



# Quality Event Investigations Application

*Leveraging Artificial and Business Intelligence to Enable Culture Change, and Drive Performance and Productivity Improvements.*



Irvine, California



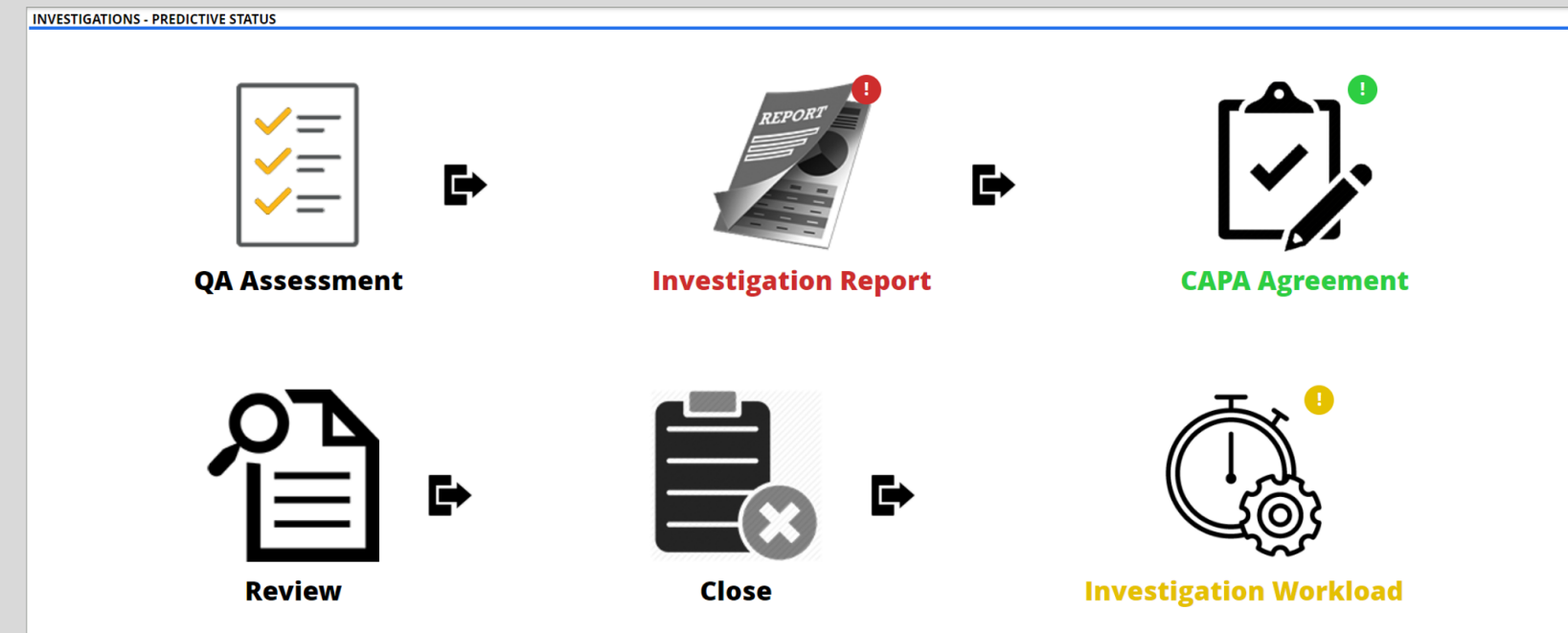
[www.oqsie.com](http://www.oqsie.com)

# What We Do

Using real-time predictive analytics, we help improve **performance, productivity**, and facilitate **culture change**.






✓ We have codified the approaches, tools and techniques that have proven successful in our work with clients over the past 30 years.

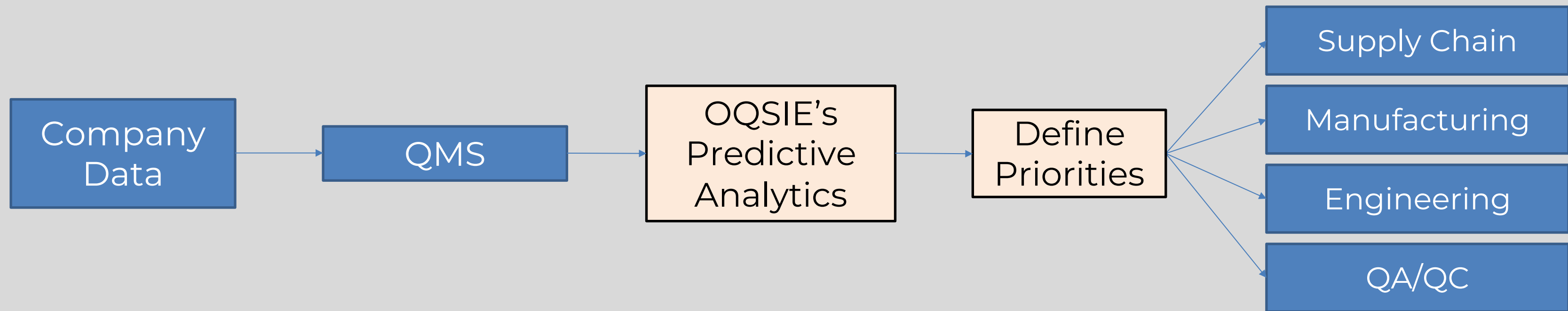
- Help you keep your finger on the pulse of what's happening on active investigations with actionable information in real time.
- Send alerts (text or email) when something significant is predicted to occur, as the situation begins to develop.
- Seamlessly align investigation-related priorities across functional groups to enable a supportive and collaborative culture.
- When connected to our Supply Chain Application, messages and priorities provided by the Investigations App will be defined based on the impact on product supply.



# How We Do It

Our predictive analytics-based Investigations App leverages **artificial** and **business intelligence** to help anticipate avoidable delays in active investigations.

-  Minimal resources required to implement from client's end.
-  Connect and integrate data from QMS System or other sources (TrackWise, ETQ Reliance, MasterControl, spreadsheets, etc.).
-  Apply advanced predictive analytics to detect and understand abnormal situations.
-  Deploy an automated alert and escalation system using text and/or email messages to accelerate response to events impacting time to closure.
-  Signal when an investigation is not progressing as expected.



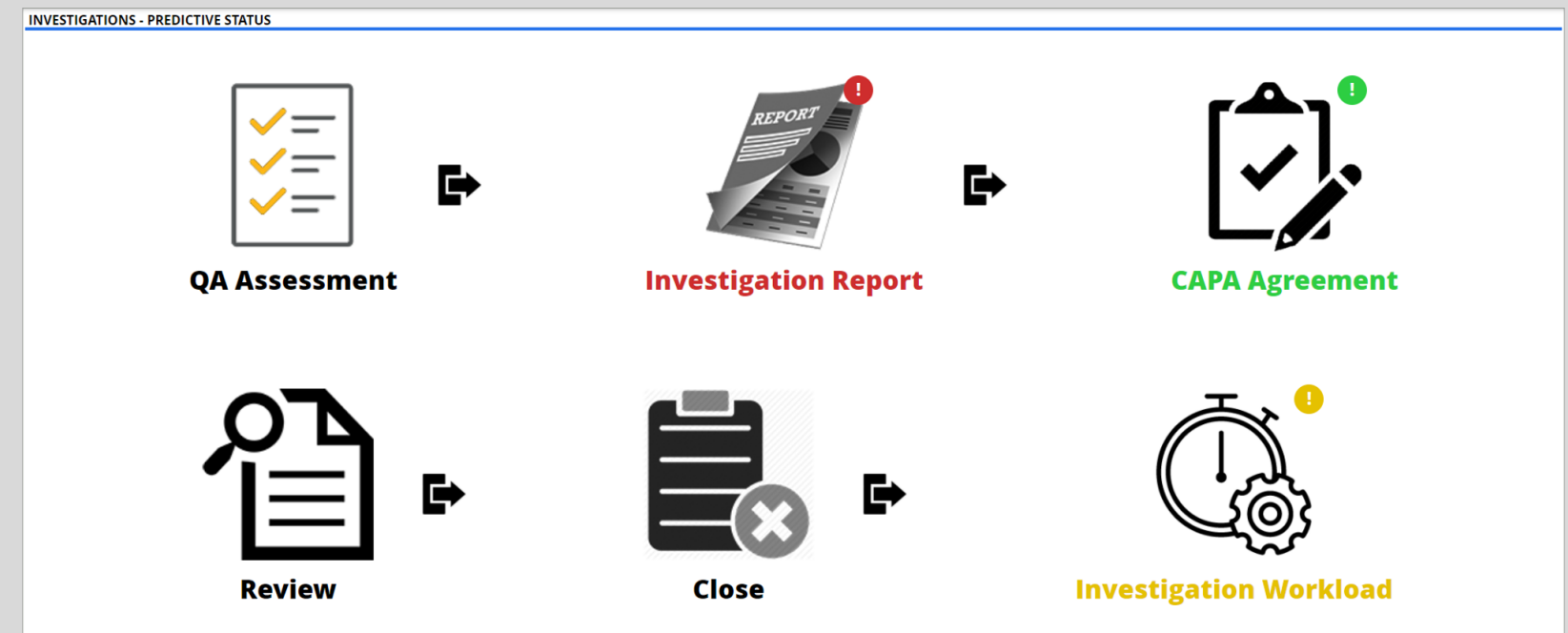
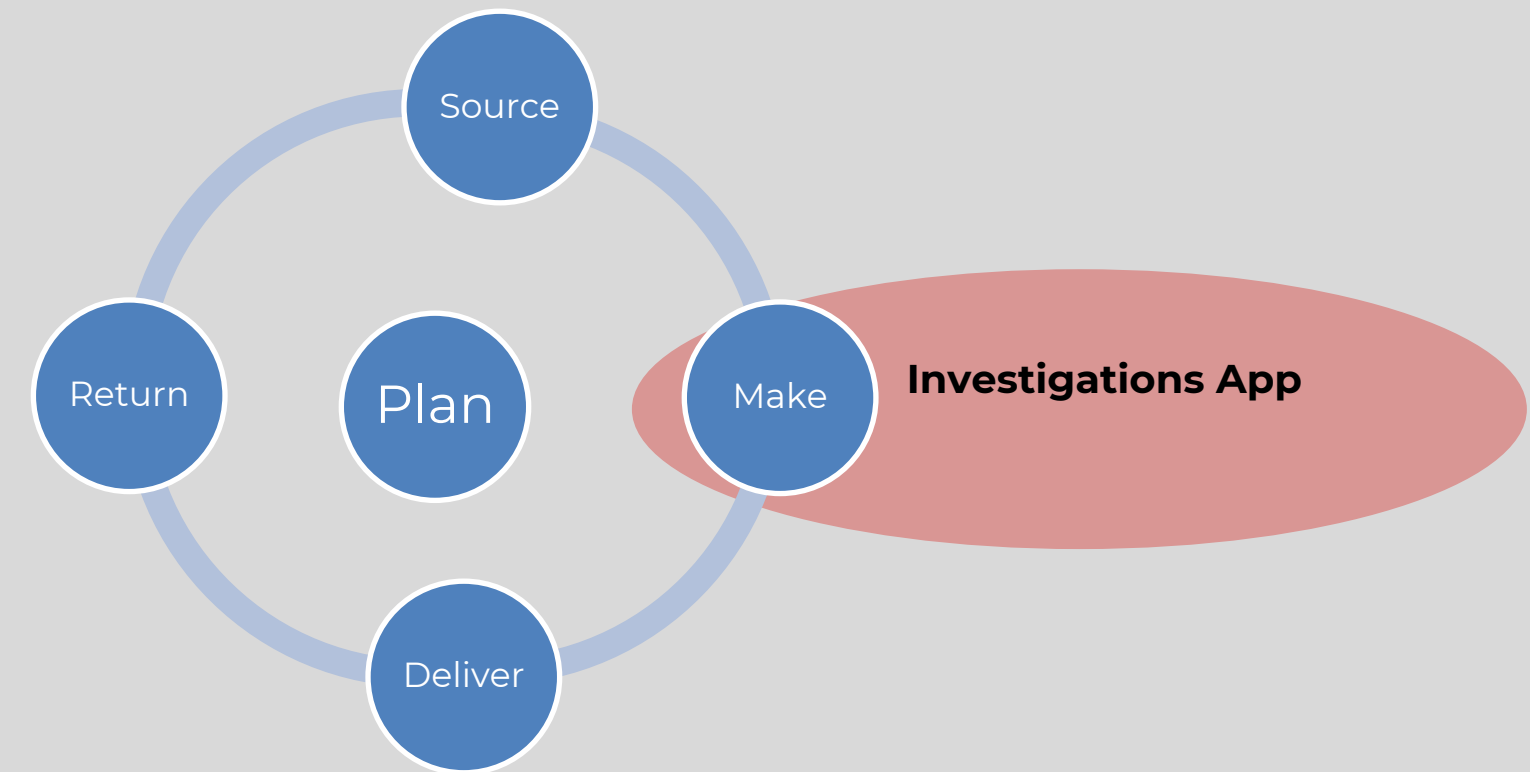
**1. Leverage your data to understand and track performance and variability patterns for each step of your investigations process.**

**2. Use rules and triggers to alert when management intervention should be considered**

- Implement an automated alert and escalation system that drives actions on issues that may impact the performance of the investigations process and team.
- When connected to our Supply Chain App, provides insights to events that may impact business performance and product availability.
- Align investigation closure-related priorities across the organization.


# Real-Time Investigations Status


- Signals when an investigation is predicted to be completed beyond the quality policy timeframe.
- Signal when an investigation is not progressing as expected, based on meaningful factors, such as:
  - Work cadence of assigned investigator
  - Prior investigations of that product
  - Investigations with similar characteristics, e.g. elapsed time from event, functional group launching it, manufacturing process involved, etc.
- When connected to our Supply Chain App, signals when the predicted closure date may impact product availability.
- Deploy an automated alert and escalation system, through text and/or email, to trigger corrective actions and alert management team of the predicted issue.




# Alerts & Escalation System

We work with you to define **real-time** rules & triggers for your team to help automate critical portions of your management activities and enable proactive steps to prevent issues in performance.

 Mark has 12 investigations in process. Historically, when he has more than 10 in process, one or more will require extensions.

 When he has too many investigations in progress, he is at risk of needing multiple extensions and should know it as soon as possible. His manager should know too, so she can help.

 Others on the team appear to have capacity to take over some of these investigations.



We use rules to implement an automated alert and escalation system that drives collaboration, alignment and accountability.



Text and email messages are sent to Jennifer, Mark's supervisor, anticipating potential issues with investigations assigned to Mark.



Text and email messages had also been sent to Mark when the 11th investigation assigned to him was detected, suggesting he raise a flag with his supervisor, Jennifer.

# Examples of Alerts and Escalation

Deborah needs her team's help defining a CAPA for investigation #2039891. Root cause was captured 8 days ago.

Historically, 80% of investigations that take more than 7 days in the CAPA definition step, end up taking more than 20 days to complete this step and require extensions.

- ✓ Text and email messages sent to John, Manufacturing Manager of area involved in this investigation, anticipating potential delay with this investigation.

3 'Documentation Error' investigations associated with your group have been launched in the last 3 days.

Historically, this has led to more than 10 additional investigations being launched in the following 2 weeks.

- ✓ Text and email messages sent to Jonathan, Manufacturing Manager responsible for this group, highlighting the need to take corrective action across this group.
- ✓ Follow up text and email messages were sent to Jonathan's supervisor after the 5<sup>th</sup> investigation was launched 2 days later.

\*Joe has an investigation open on SKUs currently at risk of stocking out, he should know it as soon as possible.

Historically, based on its characteristics after the first 5 days, it is projected to be closed in 75 days instead of the expected 30 days

*\*When connected to OQSIE Supply Chain App*

- ✓ Text and email messages sent to Sarah, Joe's supervisor, anticipating potential stock out issues caused by Joe's delays
- ✓ Text and email messages had been sent to Joe 5 days after investigations were assigned to him, suggesting he raise a flag with Sarah.

## Challenge:

- Injectables Manufacturing Plant
- Large backlog of investigations
- High variability on time to close investigations
- Management perceived that investigators were not very productive
- High turnover due to stress and dissatisfaction

## Findings of Analysis:

- Fully leveraged TrackWise data.
- Profiled cycle time and variability by investigation step across multiple dimensions, most meaningful dimensions were: investigator, product family, area launching deviation.
- Also found that the “agree on CAPA” step in the process drove most of the variability.

## Results after 6 months:

- Reduced the average time to close investigations from 52 to 23 days.
- Reduced the number of “aged” investigations, older than 30 days, from 324 to 28.
- Doubled the average number of investigations closed per investigator per week from 0.5 to 1.1, reduced number of contract investigators by 95%, total investigator headcount by 70%.

## Solution- Investigations Application:

- Designed and implemented a close-to-real-time investigation tracking system, solely based on TrackWise entries.
- Designed and deployed an alert and escalation system, tailored to the performance profile for the meaningful dimensions of each investigation, to provide an early signal for management intervention.
- Deployed performance dashboards across levels and stakeholder groups.



*Dramatically accelerate your improvement curve and quickly experience better results and lower costs.*

- Higher predictability in closure of investigations = lower variability in product supply
  - Higher productivity in the investigations process = lower costs
  - Constant alignment on priorities = collaborative culture
  - Quick implementation time (2-3 months) = faster path to better performance and lower costs
- ✓ We guarantee, in writing, that you will recover your small investment in the first year, and that software license fees will be covered by tangible cost reductions of at least 4 times larger.

# Work With Us



*Leverage our 30+ years of experience leading operational performance improvement and quickly benefit from lower costs and better results.*

*We are so confident in our ability to deliver results that we guarantee, in writing, a **short** payback period and ongoing financial benefits.*

## CONTACT:

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