

AI in Quality Management

July 31st, 2024





Andrew O'Hara


Product marketing for B2B SaaS


Andrew O'Hara is a marketing professional with 20 years' experience in quality management system (QMS) software. Andrew has worked for software vendors including Gael Quality, Ideagen, and ComplianceQuest, and across industries including aviation, food and beverage, healthcare, life sciences, manufacturing, rail, and transportation and logistics. Throughout his career, Andrew has worked to understand the needs of users across multiple markets, taken numerous products to market, and driven a customer-centric approach to QMS software.


Andrew's commitment to excellence and his passion for quality has gained the respect of his peers in the B2B marketing community. As an experienced product marketer, Andrew has worked to understand the challenges facing quality professionals in achieving and maintaining compliance, equipping organisations with the knowledge to meet their users' needs. His research and analysis skills have enabled him to guide product development and customer success, nurturing an environment of learning across industries and organisations.



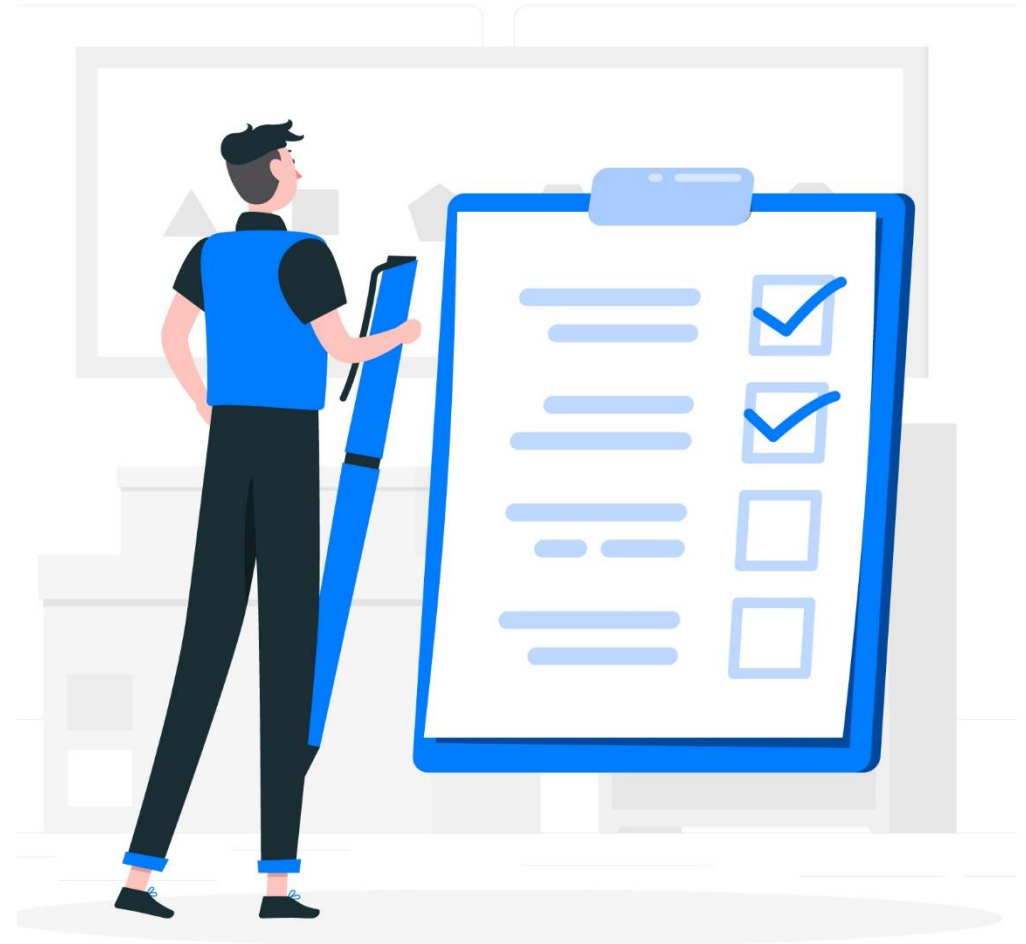
What This Session Covers

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AI in Quality Management
- 

Applied AI Use Cases
- 

What's Next?



AI in Quality Management



What is AI?

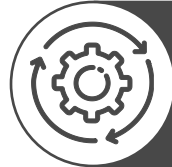
“The ability of a machine to perform cognitive functions we associate with human minds”

McKinsey & Company



Decision Support

Leveraging advanced algorithms and machine learning models to provide actionable insights and support strategic decisions



Hyper-Automation

Integrating and coordinating multiple relevant automation technologies to automate all business processes that can or should be automated



Advanced Analytics

Using complex machine learning and visualization techniques to derive data insights beyond traditional business intelligence

“In talking about AI, we include both hyper-automation and AI, as they both relate to augmenting user capabilities to complete their tasks and processes faster and more efficiently with fewer errors.”

Gartner

AI in Quality Management

Use Case

Use Case

Use Case

Process

Use Case

Use Case

Use Case

Use Case

Process

Use Case

Use Case

Process

Product

Platform

Capability

Capability

Capability

AI in Quality Management

Complaint Intake

Complaint Handling

Complaint Investigation



Complaint Management

Findings Classification

Findings Reoccurrence



Audit Management

NC Classification

NC Prioritization

CA/PA Escalation

NC Reporting



NC & CA/PA Management

Next Best Action

Report Categorization



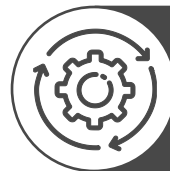
User Experience

QMS

AWS, Azure, Salesforce



Decision Support



Hyper-Automation



Advanced Analytics

Applied AI – Quality Management



Assisted Decision-Making

Smart insights served up at the right moment to help with making swifter and better-informed decisions



Guided Workflow

Recommendations to guide users while using the product so they can successfully complete their tasks and processes



Assisted Summaries

AI-powered generation of content using structured and unstructured data to reduce variability and improve compliance



Smart Recommendations

Intelligent recommendations served up at the right time to help increase efficiency and improve decision-making during workflows



Intelligent Automation

AI-powered automation of steps, tasks or processes without the need for manual effort



Predictive Visibility

Analysis of current and historical data to detect trends, predict future possible events and show these predictions to users, which allows for a proactive approach

Applied AI – Quality Processes

Improve customer satisfaction

- Automated categorization and classification
- Intelligent triage to automate Cases to Complaints
- Extract insights from Case intake to auto-populate record
- Search for similar records linked to an existing investigation to minimize duplicate entry
- Reduce redundant records by detecting duplicates and automatically merging and closing them
- Automated determination of health authority reportability
- Retrieve and select records with semantically similar descriptions to start an investigation
- Detect existing repeat/trending issues to flag potential failures for risk mitigation

Achieve compliance and take timely actions

- Automate nonconformance (NC) classification and categorization
- Identify reoccurring NCs and recommend escalation to CA/PA
- Find CA/PA records related to existing investigations to flag for potential failures to improve compliance

Applied AI – Quality Processes

Make better-informed decisions

- Embedded insights and predictions to assist decision-making within Audit, Change Control, Complaints, and Supplier
- Spot trends and reoccurrences to flag potential failures and recommend actions
- Find similar issues to recommend starting an investigation
- Quickly conduct AI power searches for fast results

Cut down manual work in audit and risk

- Identify similar audit findings to determine reoccurrence and show the resulting finding records in a related List
- Automatically prioritize risks
- Suggest audit finding type based on description of previous similar findings
- Identify and mitigate risks across Complaints, Quality, Safety, Design Controls/Product

Applied AI – Quality Processes

Improve supplier performance

- Identify communication reason from supplier emails and route to appropriate group
- Identify reoccurring supplier issues and recommend escalation to CA/PA

Improve user experience

- Deliver right contextual information to the right person at the right time
- Enhanced Task-Driven Next-Best Action (NBA) states the required prerequisites, view pending tasks and help drive the Tasks needed to be completed with guided help
- Recommend issue categories based on descriptions submitted in any intake

Use cases



Applied AI – Use Cases



Complaint Management

- Complaints Intake
- Complaints Handling
- Complaints Investigation



Audit Management

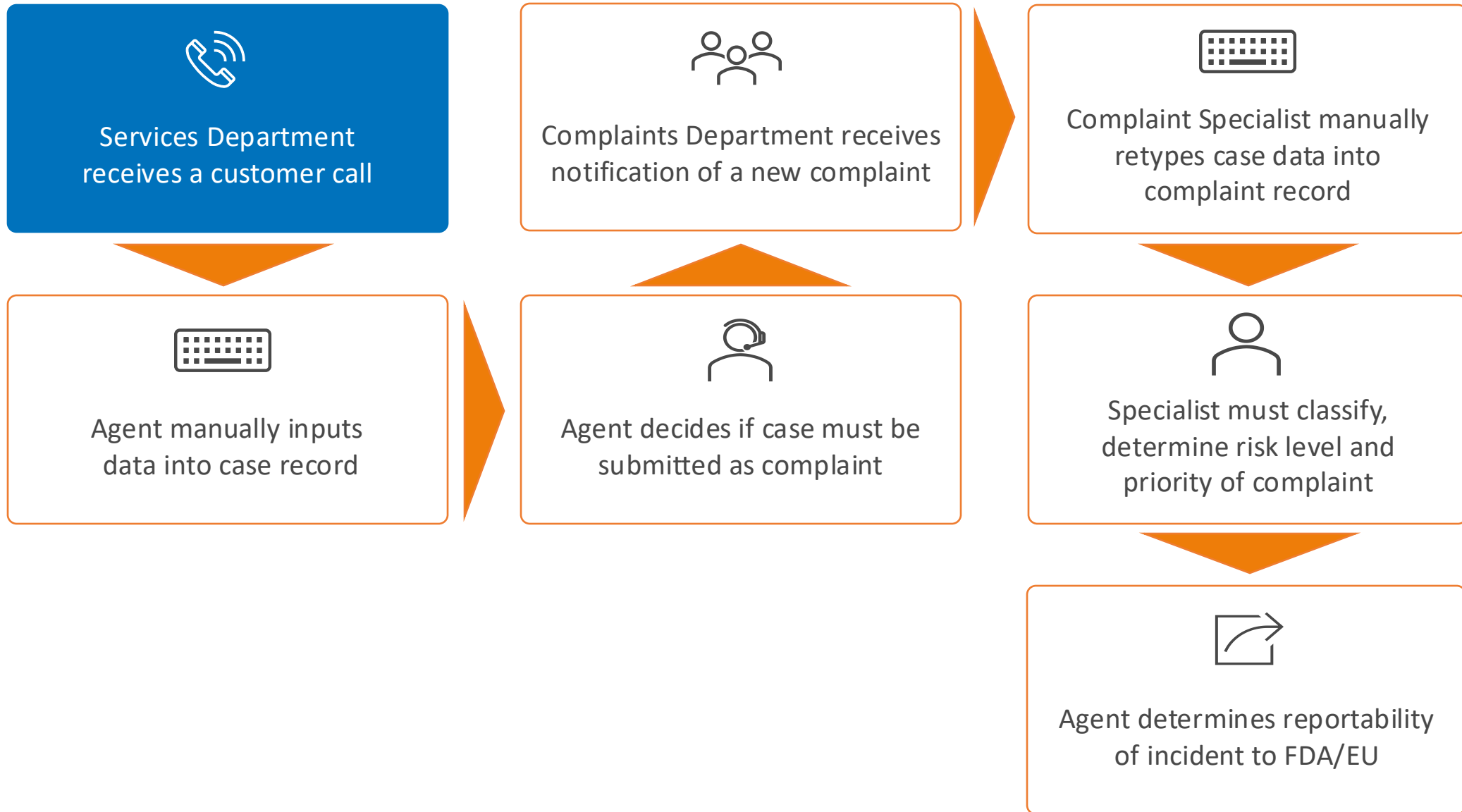


NC & CA/PA Management

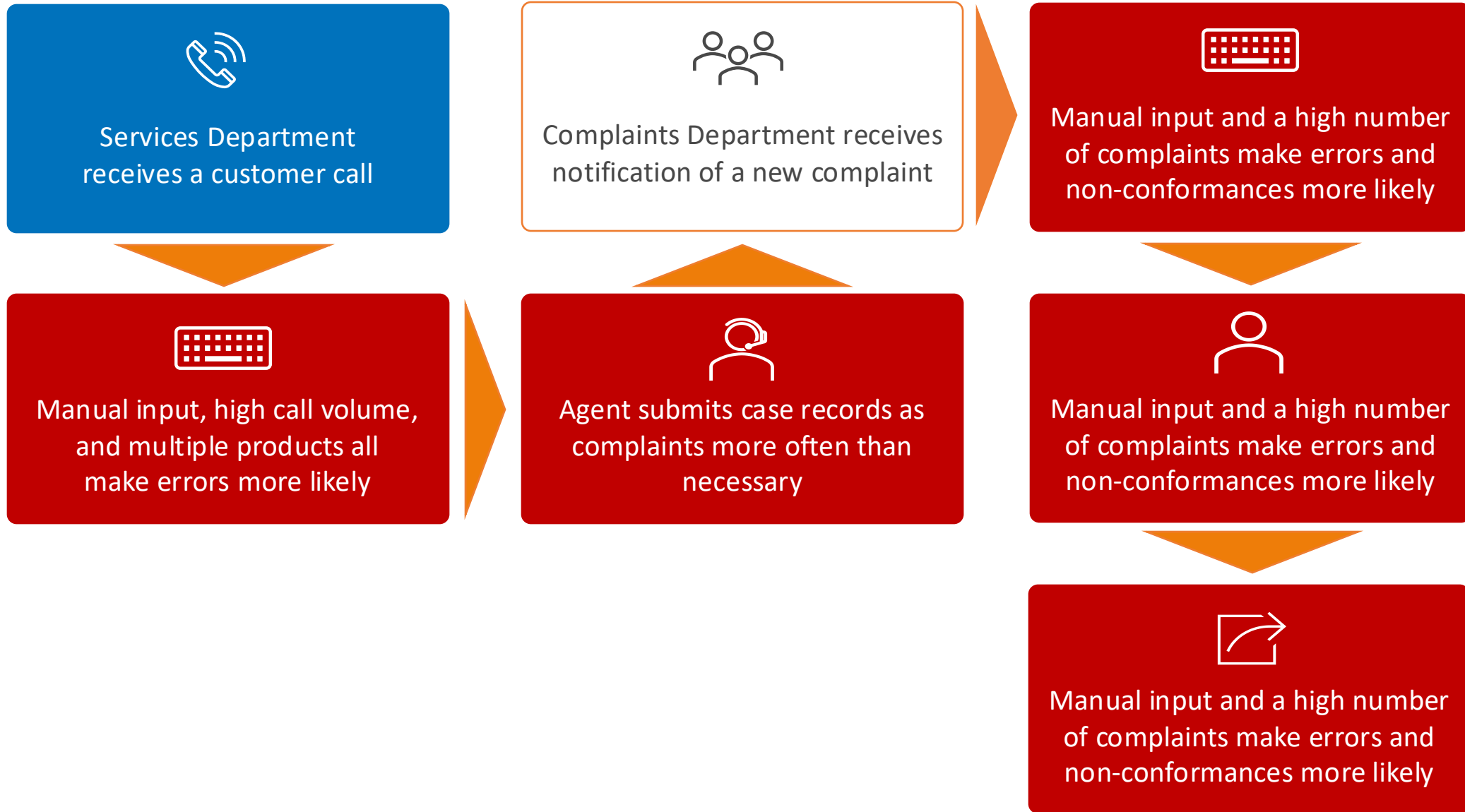


User Experience

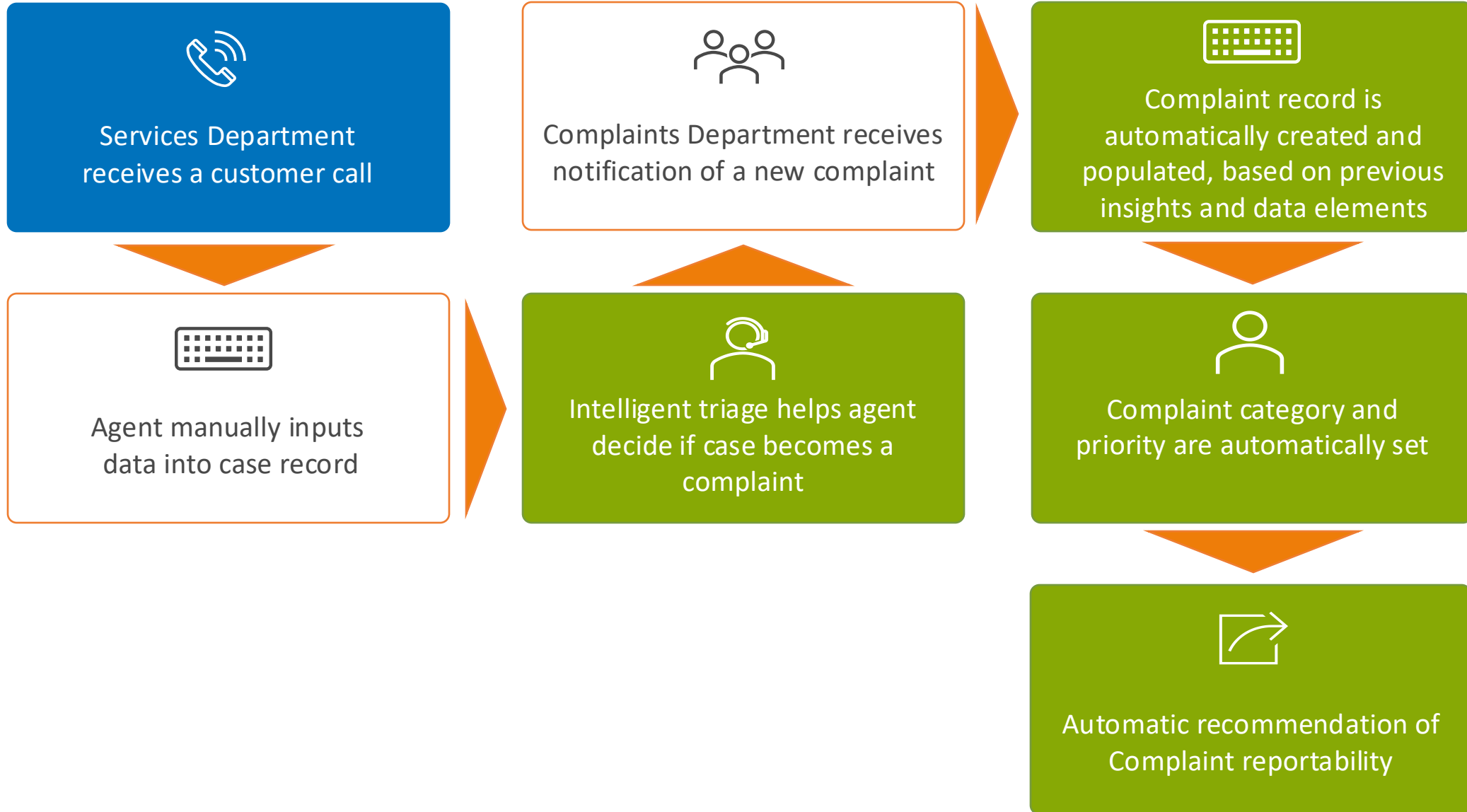
Complaints Intake



Complaints Intake



Complaint Intake



Applied AI – Case Study

Global medical device manufacturer

Without AI

With AI

400

call
scripts

40,000

complaints
per month

200

call
scripts

4000

complaints
per month

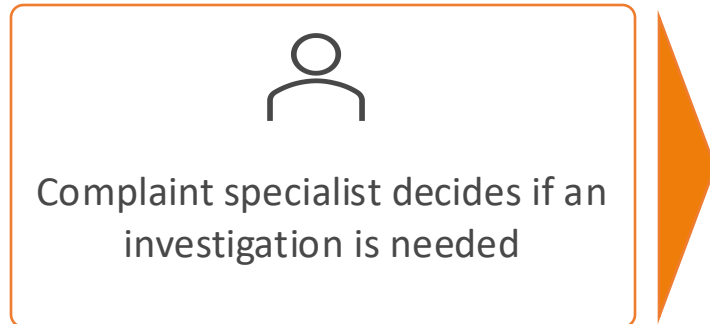
Longer to resolve complaints
More unnecessary submissions

Quicker to resolve complaints
Lower risk of non-compliance

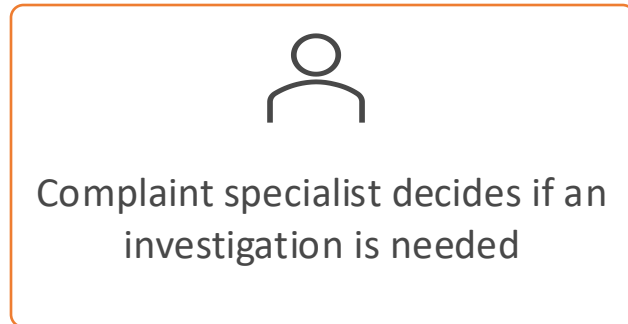
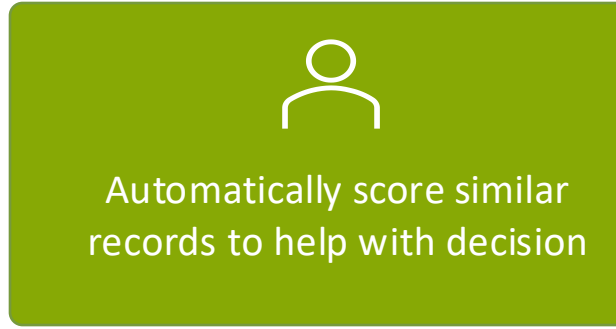
Complaint Handling



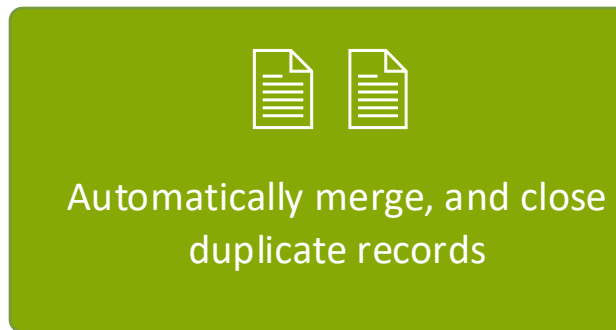
Complaint Handling



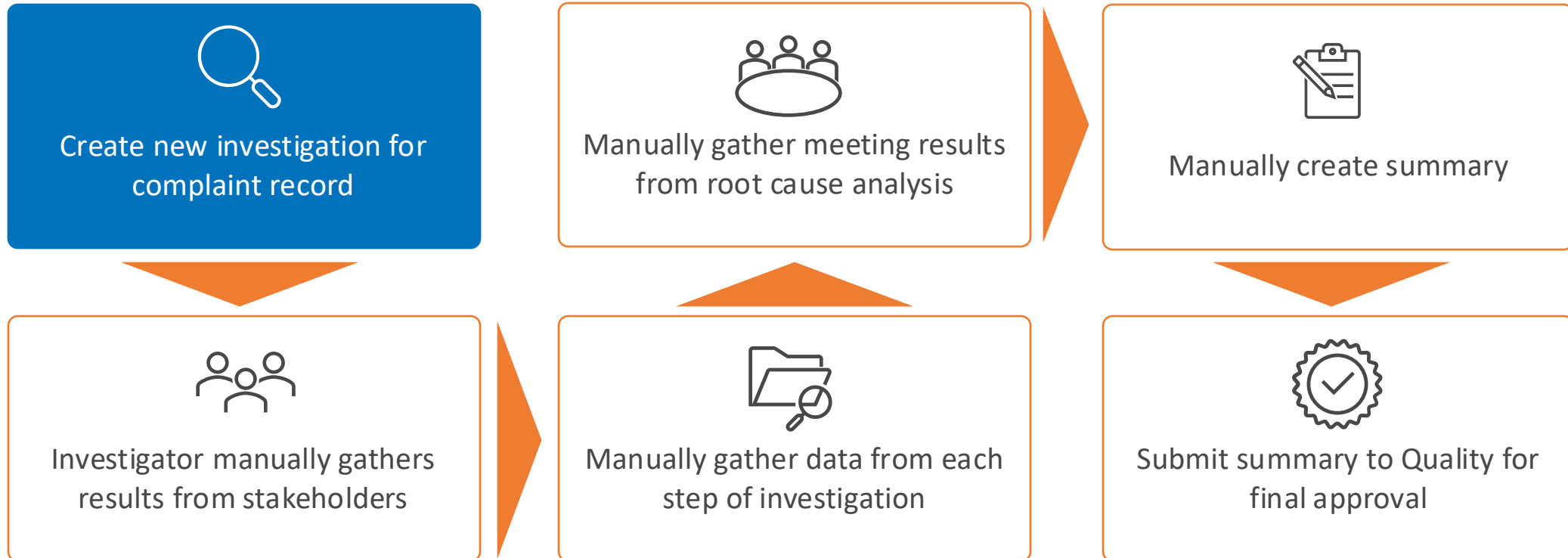
Complaint Handling



OR



Complaint Investigation



Complaint Investigation



Complaints Investigation



Applied AI – Complaint Management

Functionality

- Automation of Case to Complaints through intelligent triage
- Automated Categorization and/or Classification of Complaints
- Automated recommendation of Complaint Risk Level
- Automated determination of Complaints reportability
- Automated generation of Complaints Investigation summary

Benefits

- Decrease case to complaint triage time
- Decrease in input errors
- Reduce number of unnecessary complaints
- Less risk of error or decision bias
- Quicker complaint handling
- Cleaner data
- Improved risk management
- Faster time to regulatory submission
- Decrease in number of unnecessary submissions

Applied AI – Use Cases



Complaint Management

- Complaint Intake
- Complaint Handling
- Complaint Investigation



Audit Management

- Findings Classification
- Findings Reoccurrence



NC & CA/PA Management




User Experience

Audit Management



Audit Management



Internal audit scheduled at manufacturing site



Manually creating a new investigation for a finding is time-consuming



Track investigation for findings



Subjective decision with risk of decision bias




Quality team reviews audit report, assesses and approves findings

POTENTIALLY




Manually searching hundreds or thousands of records makes errors more likely



Escalate to CA/PA

Audit Management



Internal audit scheduled at manufacturing site



Launch new investigations, and automatically link audit findings to new investigation



Link audit finding to any ongoing investigation



AI recommendation for audit finding categorization




Quality team reviews audit report, assesses and approves findings

POTENTIALLY



Automatically score and show similar records and recommend marking as reoccurring



Escalate to CA/PA

Applied AI – Audit Management

Functionality

- Identify similar Audit Findings to determine reoccurrence and show related Audit Findings
- Suggested Audit Finding Categorization based on the description of previous similar findings

Benefits

- Less risk of error or decision bias
- Cleaner data
- Increased efficiency
- Improved compliance

Applied AI – Use Cases



Complaint Management

- Complaint Intake
- Complaint Handling
- Complaint Investigation



Audit Management

- Findings Classification
- Findings Reoccurrence



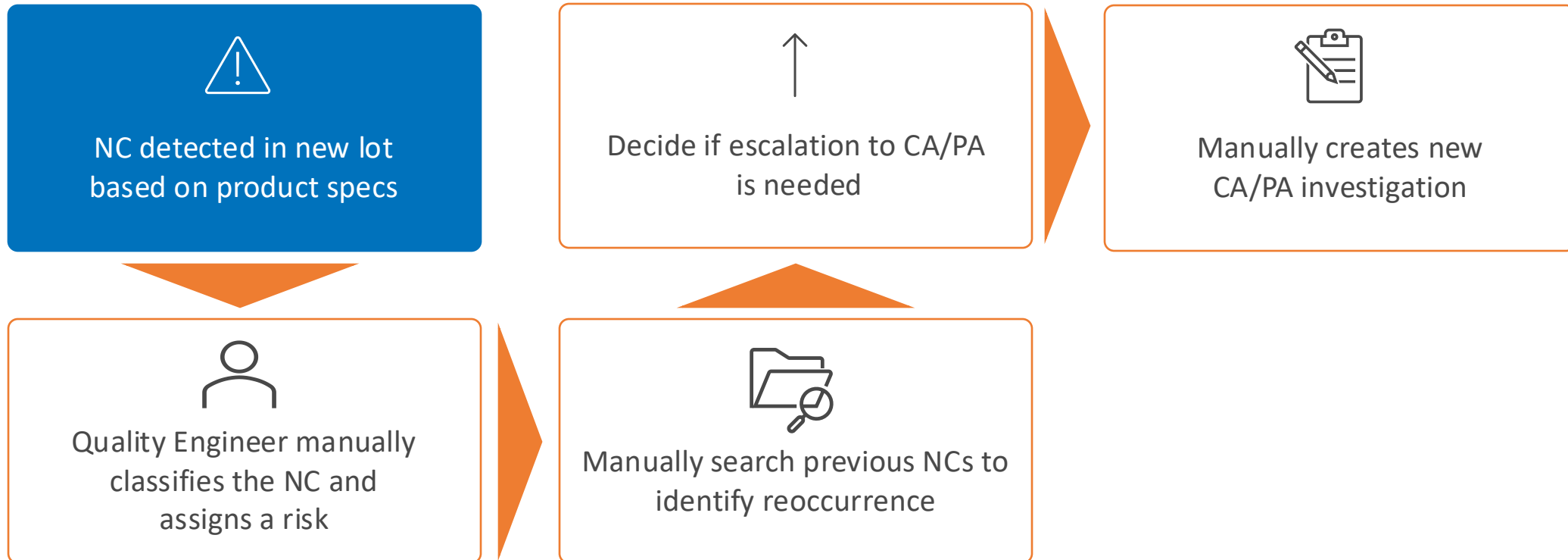
NC & CA/PA Management

- NC Classification
- NC Risk Prioritization
- CA/PA Escalation
- NC Reporting

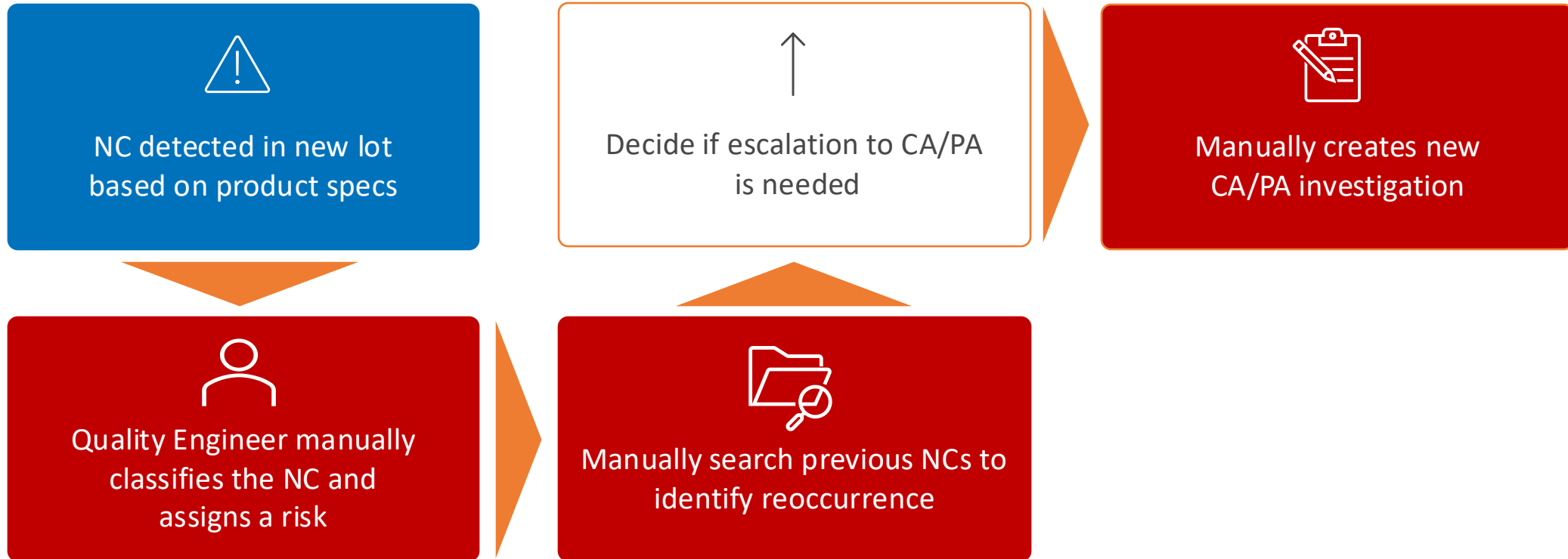


User Experience

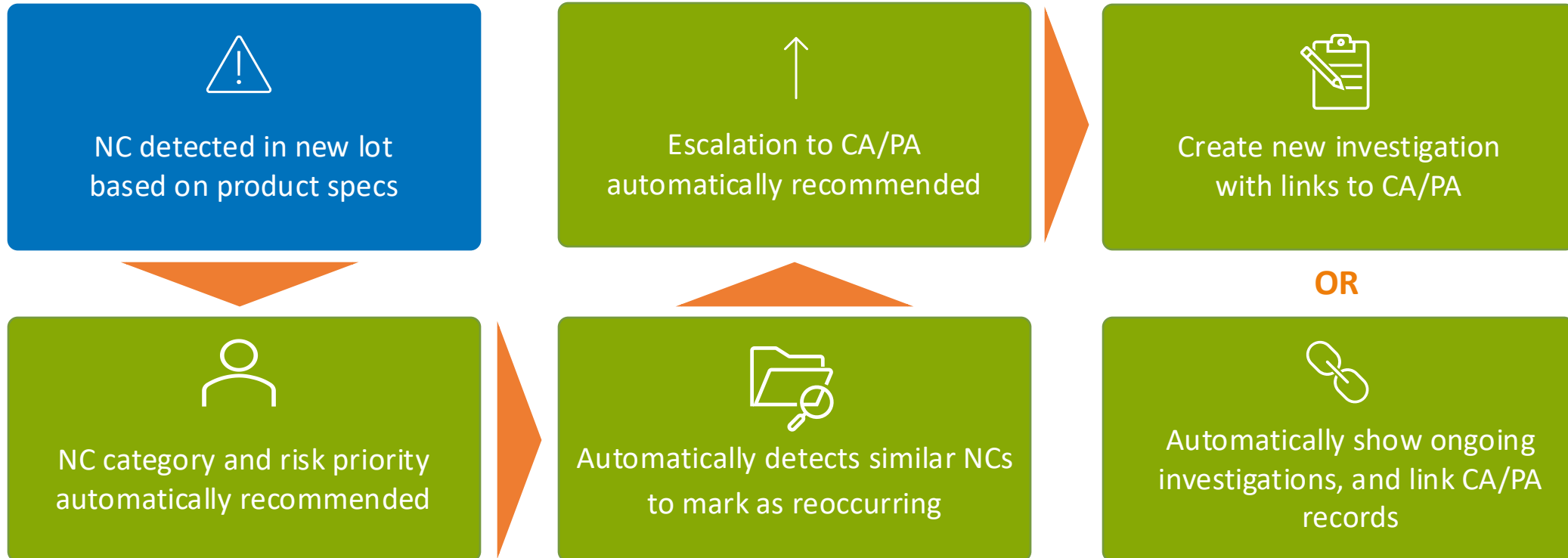
NC and CA/PA Management



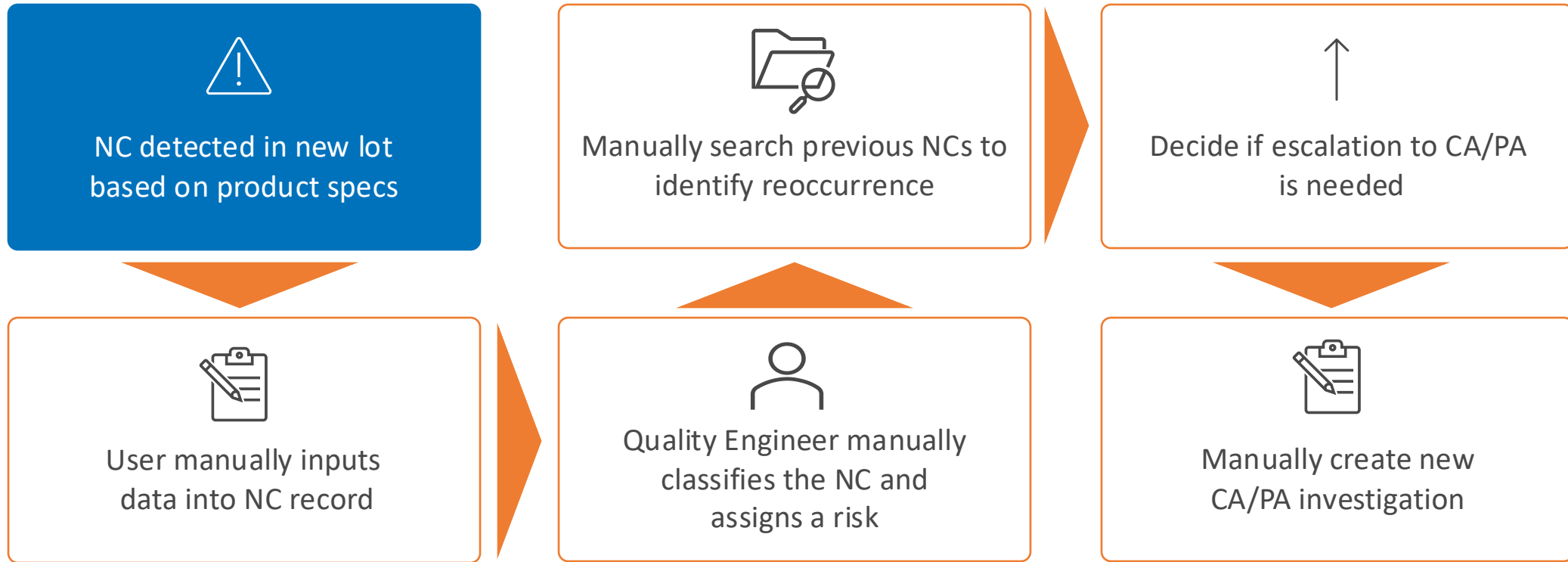
NC and CA/PA Management



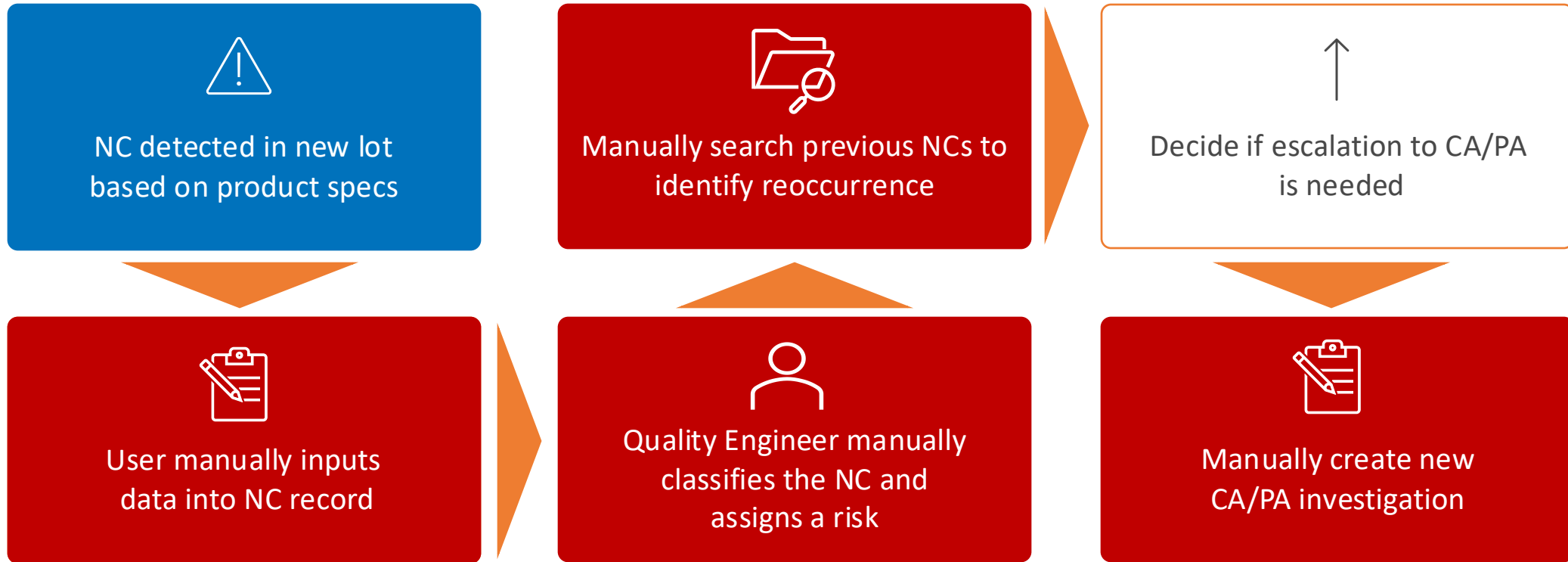
NC and CA/PA Management



NC Reporting



NC Reporting



NC Reporting



Applied AI – NC and CA/PA Management

Functionality

- Automated Categorization / Classification of Nonconformances
- Automated Risk Prioritization of Nonconformances
- Identify similar Nonconformance to determine reoccurrence and recommend escalation to CA/PA
- Search for similar CA/PA records linked to an existing investigation to minimize duplicate entry

Benefits

- Less risk of error or decision bias
- Quicker NC handling
- Cleaner data
- Improved risk management
- Catch reoccurrences more readily
- Decrease risk of quality and safety events
- Continuous improvement
- Increased efficiency
- Faster NC and CA/PA resolution

Applied AI – Use Cases



Complaint Management

- Complaint Intake
- Complaint Handling
- Complaint Investigation



Audit Management

- Findings Classification
- Findings Reoccurrence



NC & CA/PA Management

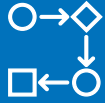
- NC Classification
- NC Risk Prioritization
- CA/PA Escalation
- NC Reporting



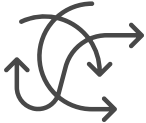
User Experience

- Next Best Action
- Report Categorization

User Experience



NC detected in new lot
based on product specs



Complicated user interface and
workflows can lead to confusion,
errors, and missed steps

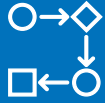


Infrequent user has a problem
while on the job



User reports the problem and
must decide on type of problem,
enter description and submit

User Experience



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based on product specs



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Adoption is difficult, making non-
compliance more likely

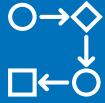


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User reports the problem and
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User Experience



NC detected in new lot
based on product specs



Intelligent Next Best Action
(NBA) guides users at each step,
in all quality workflows



Adoption is easier, making
compliance more likely



Infrequent user has a problem
while on the job



AI assistant uses the description
to identify if the problem is a
Complaint or Change Request

Applied AI – User Experience

Functionality

- Recommend Next Best Action in all quality workflows
- Recommend issue category based on report description

Benefits

- Improved efficiency
- Decreased risk of errors
- Improved user adoption
- Higher reporting rates
- Higher accuracy for reported events
- Improved quality culture

What's next?



Applied AI – What's Next?

NC and CA/PA

- Detect, identify and categorize quality issues faster from historical data, ongoing repeated events, including from IoT connections, and automatically recommend actions and escalations
- Verify action (CA/PA) effectiveness by ensuring similar quality events are not reoccurring

Training

- Recommend additional training or refreshers based on issues related to job function and declining performance

Audits

- Drive ad hoc or scheduled audits based on supplier performance, supplier audit findings or part/material inspections

Post-Market Surveillance

- Find and interpret patterns faster for market surveillance and pharmacovigilance signal detection from multiple sources

Applied AI – What's Next?

Documents

- Recommend when documents should be changed/obsoleted
- Accurate data extraction and routing for structured, semi-structured, and unstructured documents

Product Innovation

- Identify repeat complaints to flag as user requirements for product design improvement or innovation
- Detect parts/product fraud from Complaints, based on item Master for risk mitigation

Change

- Identify change actions based on Impact Assessments, Safety Observations, and customer sentiment to recommend action

Risk

- Recommend when to add a risk to the risk register
- Recommend best risk response and outcome for an identified risk, for example, mitigate, transfer, eliminate, accept

Applied AI – What's Next?

Equipment

- Predict equipment maintenance based on historical and repeated data

Control Towers

- Advanced visualization across the quality safety value chain with augmented decision support and semi-automated actions
- Augment dashboard experience with conversion of data into structured knowledge (narrative storytelling)

What this session covered



What This Session Covered

Use Case

Use Case

Use Case



Process

Use Case

Use Case



Process

Use Case

Use Case

Use Case

Use Case



Process

Use Case

Use Case




Process

Product

Platform



Capability



Capability



Capability

What This Session Covered

Complaint Intake

Complaint Handling

Complaint Investigation



Complaint Management

Findings Classification

Findings Reoccurrence



Audit Management

NC Classification

NC Prioritization

CA/PA Escalation

NC Reporting



NC & CA/PA Management

Next Best Action

Report Categorization



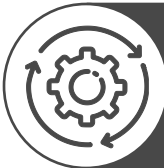
User Experience

QMS

AWS, Azure, Salesforce



Decision Support



Hyper-Automation



Advanced Analytics

What This Session Covered



Assisted Decision-Making

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What This Session Covered



Complaint Management

- Complaint Intake
- Complaint Handling
- Complaint Investigation



Audit Management

- Findings Classification
- Findings Reoccurrence



NC & CA/PA Management

- NC Classification
- NC Risk Prioritization
- CA/PA Escalation
- NC Reporting



User Experience

- Next Best Action
- Report Categorization

AI in Quality Management Q&A



About ComplianceQuest



About ComplianceQuest

Transform to a fully connected business with a next-generation AI-Powered Product Lifecycle, Quality and Safety management platform, built on Salesforce.

300,000+
Users

1000+
Customer Sites

100M+
Active Records being
Managed

1000+
Man years
Domain Expertise

Award
Winning
Solution

Frost & Sullivan

Worldwide
Direct and Partner
Locations



Financially Strong



Quality & Compliance
begins at home and
with Salesforce



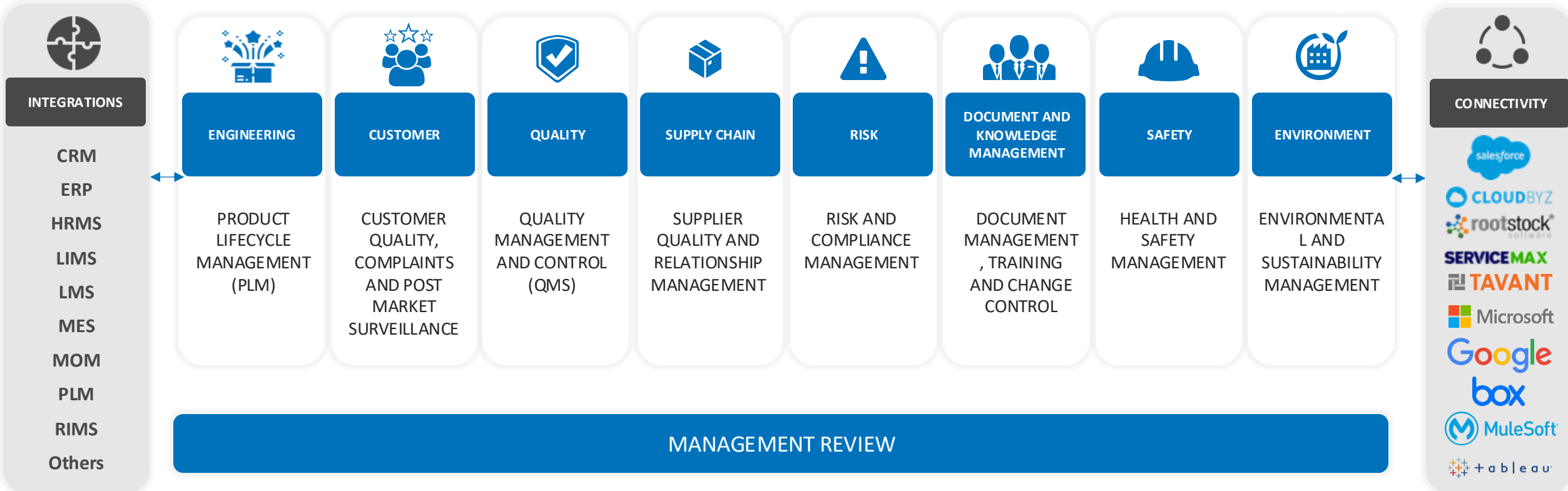
Recognized



Time Tested and Proven

Achieve your Quest for Digital Operations

CQ intelligently automates operations from product innovation to customer success



Embedded & Advanced Analytics | Collaboration (Chatter, MS Teams) | 2-Way Portal | Alerts and Notification | Forms Designer/Runner | Mobile | Pre-Validated | Ratings | CQ.AI | MyCQ for casual users

PLATFORM POWERED BY

THANK YOU



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