

IPA Session 3

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

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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 Around the Globe



Symbol Key NSF Office & Laboratory NSF Office

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



NSF Confidential

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

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Competencies – Pharma Biotech

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

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

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Tech - EU

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IVDs

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AND GMP TRAINING

MEDICAL DEVICES AND IVDS TRAINING

MEDICAL DEVICE COUNTRY- SPECIFIC REGULATORY TRAINING	MEDICAL DEVICE AUDITOR TRAINING		
Medical Device Single Audit Program	EU IVDR Internal Auditor Training		
United States Medical Device Regulations – A Comprehensive Overview	EU MDR Internal Auditor Training CQV/RCA-certified QMS Lead Auditor based on ISO 13485:2016 and MDSA requirements Internal Auditor Training Based on U. 21 CFR Part 820		
Brazil Medical Device Regulations – A Comprehensive Overview			
Canada Medical Device Regulations - A Comprehensive Overview			
Japan Medical Device Regulations – A Comprehensive Overview	MDSAP Internal Auditor Training Applying ISO 19011:2018 Principles 1 Medical Device Quality Management System Audits Medical Device Single Audit Program (MDSAP) Writing Effective Nonconformity Stat During Medical Device QMS Audits Medical Device Regulatory Requirement Five-Course MDSAP Bundle MDSAP Overview and Country-Specif Medical Device Regulations: Six-Course Bundle FDA Inspections of Medical Device Manufacturers Introduction to Writing Effective Nonconformity Statements During M Device Manufacturer QMS Audits		
Australia Medical Device Regulations - A Comprehensive Overview			
China Medical Device Regulations			
European Union Medical Device Regulation (EU MDR)			
European Union In Vitro Diagnostic Device Regulation (EU IVDR)			
ISO 13485: Medical Devices QMS - Requirements for Regulatory Purposes			
ISO 13485:2016 Overview and Country- Specific Medical Devices Regulations: Sw-Course Rundle			
MDSAP Overview and Country-Specific Medical Device Regulations: Six-Course Bundle			
FDA Inspections of Medical Device Manufacturers			
Medical Device Regulatory Requirements: Five-Course MDSAP Bundle			
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EU	IVDR Internal Auditor Training
EU	MDR Internal Auditor Training
CQ	WRCA-certified QMS Lead Auditor
ba	sed on ISO 13485:2016 and MDSAP
rec	guirements
Int	ernal Auditor Training Based on U.S. FDA
21	CFR Part 820
M	DSAP Internal Auditor Training
Ap	plying ISO 19011:2018 Principles to
Me	edical Device Quality Management
Sys	stem Audits
Me	edical Device Single Audit Program
(M	DSAP)
Wi	iting Effective Nonconformity Statements ring Medical Device QMS Audits
Mi	dical Device Regulatory Requirements:
Fly	e-Course MDSAP Bundle
MI	DSAP Overview and Country-Specific
Me	edical Device Regulations:
Six	-Course Bundle
FD	A Inspections of Medical Device
Ma	anufacturers
Int	roduction to Writing Effective
No	inconformity Statements During Medical
De	vice Manufacturer QMS Audits

bsite. Form Or if you have any questions, email nsfmdtraining@nsf.org

MEDICAL DEVICE MARKET ACCESS REGULATORY TRAINING

PHARMACEUTICAL TRAINING

AUDITOR GMP Audits and Self-Inspections Internal Auditor Auditing QC Laboratories Self-Inspections - How to Make Them Add Value to Your Organisation QUALITY SYSTEMS Responsible Person & Good Distribution Practice

Documentation Simplification Supplier Quality Management Certified Investigator Deviation and CAPA Management Quality Risk Management Data Integrity Pharmaceutical Quality Systems Changing GMP Behaviors Human Performance: Beyond Human Error Self-Inspections - How to Make Them Add Value to Your Organisation SOP Writing and revision General Drug or Pharmaceutical cGMP and **Quality Systems** Adverse Events and Product Quality Complaints A Guide for Employees Data Integrity eLearning Human Error Prevention: Best Practices From Industry Deviation Investigations and CAPA

GxP Refresher Training ICH Q8, Q9 and Q10

Change Control Overview

GXP
Pharmaceutical GMP
Responsible Person & Good Distribution Practice
Documentation Simplification
Good Clinical Practice
Good Pharmacovigilance Practice
Supplier Quality Management
Certified Investigator
Deviation and CAPA Management
GMP for Clinical Trials Manufacture & Supply
Quality Risk Management
Data Integrity
GMP for Engineers
GxP Inspection Management Lifecycle
SOP Writing and revision
The Roles and Responsibilities of an RP
Interface of GMP with GCP Quality Management Systems
Good Distribution Practices
General Drug or Pharmaceutical cGMP and Quality Systems
Deviation Investigations and CAPA
Adverse Events and Product Quality Complaints - A Guide for Employees
Data Integrity eLearning
GxP Refresher Training ICH Q8, Q9 and Q10
Change Control Overview
GMP Refresher Training

Delivery Method Instructor-led Courses (either in-person or virtual)

STERILE & BIOTECH

GMP for Biological & Biotechnology Products

Quality Risk Management for Sterile Products

Introduction to Advanced Therapy Medicinal

OTHER TECHNICAL TRAINING

GMP for Clinical Trials Manufacture & Supply

Active Substances and Excipients Training

Advanced Therapy Medicinal Products

Formulation & Processing

Cleaning Validation

Analysis and Testing

Pharmaceutical Microbiology

Sterile Manufacturing Practices

Medicinal Chemistry & Therapeutics

Mathematics & Statistics

Pharmaceutical Packaging

Statistical Process Control

Cleaning Qualification

Investigational Medicinal Products

Computerized Systems Validation

Online Courses

Analysis & Testing

Statistical Testing

Products

Pharmaceutical Microbiology

A-Z of Sterile Product Manufacture

Contamination Control Strategy

QUALIFICATION & VALIDATION Equipment Qualification and Process Validation (advanced) Introduction to Validation Training **Cleaning Validation** Process Validation & Equipment Qualification **Cleaning Qualification Computerized Systems Validation**

REGULATORY

Pharmaceutical Law and Administration		
Pharmaceutical Legislation Update Subscription Service	n	
Regulatory Affairs for QA: Variations		
Regulatory Affairs for QA: Marketing Authorizations		
Regulatory Affairs for QA: Variations Regulatory Affairs for QA: Marketing Authorizations		

QUALIFIED PERSON

Pharmaceutical Law and Administration
Medicinal Chemistry & Therapeutics
Formulation & Processing
Pharmaceutical Microbiology
Active Substances and Excipients Training
Mathematics & Statistics
Analysis & Testing
Pharmaceutical Packaging
Pharmaceutical Quality Systems
Practical
Investigational Medicinal Products
Role & Professional Duties of the QP

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





Ref: DISCERNING READERS. (2021). IBM CEOs' Yearly Market Value Performance. [online] Available at: https://www.discerningreaders.com/ibm-historical-by-ceo-yearly-market-value-performance.html.

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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 <u>behaviours</u> across IBM...

Which in turn defined their <u>new culture</u>...

And business success.





Galbraith, J. Designing Organizations, San Francisco; Josssey-Bass, 2002

Why is getting it right important?

<u>US FDA</u>

- As of December 31, 2023, FDA had identified 98 ongoing CDER- and CBERtracked 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



120

100

80

60

40

20

Number of Ongoing Shortages

CDER CBER

Source:https://www.fda.gov/media/179156/download?attachment=&utm_me dium=email&utm_source=govdelivery





Road to Success





How to deliver the change

NSF



NSF's Quality Management Maturity (QMM) Assessment Model

Future-Proofing Quality and Supporting Supply Chain Robustness

Executive Summary

If is well incognized that the Quality Management System (2015) — whether documentations, deviation and sweet, management or CAMA — on the facus of Regulatory Impectatory and Indeed the cause of many Indeeg, Given the responsives have been traceable (the salve tar is long, only is this still are are an inco-compliance).

Historically, and justifiates a harsh and sampletic assertion, is that the QMS has been managed as a factoses with a competensate set of interactions. However, more executly equilates, industry and guidity anterbasional are looking as the QMS signify attilenessy. The QMS must be the hard and loop of an expectation— is needs to because the interact the angumention and must ensure that each operational part— from individual, individually experiment, to functions, taxes and the leadership — operation in utrues. This shift is mindret receptores the needs to understand the engance and and of preside and charter in the saturational part.

So, how alow, the QMS final every part of the organization with organi and that these within the organization recognize the importance of the QMD Heav do regulators assum the impact of these inlanguage within the effectiveness and obstatrons of a QMS, and therefore complement).

The NSE QMM Assessment Mudei ideveloped and introduced in 2022, following the publication of the US FDA Shig Shortages Salk funce report in 2019) requireds description that ch

organizational quality maturity across the regulated landscape. It of the QMS, in gassilet to the traditional considerations of complithe NSF model has been designed to align and respond to the H



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 organisation'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_{*})



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_®)

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.

What Success Looks Like

(NSF.

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 <u>25 and 40 percent</u> of total sales revenue".

Source: https://www.nsf.org/knowledge-library/the-importance-of-copq-for-the-pharmaceutical-industry.



NSF's White Papers

QMM:

https://www2.nsf.org/qmmwhitepaper

Quality Culture:

https://www2.nsf.org/gualityculture

NSF's Quality Management Maturity (QMM) **Assessment Model**



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Future-Proofing Quality and Supporting Supply Chain Robustness

Executive Summary

It's well recepted that the Quilty Management System (CMS) -- whether Bacamertation, Broalbart and ment. management or CAM. - is the facul of Regulatory regretcers and extend the cause of many Bollings. Given the requirements have been browly the same far in teng, why is the still an area of new compliance?

Historically, and perhaps a hards and simpletic assertion, is that the QUE has been changed as a hardnes with a competensive set of monutors. Havener, more recently regulators, industry and quality professionals are looking at the ONS signify attiently. The ONI must be the heart and large of an imperiation - 8 needs to breather We into the argumption and must ensure that each operational part -- how individual, technology, equipment, to functions, insure and the instanting - operate invariant. The stellar model on spring the result to independent and the of people and indices in the incomoful deployment of a mature QUE.

to, how may the QMS heet every part of the organization with oxygen and that these within the organization receptor the reportance of the QAS' More do regulation assess the impact of these intergible elements on the offectiveness and tobustness of a QNPs, and therefore compliance?

The YOP QNMF Automated Machini Destroped and employees in 2022, following the publication of the ULE YOR Drug. (Instages Talk force report # 2018) responds already to the challenge. It is a strengther encoded load to asses propriorities and prototy active the replaced backcore. It requires a different mechan, using a holistic rese of the QML is parallel to the traditional considerations of compliance.

The NDF model has been attrigened to align and respond to the FDF's builtings, to the assessment process asmadenet

Executive Summary

Optimising organisational culture and quality insturity is crucial in promoting consistent, reliable business processes and to minimise supply disruptions. This anding the visible and invisible aspects

wir impact on the quality system.

Compliance to Performance

How to optimise your Organisational Culture and **Quality Maturity for Success**





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

THANK YOU!

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Why NSF?

Experienced

NSF employees have **significant experience** of working in/with regulatory authorities and in industry.

Professional

We are dedicated to providing **high quality** outputs that **add real value** to an organisation.

Strategic

We look beyond the immediate environment and consider the wider regulatory landscape to provide **tailored advice**.

Flexible & Competitive

We can work onsite, hybrid or remotely, as needed. We offer **best-in-class** services at a **market competitive rate**.

Evidence Based

NSF have access to leading benchmarking data to support development of the NSF QMM model.

Track Record

NSF have successfully used the QMM model to assess other organisations and provide recommendations for further maturity.