IPA Session 3

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

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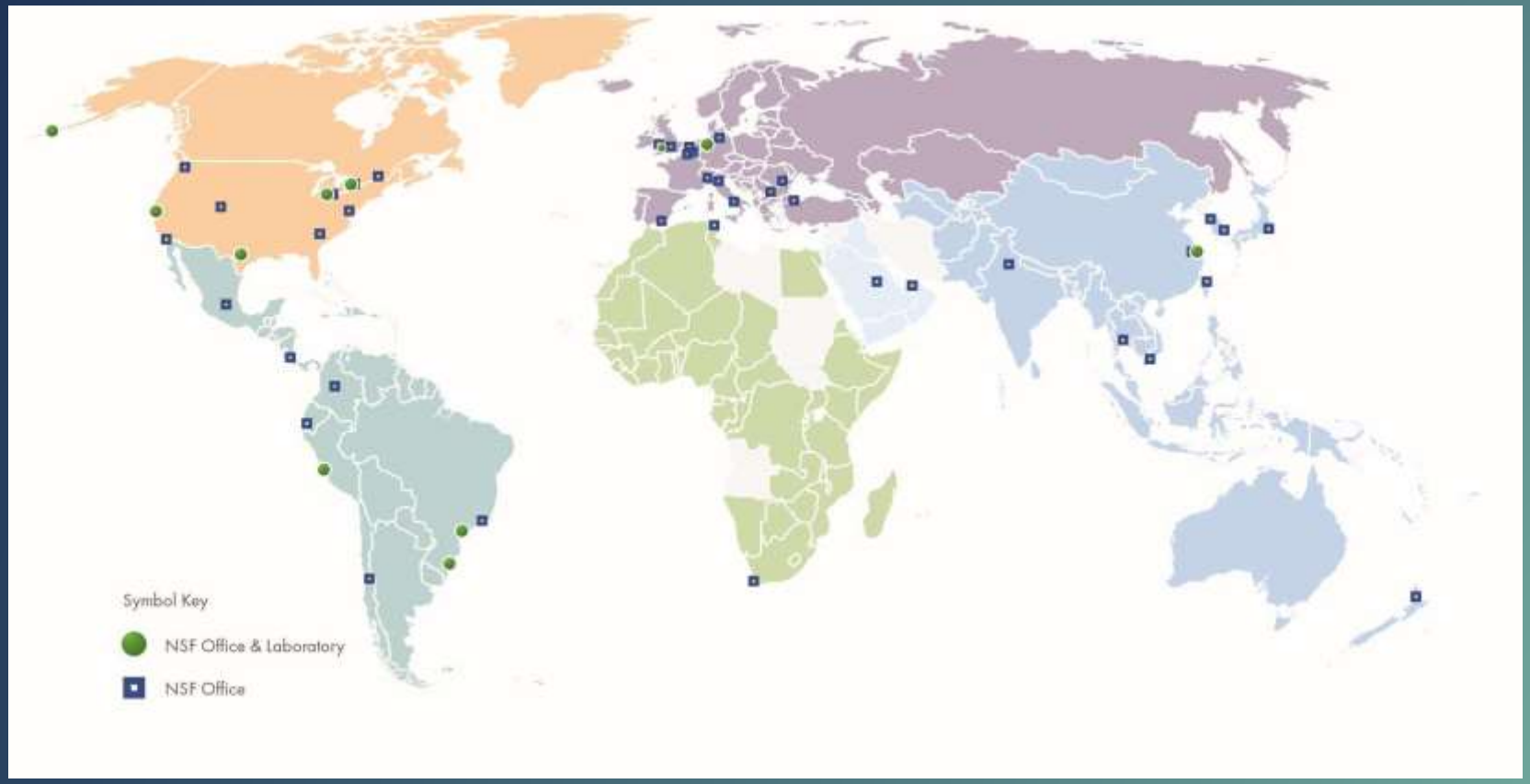
Exec Vice President, NSF Health Sciences

- 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 Around the Globe



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

STANDARDS | TESTING | CERTIFICATION | AUDITING | CONSULTING | TRAINING

◄ *INDEPENDENT FROM CERTIFICATION* ►

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

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	3rd 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

MEDICAL DEVICES AND IVDS TRAINING

MEDICAL DEVICE COUNTRY-SPECIFIC REGULATORY TRAINING

- Medical Device Single Audit Program (MDSAP) Training
- United States Medical Device Regulations – A Comprehensive Overview
- Brazil Medical Device Regulations – A Comprehensive Overview
- Canada Medical Device Regulations – A Comprehensive Overview
- Japan Medical Device Regulations – A Comprehensive Overview
- Australia Medical Device Regulations – A Comprehensive Overview
- China Medical Device Regulations – A Comprehensive Overview
- 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: Six-Course Bundle
- 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

MEDICAL DEVICE AUDITOR TRAINING

- EU IVDR Internal Auditor Training
- EU MDR Internal Auditor Training
- CQI/IRCA-certified QMS Lead Auditor based on ISO 13485:2016 and MDSAP requirements
- Internal Auditor Training Based on U.S. FDA 21 CFR Part 820
- MDSAP Internal Auditor Training
- Applying ISO 19011:2018 Principles to Medical Device Quality Management System Audits
- Medical Device Single Audit Program (MDSAP)
- Writing Effective Nonconformity Statements During Medical Device QMS Audits
- Medical Device Regulatory Requirements: Five-Course MDSAP Bundle
- MDSAP Overview and Country-Specific Medical Device Regulations: Six-Course Bundle
- FDA Inspections of Medical Device Manufacturers
- Introduction to Writing Effective Nonconformity Statements During Medical Device Manufacturer QMS Audits

MEDICAL DEVICE MARKET ACCESS REGULATORY TRAINING

MEDICAL DEVICE QMS AND GMP TRAINING

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

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

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

STERILE & BIOTECH

- Formulation & Processing
- Pharmaceutical Microbiology
- A-Z of Sterile Product Manufacture
- Cleaning Validation
- Contamination Control Strategy
- GMP for Biological & Biotechnology Products
- Quality Risk Management for Sterile Products
- Advanced Therapy Medicinal Products
- Introduction to Advanced Therapy Medicinal Products
- Analysis and Testing
- Pharmaceutical Microbiology
- Sterile Manufacturing Practices

OTHER TECHNICAL TRAINING

- GMP for Clinical Trials Manufacture & Supply
- Medicinal Chemistry & Therapeutics
- Active Substances and Excipients Training
- Mathematics & Statistics
- Analysis & Testing
- Pharmaceutical Packaging
- Investigational Medicinal Products
- Statistical Testing
- Statistical Process Control
- Cleaning Qualification
- Computerized Systems Validation

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
- 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

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

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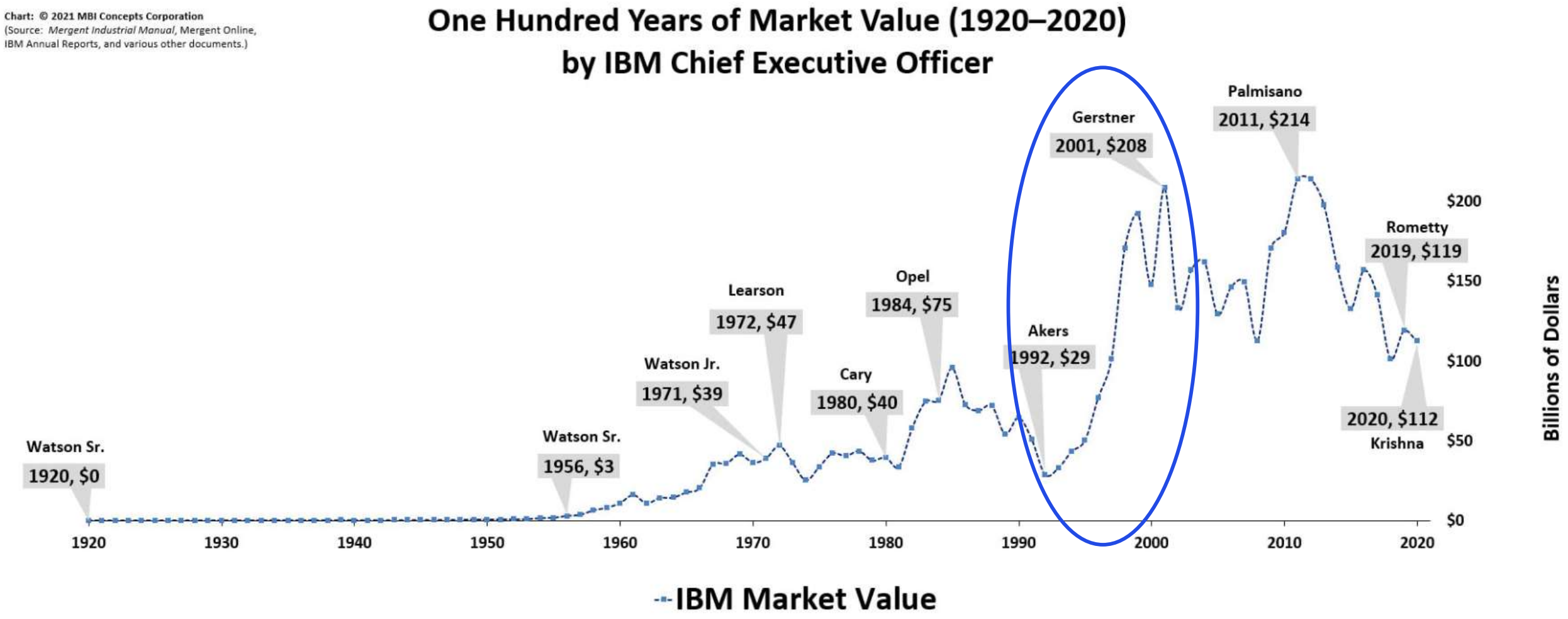
Today

- 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.

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

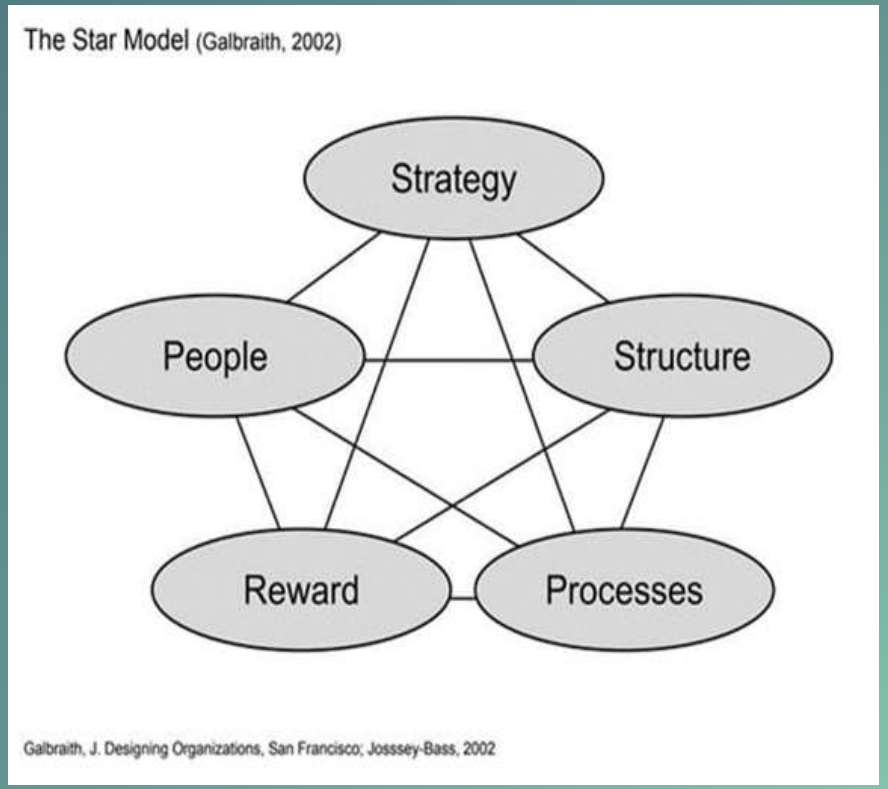
Galbraith's Star Model

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

This drove different behaviours across IBM…

Which in turn defined their new culture…

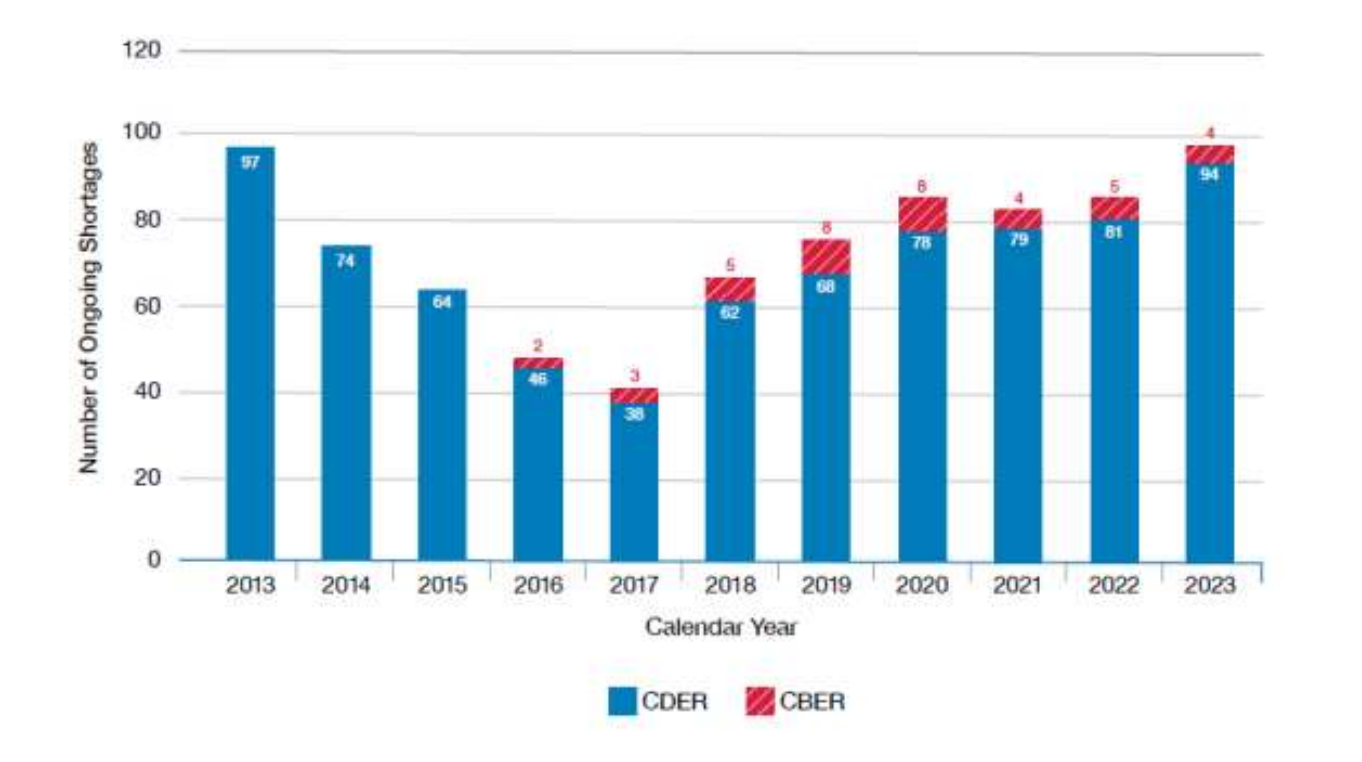
And business success.



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.

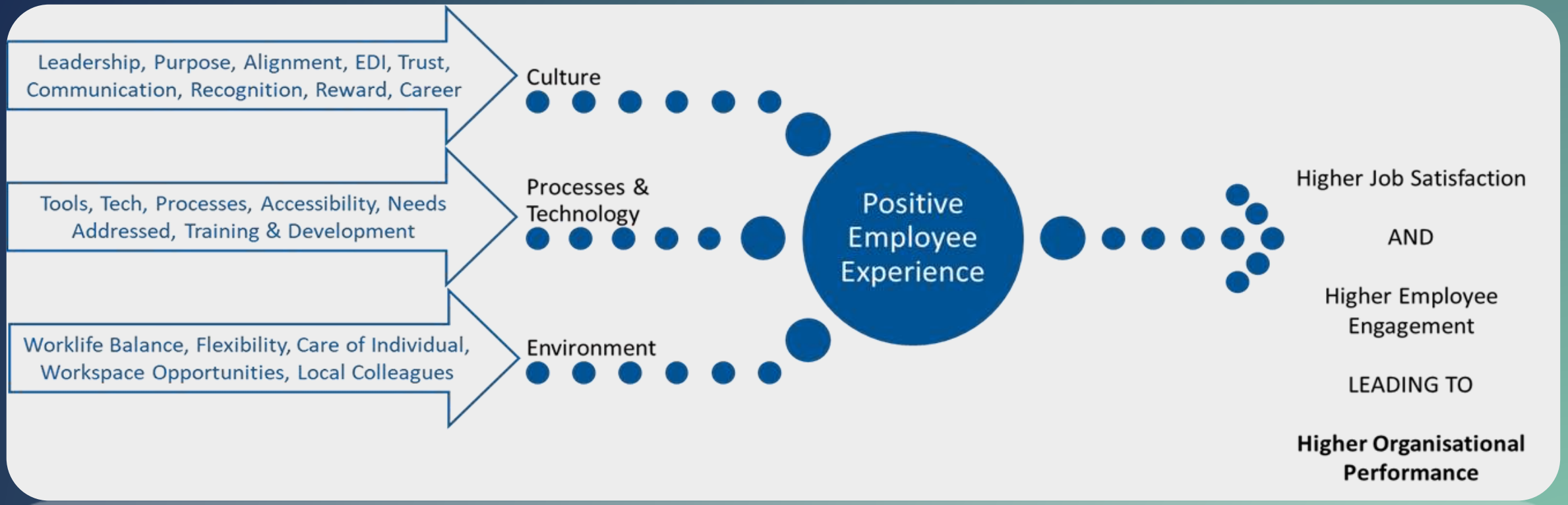


Source:https://www.fda.gov/media/179156/download?attachment=&utm_medium=email&utm_source=govdelivery

Impacts

- Patients
- Health Service Challenges
- Financial Costs

Road to Success



How to deliver the change

NSF's QMM


NSF's Quality Management Maturity (QMM) Assessment Model

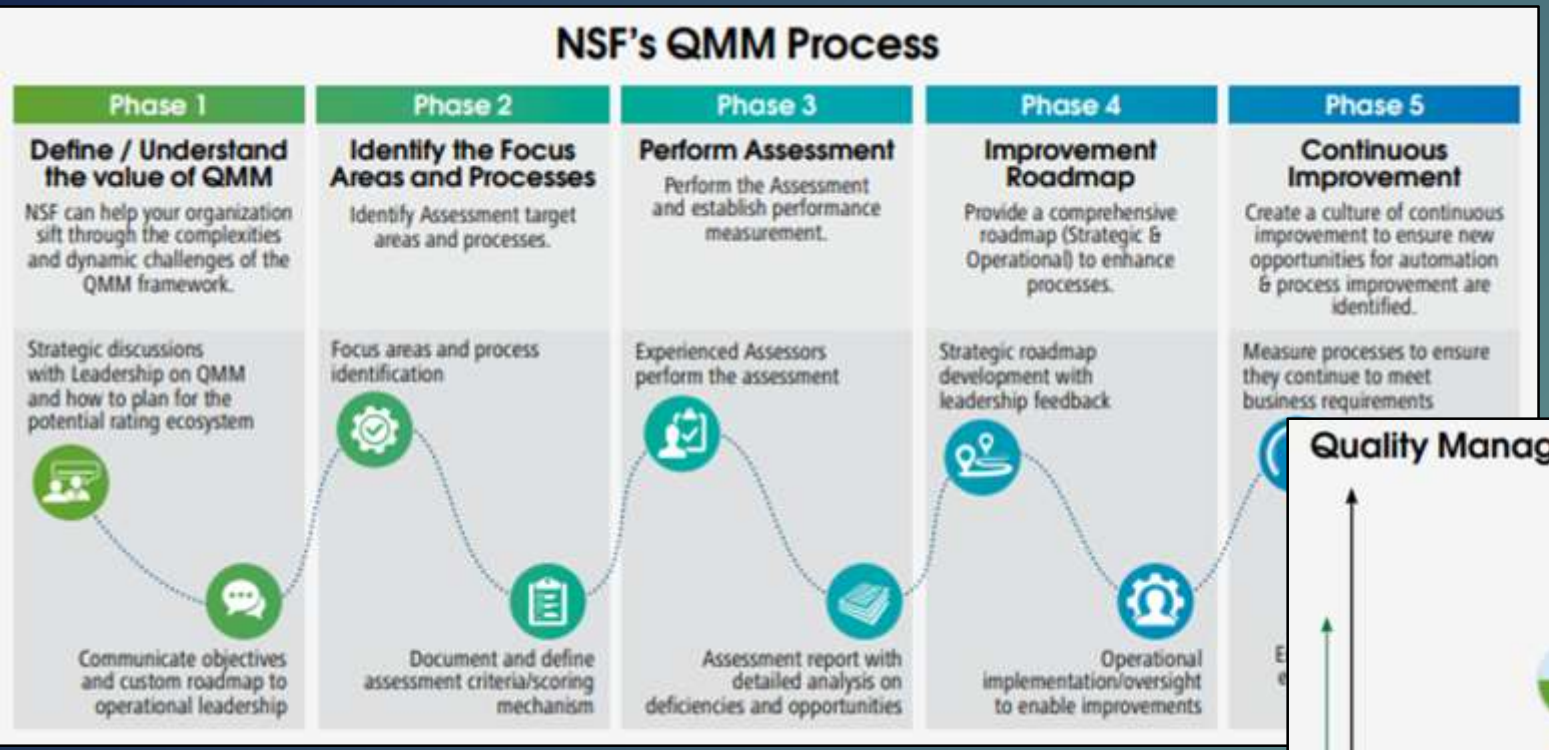
Future-Proofing Quality and Supporting Supply Chain Robustness

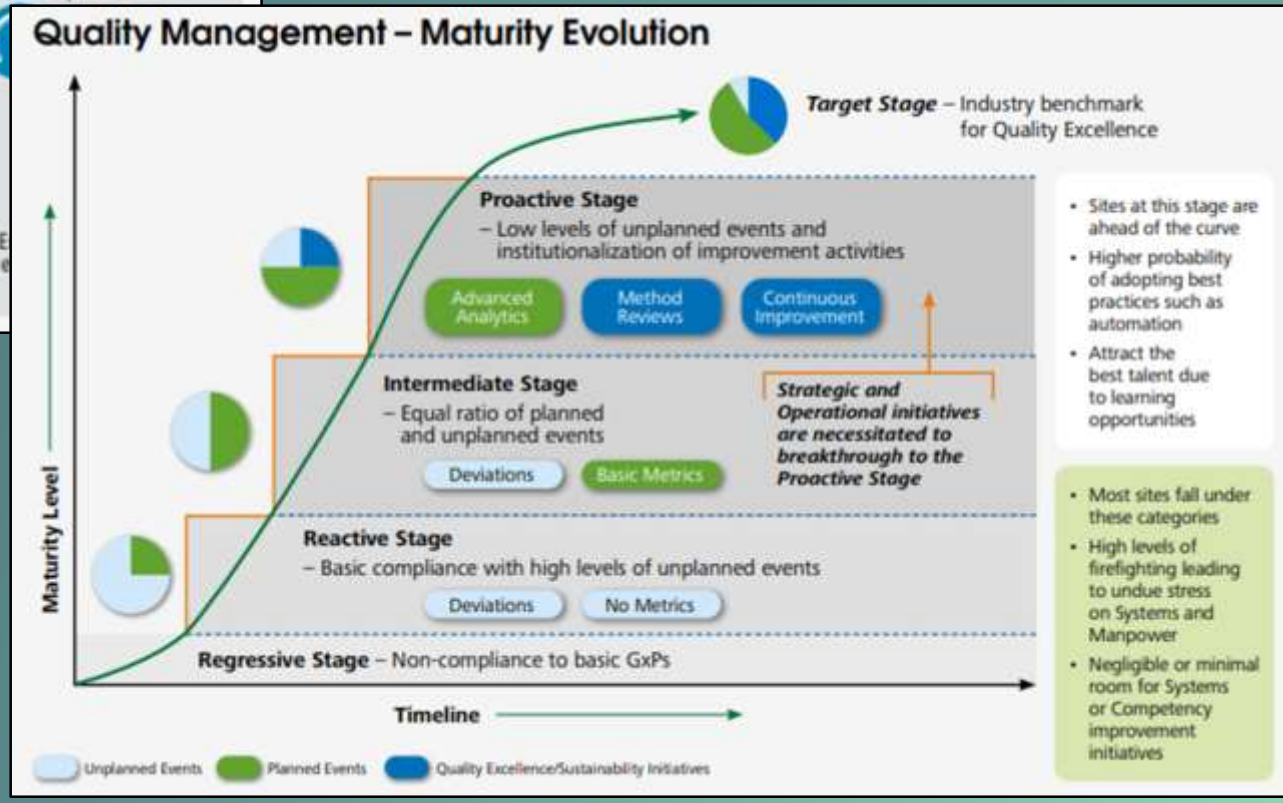
Executive Summary

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





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:

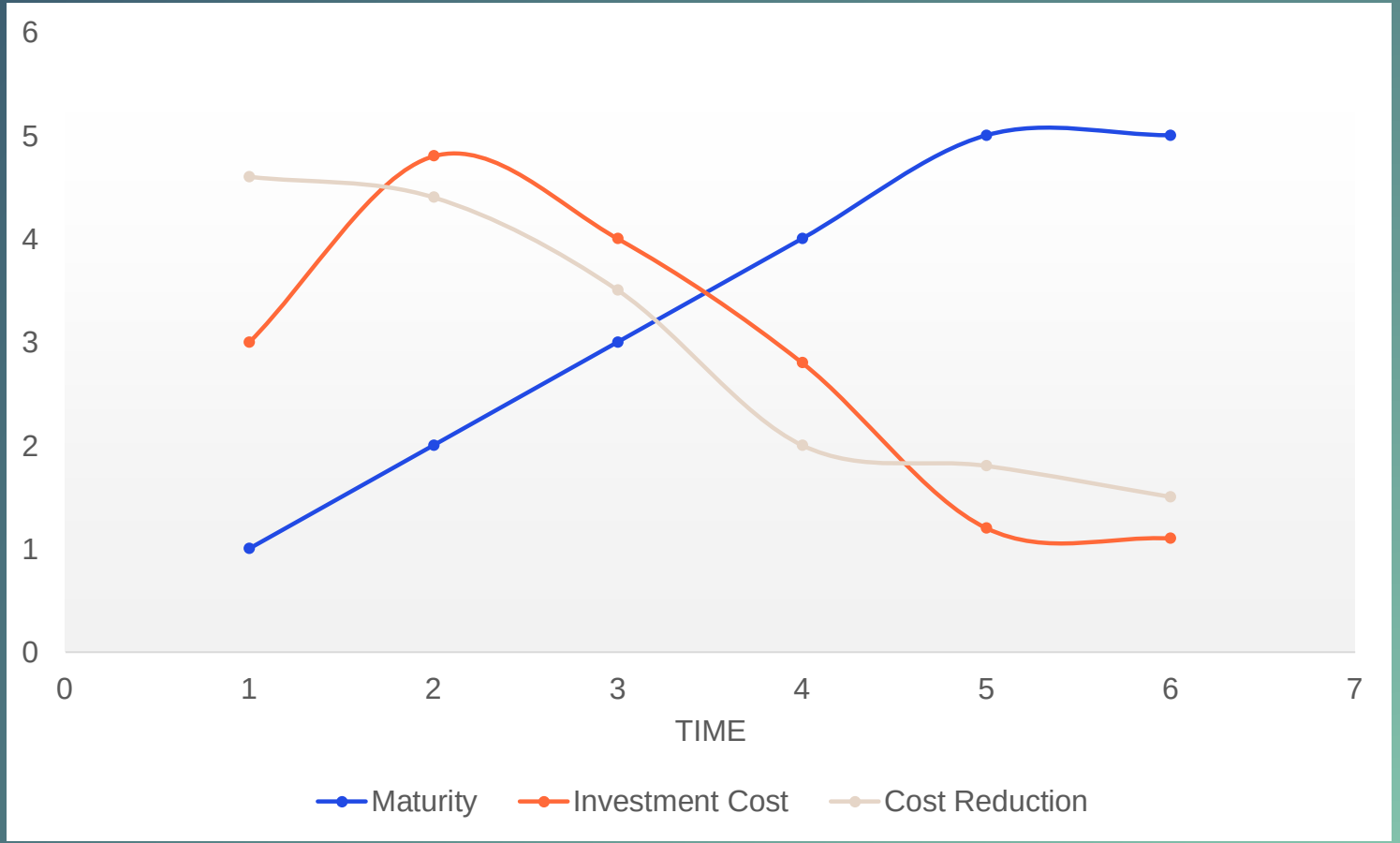
- Low levels of re-work and unplanned activities
- High levels of continuous improvement, application of best practice and workforce efficiency
- Higher levels of trust and autonomy leading to enhanced engagement and retention
- Better risk and investment decisions.

What Success Looks Like

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".

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



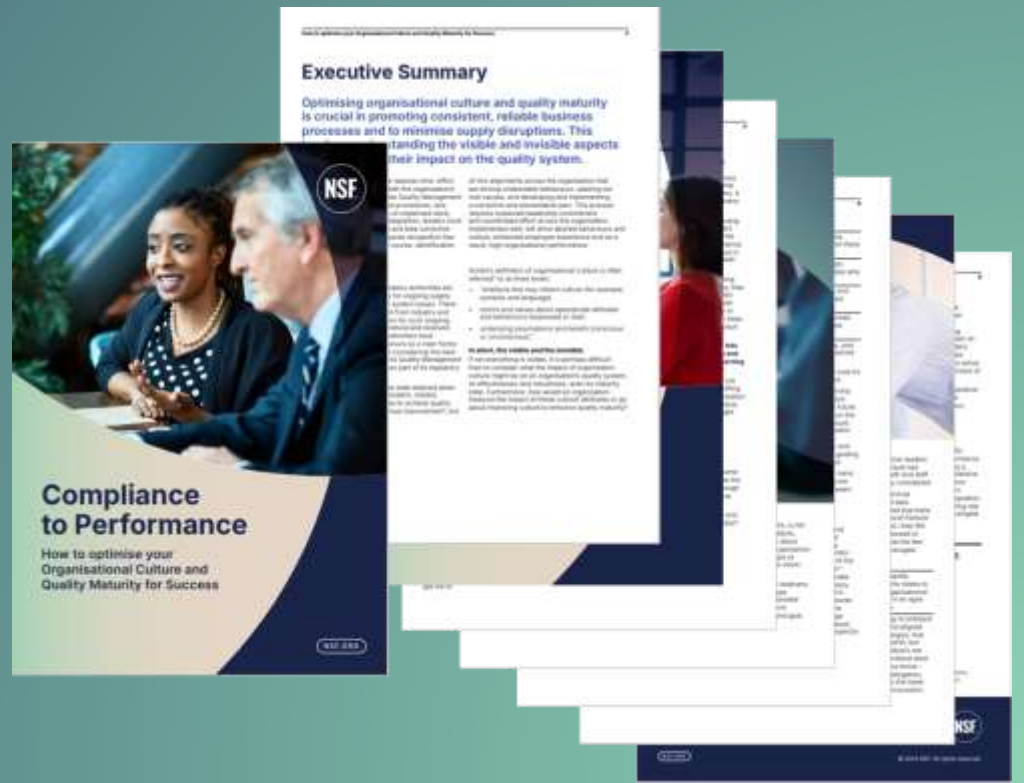
NSF's White Papers

QMM:

https://www2.nsf.org/qmmwhitepaper

Quality Culture:

https://www2.nsf.org/qualityculture



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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.