Quality 4.0

Veeva Summit

pwc

The Value of Quality

From Compliance-centric to Product & Patient-centric Quality

Patient Centric

Quality is focused on ensuring effectiveness of treatment, patient quality-of-life and driving revenue growth

Product Centric

Quality is focused on designing and manufacturing highly reliable products with highly capable processes and driving tangible bottom line ROI

Compliance Centric

Quality is primarily focused on meeting regulatory requirements and is considered a cost-of-doing business

This transformation requires a structured approach

Patient Centric

Product Centric

Compliance Centric

Quality 4.0 framework

Robust Product and Data

Innovation

Speed to Market

Competitive Compliance

Reliable Supply

Organizational DNA / Culture

Processes & Procedures

Scientific & Operational Excellence

Digital Quality

Patient Centric

Quality Outcomes

The 4 Quality Elements Centered around the patient

Quality can be measured and linked to Business Value

Quality Outcomes	Business Value - Return on Investment (ROI)				
	Metrics	↑Revenue	↓Costs	↓Inventory	↓Reg. Risk
Competitive Compliance	• Culture & Employee Engagement • Audit & Inspection Observations • Recall & Deviation Rates • Supplier Risk Profile • Total Cost of Quality *Compliance Risk Dashboard*		✓✓		✓✓✓
Innovation	• Use of Modern Mfg. Processes & Analytical Automation • Use of Emerging Technologies (e.g.: AI, Analytics) • Adoption of Enterprise Quality Systems • Use of Adaptive Clinical Trial Design • Use of QbD, QRM, CPV, etc.		✓✓		✓✓
Speed to Market	• LPO – Database Lock & CSR (by study) • LPO – 1st Major MAA Approval • Protocol Amendment Rate • Serious Breach & Critical Data Error Rate • % Post Approval Changes approved on time	✓✓✓			
Robust Products & Data	• Product & Process Knowledge (data) • Brand Image (Patient perspective) • Release Cycle Time (& variability) • Yield, OOS, OOT, OEE, Cpk • Complaint Rate *Product Quality Dashboard*	✓	✓✓✓	✓✓✓	✓
Reliable Supply	• E2E Cycle Time (DS, DP, FG, Customer Shipment) • Manufacturing Schedule Adherence • Service Levels (on time, in full) • Shipping-Related Complaints • % Dual Sourced Supply	✓		✓✓✓	

Talking the language of the CxO

CxO	Talking Points
CEO (Executive)	**Improving the company brand image** **Improving profitability**
COO (Operation)	**Robustness of processes & products** **Improved yields & cycle times**
CFO (Finance)	**Reduction in overall cost of (poor) quality** **Total cost of ownership for eQMS / eDMS**
CCO (Commercial)	**Speed to market** **Reliability of supply**
CQO (Quality)	**Competitive Compliance** **Higher compliance at reduced cost**
CSO (Science)	**Reduced # of protocol deviations & amendments** **Robustness & speed of clinical trials & approvals**

QMS Trends & Maturity
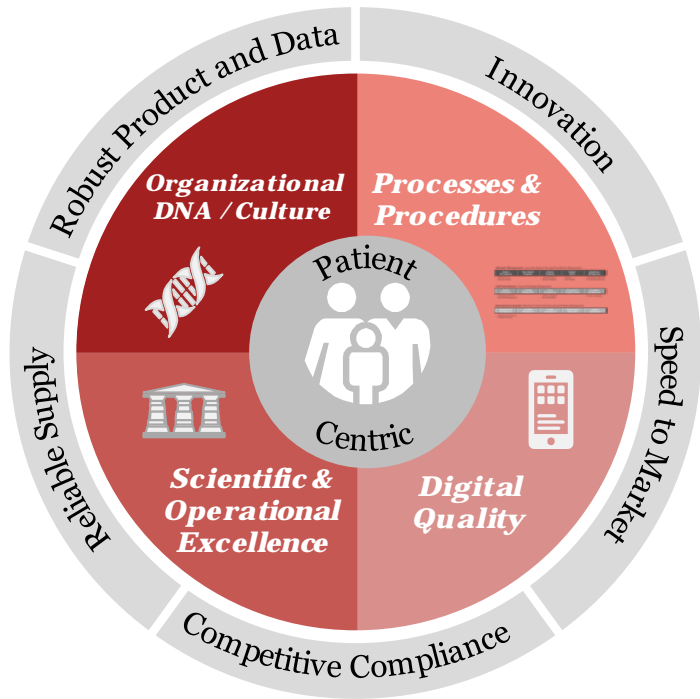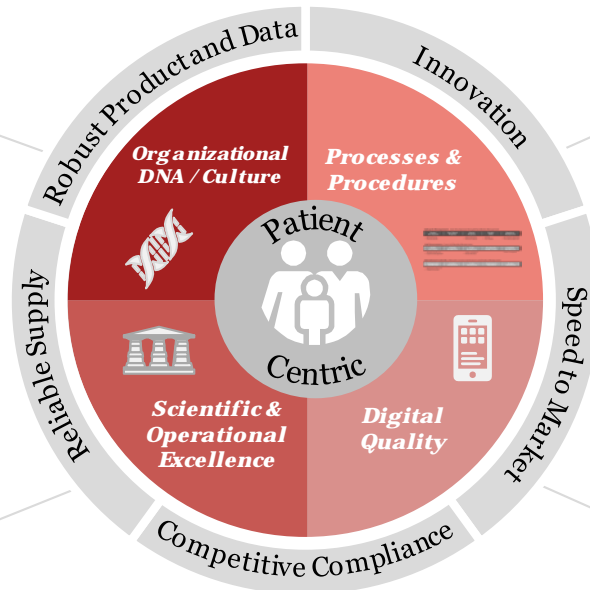
Major Trends

Big Pharma is fundamentally shifting from a Compliance-centric to a Product & Patient-centric (Big "Q") philosophy

Organizational DNA / Culture
- The quality unit is becoming more **integrated across GxP** as well as focusing on becoming **business partners**
- **Global Process Owners** responsible for driving effective and efficient Quality elements
- **Building capabilities** to manage emerging technologies (e.g.: Analytics, AI, Cell Therapy)

Processes & Procedures
- **Process-centric standardization** across GxP areas; however, with tailored, 'fit for purpose' workflows based on GxP area & risks Documentation hierarchies & procedures are being greatly simplified and aligned with the process architecture
- **Risk-based** approaches drive compliance

Scientific & Operational Excellence
- **Process Excellence** across the business, manufacturing & clinical operations
- **Product-centric quality** drives operational improvements in manufacturing & QC testing to improve yields and reduce cycle times & inventory
- **Patient-centric** clinical protocols improve data quality, lead times, product/process designs as well as speed to market
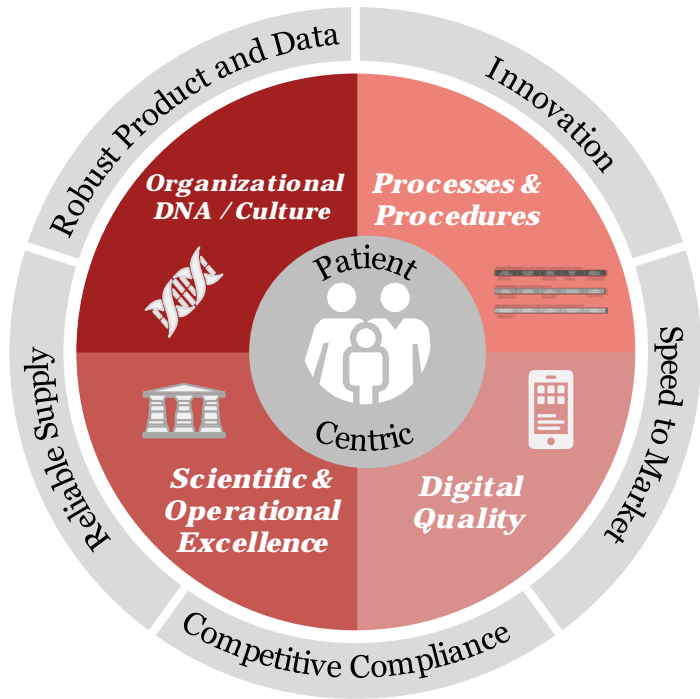
Digital Quality
- The next 3 years will see a fundamental shift towards cloud based, **Enterprise Quality Systems** ('EQS' - QMS, DMS, LMS, RIMS, TMF, etc.) or the 'ERP of Non-ERP' Systems
- Emerging technologies (**AI, Big Data, NLP**, etc.) will play an increasing role in driving Product & Patient-centric quality

03 Process Architecture & Document Hierarchy

Processes are the foundation of a strong QMS

8. Process Owners
Aligns Global & Local Process Owners with the processes to drive continuous improvement

7. Roles & Responsibilities
Defines the decision making authority between the functions and quality unit to improve compliance and speed

6. Competency Models
Creates competency-based training and career development models to build a high performing organization

5. Annual Performance Goals
Provides a direct line of sight from the business objectives to annual performance goals & priorities
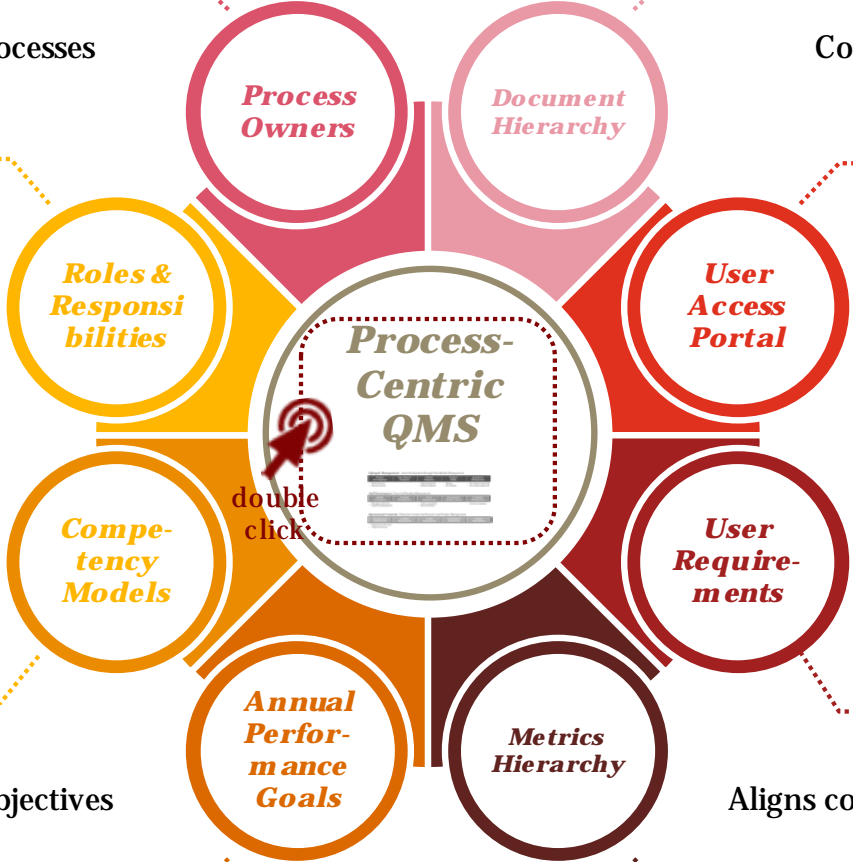
1. Document Hierarchy
Connects the GxP documents directly to the Business Processes to ensure an effective & efficient QMS

2. User Access Portal
Provides a portal to allow users easy access to documents from any device at the point & time of use

3. User Requirements
Links User / IT requirements to the business processes to ensure integrated & optimized IT systems

4. Metrics Hierarchy
Aligns compliance & product quality dashboards across the business (incl. predictive metrics)
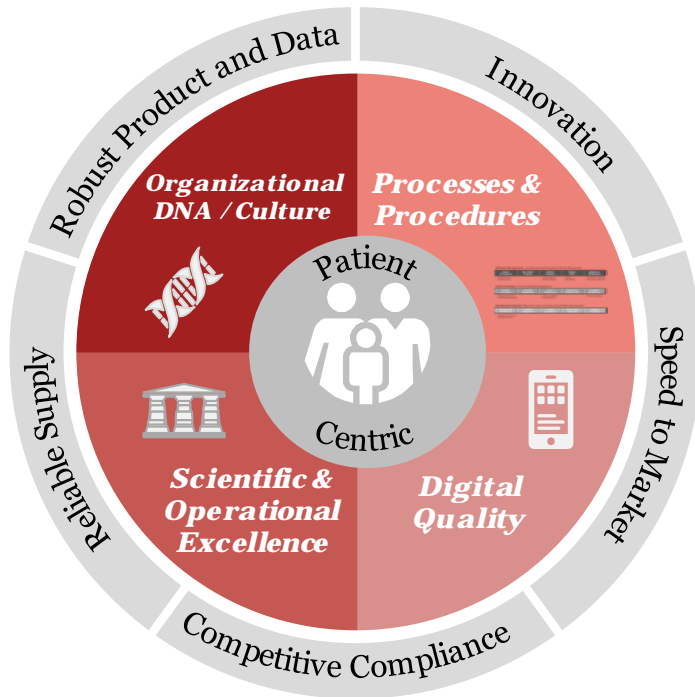
Process Owners

Document Hierarchy

Roles & Responsibilities

User Access Portal

Process-Centric QMS

double click

Competency Models

User Requirements

Annual Performance Goals

Metrics Hierarchy
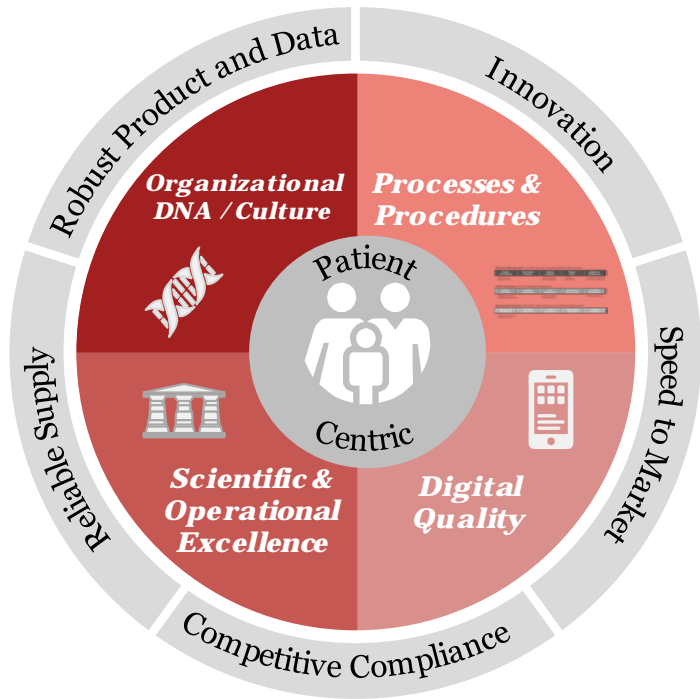
04 Digital Quality

Higher levels of Digital Quality Maturity will drive product & patient-centric quality

Patient Centric

Product Centric

Compliance Centric

New Patient-Driven Operating Models
New operating models leveraging the quality platform with external networks to ensure patient-centric quality: outcome monitoring, supply assurance, anti-counterfeiting, re-imbursement

Layer 5

Artificial Intelligence (AI)
Digital tools to proactively improve **product-centric quality** through predicting & preventing defects/failures, process optimization/ monitoring, complaint/deviation investigations, and risk management

Layer 4

QMS Analytics & Reporting
Real time reporting, trending and analysis using advanced tools (graphical user interfaces with drill down capabilities, trigger points, alerts, data lakes, and querying)

Layer 3

Enterprise Quality Systems
Standardized, integrated core enterprise applications related to Quality; including DMS, QMS, LMS, with integrations to ERP, MES, CRM/Complaints, LIMS, PLM, RIM, CTMS, and Vendor Collaborations

Layer 2

Manufacturing & Lab Automation
Leveraging new technologies to automate the manufacturing and laboratory processes as well as moving testing out of the lab to the shop floor or warehouse and implementing continuous manufacturing and processes analytics (PAT)

Layer 1

Quality 4.0 Contacts

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