Continuous Quality Improvement for Pharmaceutical and Medical Device Manufacturers:

Using Artificial Intelligence and Robotics Process Automation

FDANews Webinar

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Agenda

Continuous Quality Improvement (CQI) Overview
• What is CQI?
• Benefits and challenges of CQI?
• Implementation of CQI

Digital Transformation Across the Enterprise
• Robotics Process Automation (RPA)
• Artificial Intelligence (AI)

Robotics Process Automation Strategy
Driving Business Value
Connected Quality
Use Cases
Continuous Quality Improvement Overview
Continuous Quality Improvement (CQI)

CQI is a **process** used by an organization to support improvements in the business processes and outputs through the use of **data** and **tools**.
Benefits of CQI

- Increase sense of empowerment for employees
- Reduce compliance risks and support agency inspections
- Improve communication enterprise-wide
- Reduce costs (deviations, reworks, scrap, turnover, etc.)
- Increase efficiencies and consistency
- Build a quality culture

Meet or Exceed Customer Expectations!
Challenges for Driving CQI

- Lack of process understanding
- Lack of stakeholder involvement
- Lack of support from the top
- No true strategy or approach
- No commitment for a continuous CQI process (Remember this is a cycle!)
- Quality being seen as a cost center and not a valued business partner to drive improvements
Implementing CQI Across the Organization

1. Build a core CQI team.
2. Define and evaluate customer needs.
3. Perform a current state assessment.
5. Create a robust action plan.
6. Gather and evaluate data.
7. Learn through success and failures as a team.
8. Define and evaluate company goals.
Digital Transformation Across the Enterprise
Digital Transformation

Innovative ways Quality can digitally transform their organizations and re-imagine ways of working to accelerate growth and gain operational efficiencies.

- **Intelligent Automation & Analytics**: Unveiling efficiency and unlocking value through human augmentation.
- **Human-centered design**: Focusing on better experiences for customers and employees.
- **Innovation**: Surfacing, testing, and scaling new business ideas.
- **Emerging technologies**: Discovering and integrating new technologies.
- **IT modernization**: Modernizing legacy applications and cloud adoption.
- **Transformation Strategy**: Advising on how to create a greater business strategy enabled by technology.
Digital transformation must be supported by integrating emerging technologies and related implementation approaches to drive rapid transformation and equip teams for ongoing innovation.
Intelligent Automation (IA) Spectrum

Businesses should try to capitalize on the full IA spectrum to achieve their continuous improvement goals using technology

**Basic Automation**
- Human triggered
- Simple rules based
- Single system
- Screen scraping, Scripts, Macros, Workflows

**Robotic Process Automation (RPA)**
- Human or system-triggered
- Rules based, high-volume processes (business & IT)
- Front, middle, back office
- Structured data
- Multiple system (swivel-chair operators)
- Enterprise-level

**Enhanced Process Automation**
- Supported by basic analytics / decision support
- Optical Character Recognition (OCR)
- Intelligent document processing
- Structured and unstructured data
- Simple web chatbot integration (e.g. FAQ)

**Algorithmic Automation**
- Complex processes and decisions
- Supported by predictive / prescriptive analytics
- Machine learning, narrow intelligence, basic reasoning
- Unstructured & big data
- Internet of Things integration
- Natural Language Processing (NLP), chatbots

**Artificial Intelligence (AI)**
- Technology capable of emulating human capability incl empathy
- Full end-to-end autonomy, hypothesizing, reasoning
- Deep learning, deep neural networks, AI
- Full speech recognition and generation
- Fully capable virtual agents, omni-channel
- Augmented & virtual reality

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Areas of Most Potential for IA in Life Sciences

The life science areas below showcase the best case scenarios for automating parts of the business through innovation and new technologies.
Today’s modern workforce needs advanced technology solutions that empower them to excel in new digital service delivery models.

RPA automates repetitive, high-volume manual processes involving multiple applications, enhancing employee productivity and lowering costs.

**RPA offers:**
- A virtual workforce that mimics and emulates the human workforce
- Improved customer & staff engagement
- Automated high volume, manual & repetitive tasks
- Reduced operating costs with improved customer acquisition & retention
Artificial Intelligence (AI)

AI is the ability of computer to perform cognitive tasks normally associated with humans: decision making, reasoning, learning and emotions. The possibilities for applying AI in improving human lives are growing exponentially.
Why Transform now?

Who led the digital transformation of your company?
A) CEO
B) CTO
C) COVID-19
Intelligent Automation
Strategy & Driving Business Value
Envision Implementing RPA Across the Firm

**RPA Assessment**
Work to define and prioritize automation goals through structured workshops, assessments.

**RPA Pilot**
Develop Bot for automation pilot; create operational deployment plan; automation BCA; Pilot Bot in development environment; prove value and business case.

**RPA Operations**
Operate, monitor and maintain production Bots; establish and staff organization-wide Automation CoE; conduct automation methodology and tools training.

**RPA Strategy**
Develop comprehensive enterprise roadmap including governance, change management and security; select technology; document scenario steps; conduct time and motion study to capture saving; create high-level business case and phased project plan.

**RPA Implementation**
Scale and transition Pilot Bot into an operational environment; test bot, capture and program exceptions process; implement relevant aspects of automation strategy.
Automation Drives Organizational Value

**Cost Savings**
The average cost of implementing a robot is much less than equivalent FTE costs and decreases with large-scale deployments.

**Speed & Productivity**
Automation is typically 2-3X faster than humans. Robots can also work 24/7.

**Accuracy & Compliance**
Robots work to 100% accuracy levels and enable compliance. Avoiding human error saves costs.

**Scalability & Flexibility**
Robots can be easily scaled up and down to handle demand fluctuation and seasonal variations.

**Removal of Non-Value-Add Processes**
Robots free up the workforce to focus on a broader set of responsibilities and new initiatives.

**Knowledge Capture & Transfer**
Transfer knowledge from humans to bots to preserve critical knowledge.
Connected Quality
Leveraging Emerging Technologies in an “Ideal” QMS

The ability of RPA, AI, and Intelligent Automation to deliver business value and continuous improvement is strongly correlated with two properties for QMS Processes and Data:

<table>
<thead>
<tr>
<th>01</th>
<th>Process Definition &amp; Harmonization</th>
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<tbody>
<tr>
<td>• Robotic Process Automation (RPA) can only be implemented when a process is well-defined and repeatable, with clear rules for exceptions</td>
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<tr>
<td>• Machine Learning (ML) and other Intelligent Automation Approaches work within in a well-specified scope for a specific purpose</td>
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<tr>
<td>• Artificial Intelligence (AI) can handle more variation than RPA or ML, but is aspirational in the sector and will come only after further maturation of RPA and ML</td>
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<table>
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<th>02</th>
<th>Data Quality &amp; Availability</th>
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<tr>
<td>• RPA is limited by the “garbage in – garbage out” adage—bots will only process data according to rules, so if the data is not properly mastered, consistent, and available, the bot will either fail or produce garbage</td>
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<tr>
<td>• Both Intelligent Automation (ML and other approaches) and Artificial Intelligence require large, high quality data sets to function properly, “learn” effectively, and produce valuable results</td>
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How Closely Life Sciences Approximates the “Ideal”

It does not:

• The ecosystem of platforms that contribute to Quality Management and Continuous Improvement is often siloed by system / function, by site / legacy organization, and/or between “on premise” and hosted/cloud solutions

• In many cases the business processes serving similar goals in the disparate systems are very dissimilar

• Data is often not mastered across this ecosystem, and the metadata architecture within seemingly similar systems can vary greatly

• Data is not shared or consolidated across the landscape, making reporting and decision making time-intensive and difficult

Representative Systems

- Enterprise Resource Planning (ERP)
- Manufacturing Execution System (MES)
- Production Historian
- Regulatory Asset Management System (RAM/EAM)
- Document Management System (DMS)
- Learning Management System (LMS)
- Quality Management System (QMS)
- Laboratory Information Management System (LIMS)
- Scientific Data Management System (SDMS)
- Regulatory Information Management System (RIMS)
- Reporting and Business Intelligence (BI)
- Records Retention & Archiving Platform
Connected Quality: A foundation for CQI

Establishing a Connected Quality architecture sets the stage for continuous improvement and allows a firm to unlock the value of emerging technology by:

- Mastering data definitions and handling
- Pooling like data sets to create sufficient volume to implement Machine Learning and Artificial Intelligence
- Providing visibility and signal detection to identify both risks and best practices
  - This empowers the identification of best practices and the development of robust metrics
  - Process harmonization becomes organically driven through the process of risk mitigation and best practice sharing

Benefits

- Near real-time data-driven decision making at all levels of the enterprise
- Far more insightful understanding of in-network risk, plus the ability to identify and drive best practice sharing
- Scalable solution that is able to integrate the full landscape of operational and quality systems
- More agile and effective regulatory reporting and remediation of observations

Assets

- Internal IT infrastructure to host integrated data layer, and/or alliance with 3rd party cloud hosting
- Internal licences and capacity to host Analytics / RPA / AI platforms, and/or alliance with 3rd party SaaS partner

Risks

- Global buy-in and support for change initiative
- Data integrity and security
- Developing capabilities for application and lifecycle support
When embarking on a digital transformation to enhance Quality and Continuous improvement, firms need to consider whether to keep their platforms on premise or move to the private cloud:

<table>
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<tr>
<th>All-In-One Cloud Platform(s)</th>
<th>On Premise Enterprise Platform(s)</th>
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<td><strong>PROS</strong></td>
<td><strong>CONS</strong></td>
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<tr>
<td>Reduces integration points &amp; transformations: Provide a spectrum of component Modules (CTMS, RIMS, DMS, QMS) on a shared platform</td>
<td><strong>3rd Party is handling your data</strong>: Contracting for and building out the Push/Pull of data from the hosted solution to the firm’s data layer can be challenging</td>
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<td>Drives process harmonization: Workflows honed by market best practices with frequent enhancements and minimized customization</td>
<td><strong>Boundary System challenges</strong>: Integrations between separate cloud platforms and cloud to on-premise integration can be difficult depending on the solution</td>
</tr>
<tr>
<td>Expanded access and outsourced Disaster Recovery / Business Continuity burden</td>
<td><strong>Change Management</strong>: to a global platform with shared business processes requires significant up-front work on process harmonization and subsequent change management and training to achieve understanding and adoption</td>
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**Consolidates like processes and data into platform(s) shared across regions, sites, and functions**: Reduces integrations and transformations

**Drives process harmonization**: The act of consolidating requires up-front workshops to define common workflows

**IT Infrastructure & Lifecycle Maintenance Challenges**: Firm incurs ongoing cost of maintaining applications/databases; upgrades can be difficult and infrequent

**Change Management**: Consolidation to a global platform with shared business processes requires significant up-front work on process harmonization and subsequent change management
Evaluating component systems to achieve “Ideal” (continued)

Whether the chosen solution set is cloud-based, on premise, or a combination, several additional characteristics can help accelerate a firm towards Connected Quality:

### Native Reporting & Analytics Capabilities

**Don’t overvalue native analytics and reporting features that work only within a given platform:** Most platforms have searching, filtering, trending, and reporting capabilities which can be used to meet basic needs. However, to achieve a truly connected quality ecosystem, these capabilities are either not sufficiently advanced or only work within the platform and can’t ingest relevant and related data from other sources. **Firms are better suited implementing fit-for-purpose analytics and reporting engines atop their integrated data layer.**

### Ease of Integrations

**Do place a high value on platforms offering proven Application Processing Interfaces (APIs) and flat data architectures:** Most leading platform vendors are aware of the ecosystem into which their systems get implemented and have developed APIs to the most common edge ware and middleware systems they encounter (for example LIMS to SDMS or Instrument Management interfaces).
Visioning the Future with Connected Quality

Visualizing and Forecasting the Impact of Quality and Laboratory activities on the Supply Chain

Realizing the value of an integrated data lake to provide drill-downs to:

- Process Control Charts
- CART / Decision Tree Analysis
- Logistic Regression
- Time Series Analysis
- Heat Mapping
- Pareto / Stacked Pareto
- Geographic Distribution / Gravity Mapping
- Personnel Load Diagrams
- Workflow Status / Cycle Time Diagrams
- Box & Whisker Process Performance Monitoring
- Tactical Workload Calendars
- Standard / Management Review Reports
- Automated APR/PQR Content Collection
Use Cases in the Industry
Leading Biopharmaceutical Firm - CRO Onboarding & Registration Automation

Robotic Process Automation reduces effort required for manual data entry while improving quality and providing enhanced visibility into the process.

**Bot Inbox**

- Requests include New Accounts, Access Changes, and Revocations
- 150 requests/week
- 10 min/request manual

**Ingest**

**Automated Process**

- Robot monitors RPA Intake Mail Folder for new E-mails to initiate the process
  1. Validates account request against Business Rules
  2. Launches system and enters account details
  3. Reports Status of each request

- <1 min/request automated

**Output**

**Results**

- Support Team is freed up to focus on complex support tasks.
- 25+ hours/week saved
- 1300+ hours/year saved
Thousands of documents created or received daily

**How to classify documents**

- eTMF Use Case
  - Backlog of files to classify
  - Duplicate requests for documents
  - Long cycle time to resolve queries
  - Documents in various languages
  - Missing documents
  - Difficulty tracking completeness
  - Compliance risks/inspection findings

**Current State**

**Future State**

- Document auto classification proposed to user

**Benefits:**
- Reduction in user training
- Faster document output
- Fewer misclassified documents
- Better reporting

**Timeline:**
- 5-6 months
CLIENT CHALLENGES

• A large global pharmaceutical company, with over 100 years of history of providing innovations, improving lives, and saving patients.
  – Maintenance data concerning equipment downtime is spread across multiple sources in multiple formats
  – Efforts to identify key trends is intensive
  – Preventive maintenance is difficult to forecast

CGI SOLUTIONS

• Implemented CGI’s Asset & Resource Management (ARM) with a focus on Enterprise Asset Management (EAM)
• Used artificial intelligence and machine learning to trend predictive maintenance
  – Performed data cleansing on raw data in order to yield accurate results
  – Built and tested a model using training and validation data
  – Deployed the model using analytics and trend visualizations

BENEFITS DELIVERED

• Consolidated report of data, equipment list, deviation, component failures and downtime into a single view for the Manufacturing Center of Excellence
• Ability to trend predictive asset maintenance
• Decrease asset downtime, leading to reduced production loss and cost to quality
• Delivered POC in 3 months
Continual improvement should be a permanent objective of the organization”, as mentioned in ISO 9001…The one true goal for any company is for quality to be owned by the entire organization and embedded in its culture.
Thank you! Questions?

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