- Strategic roadmap development with leadership feedback.

Quality Management – Maturity Evolution

Target Stage – Industry benchmark for Quality Excellence

Proactive Stage
- Low levels of unplanned events and institutionalization of improvement activities

Intermediate Stage
- Equal ratio of planned and unplanned events

Reactive Stage
- Basic compliance with high levels of unplanned events

Regressive Stage
- Non-compliance to basic KPIs

Timeline

- 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

NSF Confidential
How to deliver the change

Culture Roadmap

Building a strong quality culture is essential for organisations striving for excellence in performance, compliance, and patient outcomes.

It requires:
- Comprehensive analysis and assessment of the organisation’s current state
- Sustained commitment from leadership
- Collective accountability for quality
- Clear and aligned plan for ongoing maturity

By recognising the signs, implementing effective strategies, and fostering role modelling and alignment, organisations can navigate toward success.
What Success Looks Like

NSF have observed

Organisations with lower levels of Quality Management & Culture Maturity tend to exhibit
- Out of date procedures, procedures not being adequately or correctly followed, little to no proactive work on continuous improvement
- Minimal innovation and/or low level of creativity
- Higher than average levels of unplanned work resulting from deviations and excursions
- Lower levels of staff morale and higher levels of attrition

At a high level, organisations are operating in an optimal state and exhibit:
- Low levels of re-work and unplanned activities
- High levels of continuous improvement, application of best practice and workforce efficiency
- Higher levels of trust and autonomy leading to enhanced engagement and retention
- Better risk and investment decisions.
NSF’s own study in 2015 suggested, when referring to COPQ…

“in the pharmaceutical industry, it is not uncommon for such costs to range between 25 and 40 percent of total sales revenue”.

NSF’s White Papers

QMM:
https://www2.nsf.org/qmmwhitepaper

Quality Culture:
https://www2.nsf.org/qualityculture
THANK YOU!
satkinson:@nsf.org