TRANSFORMING COMPLIANCE INTO PERFORMANCE WITH A NEW APPROACH TO QUALITY REVIEWS

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AGENDA

01 **Introduction**
Overview of systems

02 **PQR**
Product Quality Review overview and demo

03 **QMR**
Quality Management Review and demo

04 **Conclusion**
Future and Q&A

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INTRODUCTION







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POLL QUESTIONS 1 AND 2

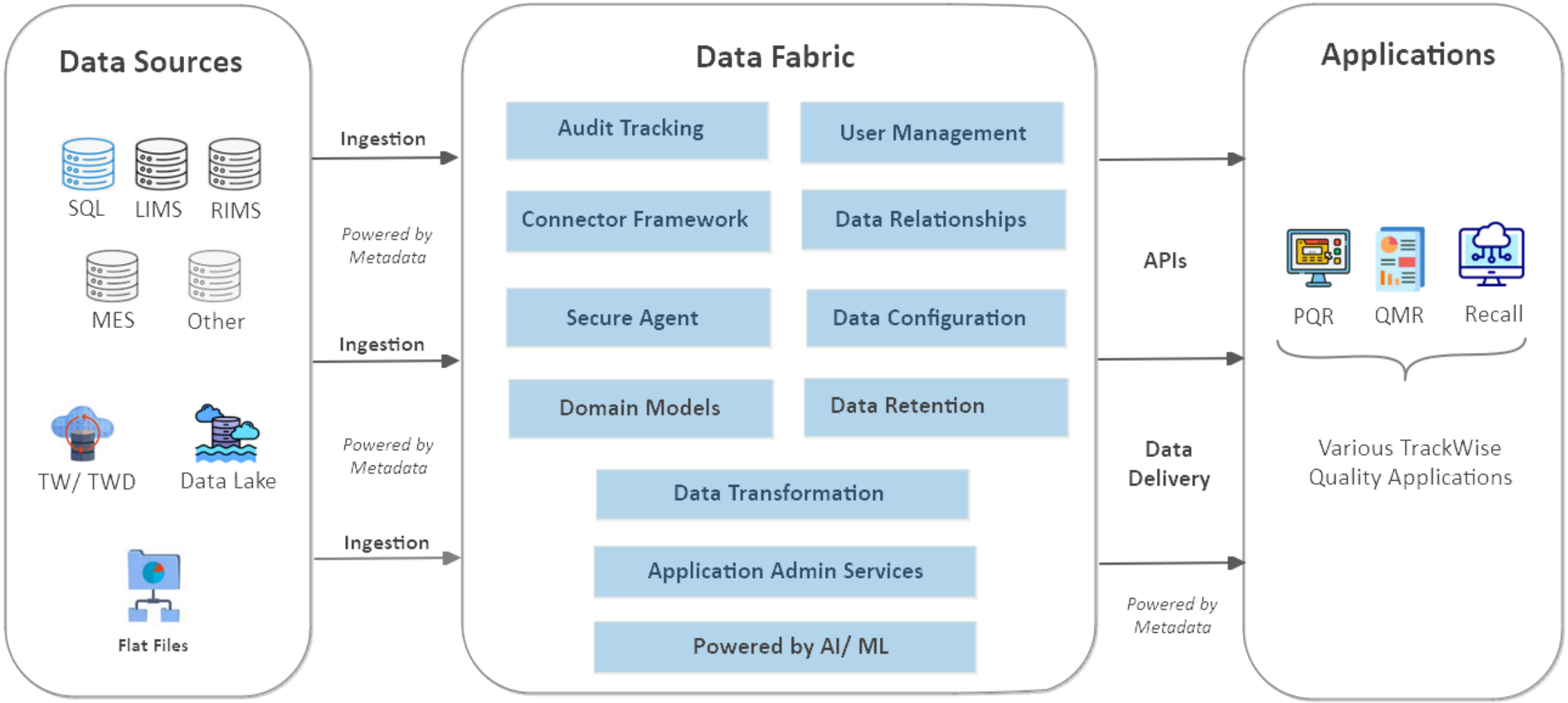


How many SORs do you connect to bring the required data for your PQR?

How many SORs do you connect to bring the required data for your QMR?

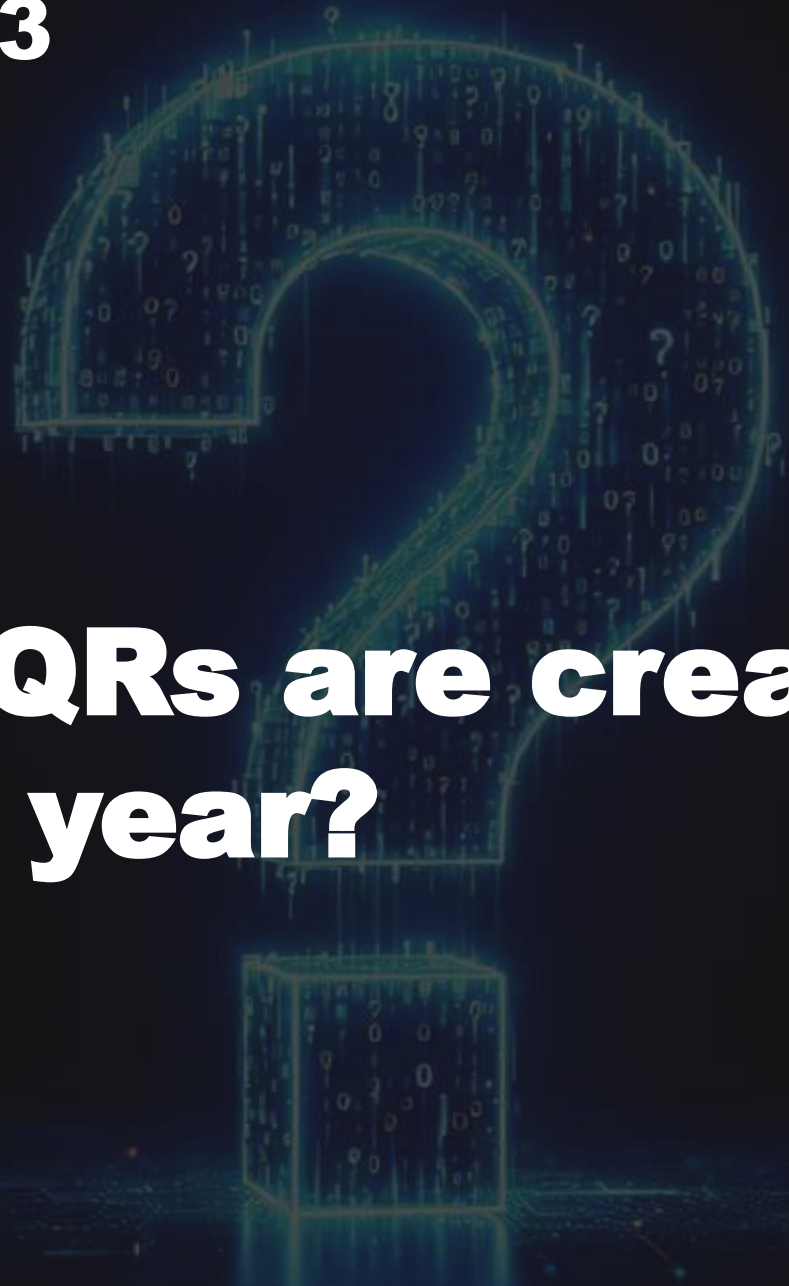
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DATA FABRIC ARCHITECTURE



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POLL QUESTIONS 3



How many PQRs are created in your org in a year?

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PRODUCT QUALITY REVIEW (PQR)

Why? What? Who?

Comprehensive evaluation conducted by **Pharmaceutical** manufacturers to assess the **quality, safety, and efficacy** of their marketed drug products on an annual basis.



Regulatory requirements include:

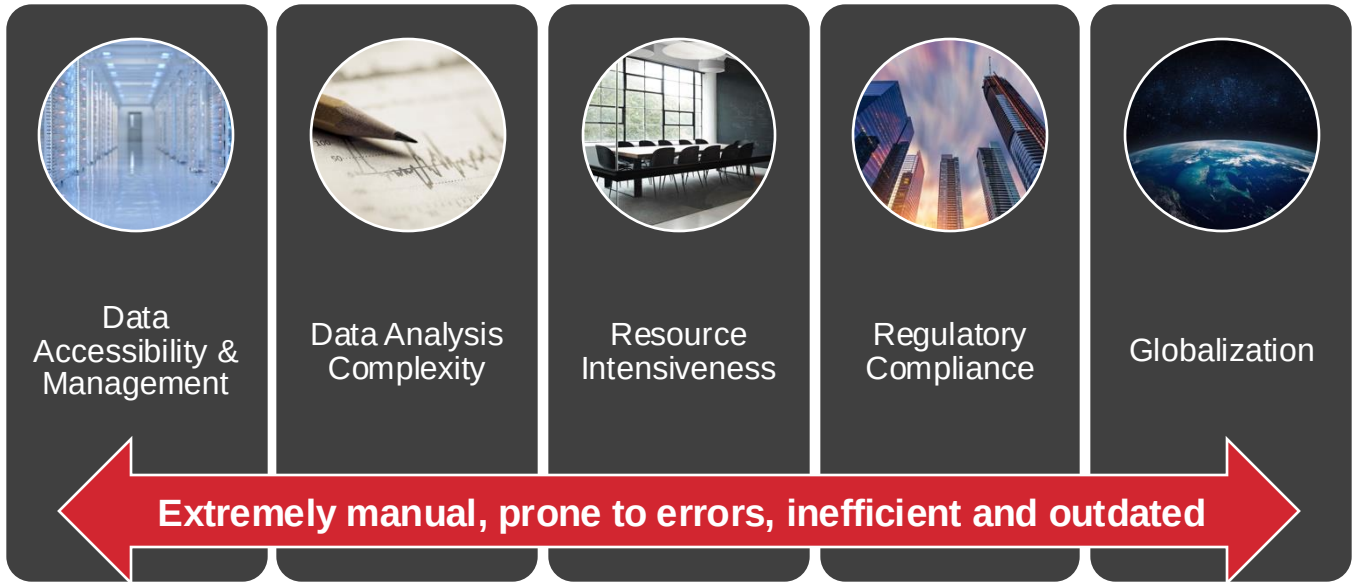
- United States, per 21 CFR 211.180(e)
- European Union European Drug Regulating Authorities and Lex (EudraLex) Volume 4 Chapter 1
- International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) (per ICH Q11 Development and Manufacture of Drug Substances (Chemical Entities and Biotechnological/Biological Entities) and ICH Q7 Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients)

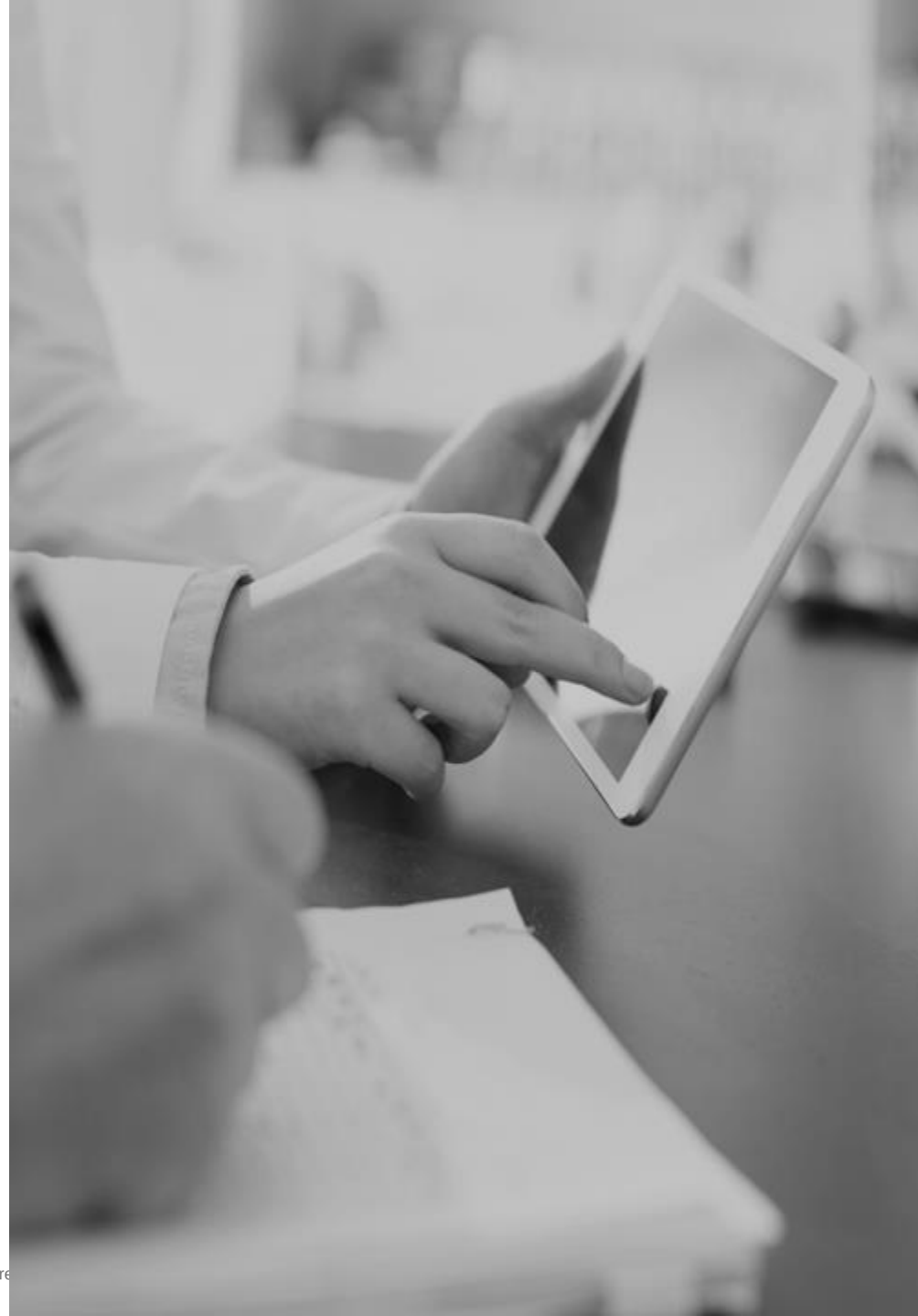
Enables pharmaceutical companies to identify any potential issues and take appropriate corrective actions to maintain product quality and safety.

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PQR CHALLENGES

While PQRs are crucial for maintaining high standards in pharmaceutical manufacturing, there are several challenges:





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DID YOU KNOW?

ENHANCING THE PQR

FACT 1:
On average, an APQR report contains 150 + pages with 21 or more chapters

FACT 2:
Preparing a report takes the Quality team ~2-3 months, often stretching to ~4-5 months

FACT 3:
Typically, 7-8 individuals from multiple departments are involved in collecting, validating, and compiling the data

FACT 4:
Manual processes and disparate systems lead to data inaccuracies, delays, and rework in %30 cases

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TRACKWISE PRODUCT QUALITY REVIEW

The Honeywell Product Quality Review streamlines the review process by digitizing process workflows and enabling real-time data access, statistical analysis, collaboration and electronic approvals.

Pharma companies significantly improve efficiency and gain confidence in a reliable real-time product and process health check.

10k
branded pharmaceutical manufacturers world-wide

2M
Drug products being produced

1000s
Hours per year on PQRs



> *This is a dream come true for a quality professional. We'd love to partner with Sparta on this.*

> *We are really, really excited to use an Automated PQR application.*

SIMPLIFY REPORT CREATION AND COLLABORATION

Automatically conduct complex analysis of Quality Data, and collaborate with cross-functional groups

IMPROVE EFFICIENCY AND DATA INTEGRITY

Automated Data Collection using Native Data Connectors; Quickly obtain data to increase operational efficiency

ANYTIME REVIEWS

Monitor & assess quality on-demand to monitor issues ahead of product complaints or recalls for proactive quality insight.

BENEFITS OF HPQR



PROCESS AUTOMATION

Gather data across all quality processes quickly and efficiently



CROSS-FUNCTIONAL COLLABORATION

Review data across groups to assess and correct product quality issues at any time



REGULATORY COMPLIANCE

Manage regulation guidelines with a report template that meets regulatory requirements



PROACTIVE QUALITY INSIGHT

Monitor quality in near real-time so reviews can catch issues ahead of product complaints or recalls



EASY REPORT CREATION

Automatically conduct complex analysis of Quality Data with configured reports that can be easily generated

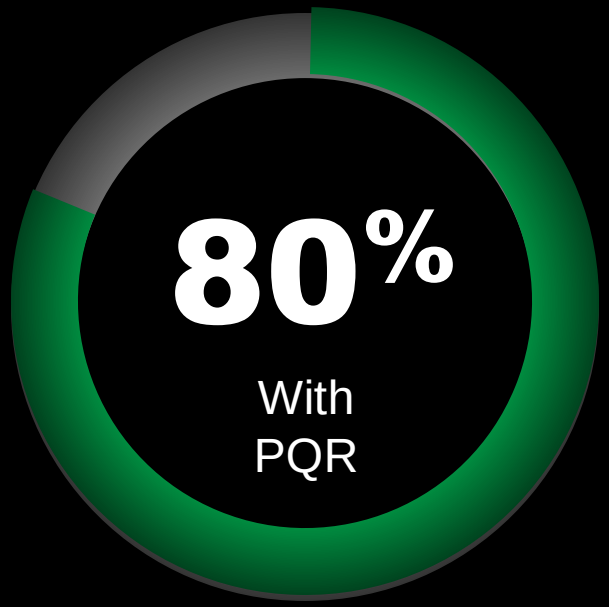


IMPROVE EFFICIENCY & DECISION MAKING

Streamlined processes, intelligent workflows and automation for faster, more informed decision making

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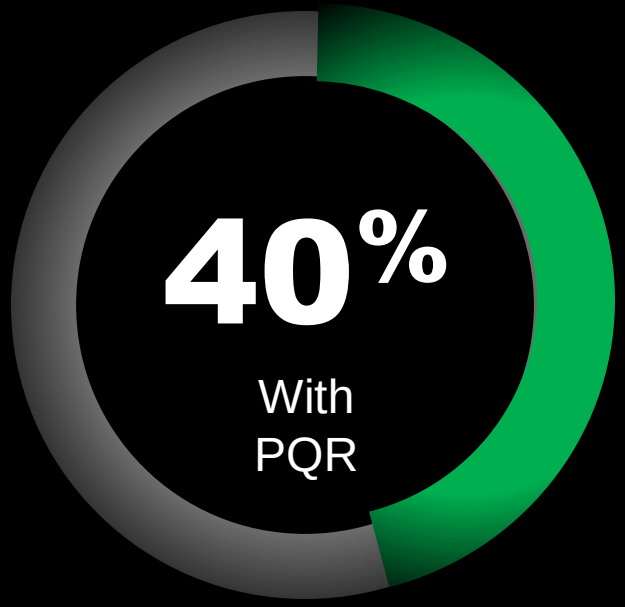
UNLOCK THE POWER OF AUTOMATED PQR



Information retrieval



Report Preparation



Review and Approval

Source: Internal study.

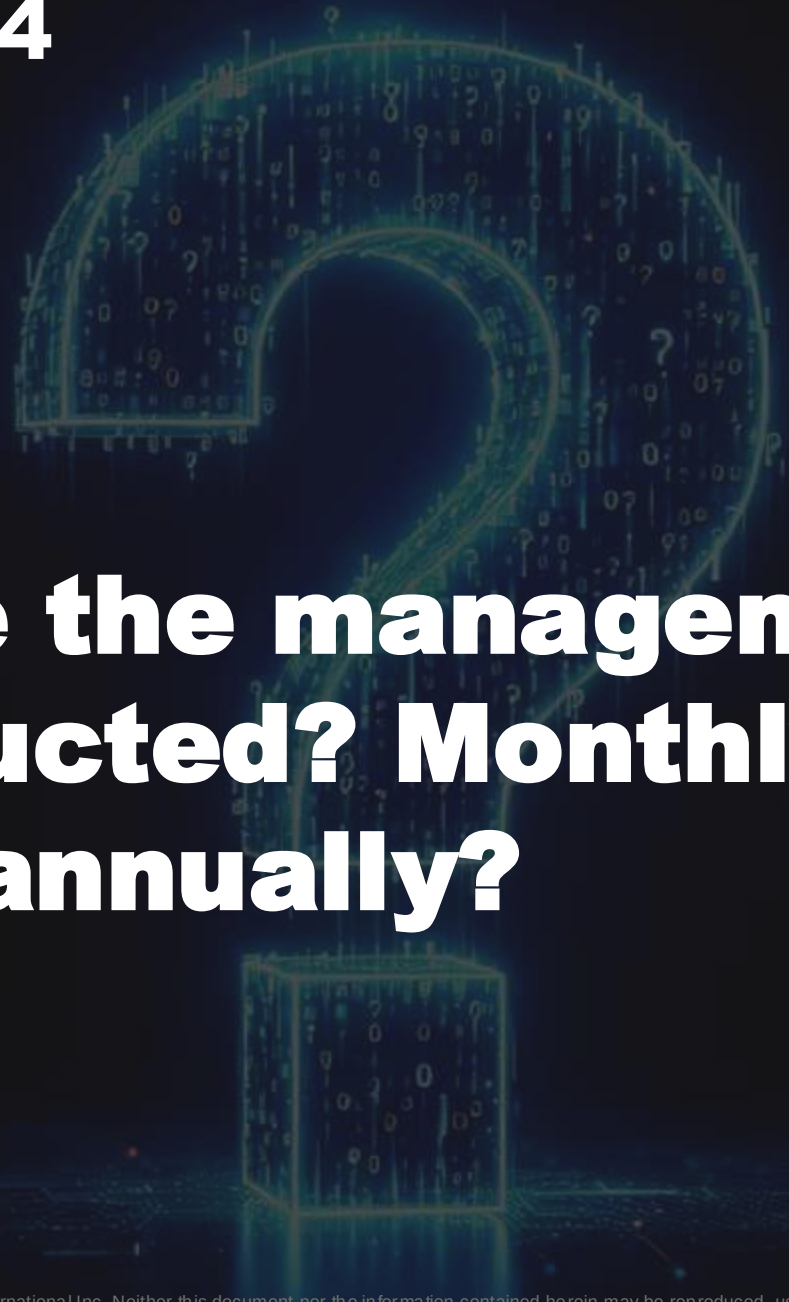
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DEMO



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POLL QUESTIONS 4



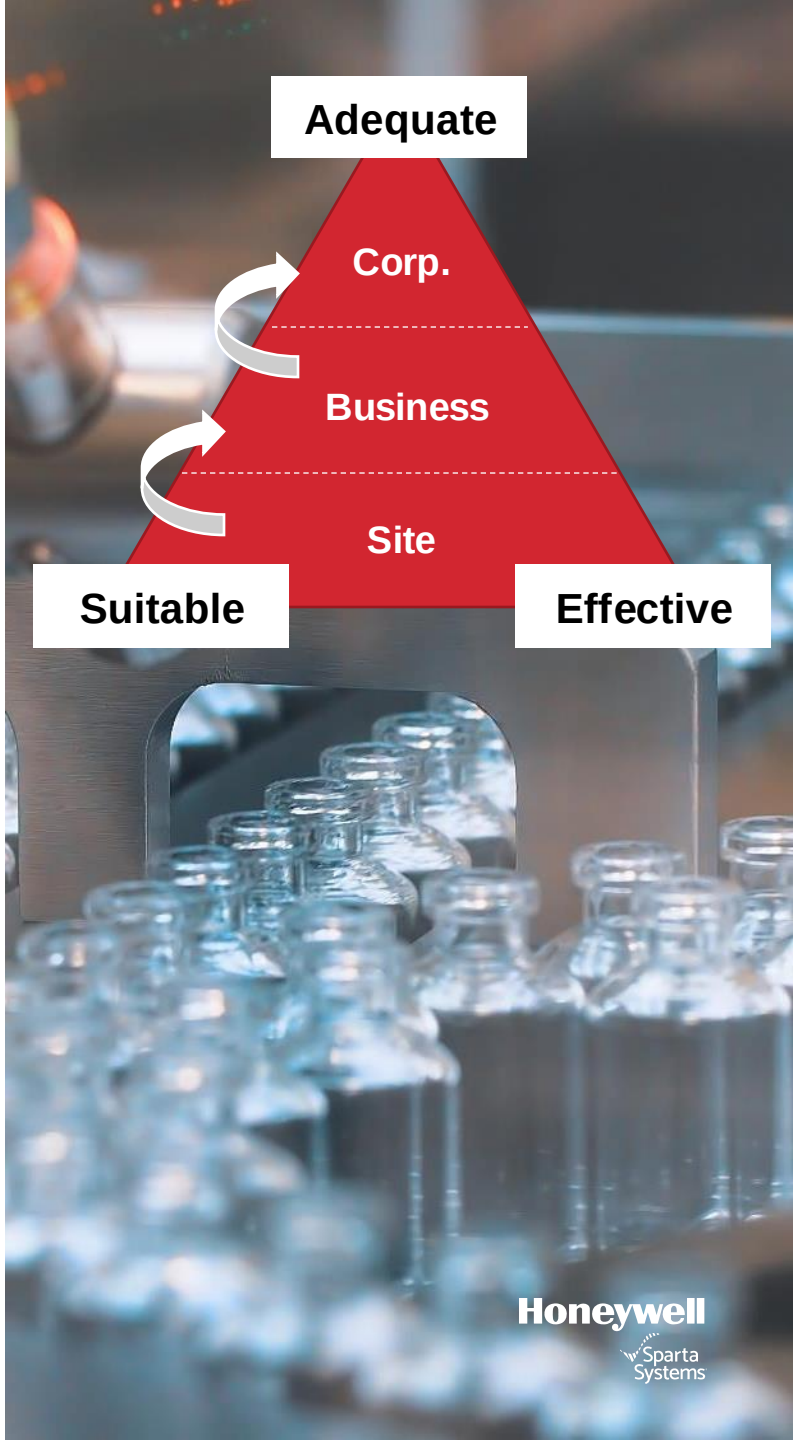
How often are the management reviews conducted? Monthly, bi-annually and annually?

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INTRODUCTION

WHAT IS A QUALITY MANAGEMENT REVIEW (QMR)

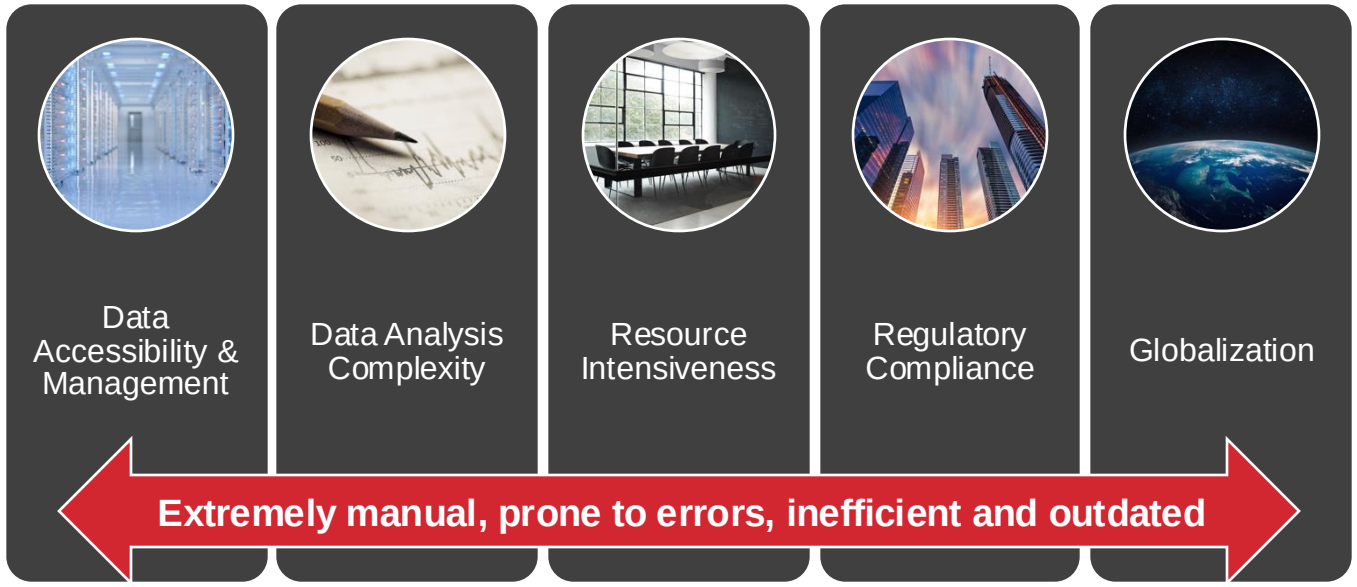
- A process for understanding the performance of the quality system
- A **required** activity to assess, assure, and improve the **suitability**, **adequacy**, and **effectiveness** of the Quality system
- A comprehensive review of various areas within quality, such as:
  - Compliance and Performance Metrics
  - Internal / External / Supplier Audits
  - Complaint / Post-market feedback
  - Changes that could affect the QMS
  - Results and follow-ups from previous QMRs
- Regulated under:
  - **21 CFR Part 820 & ISO 13485** – For the medical device industry
  - **ISO 9001 & (ICH) Q10** – For the pharmaceutical industry

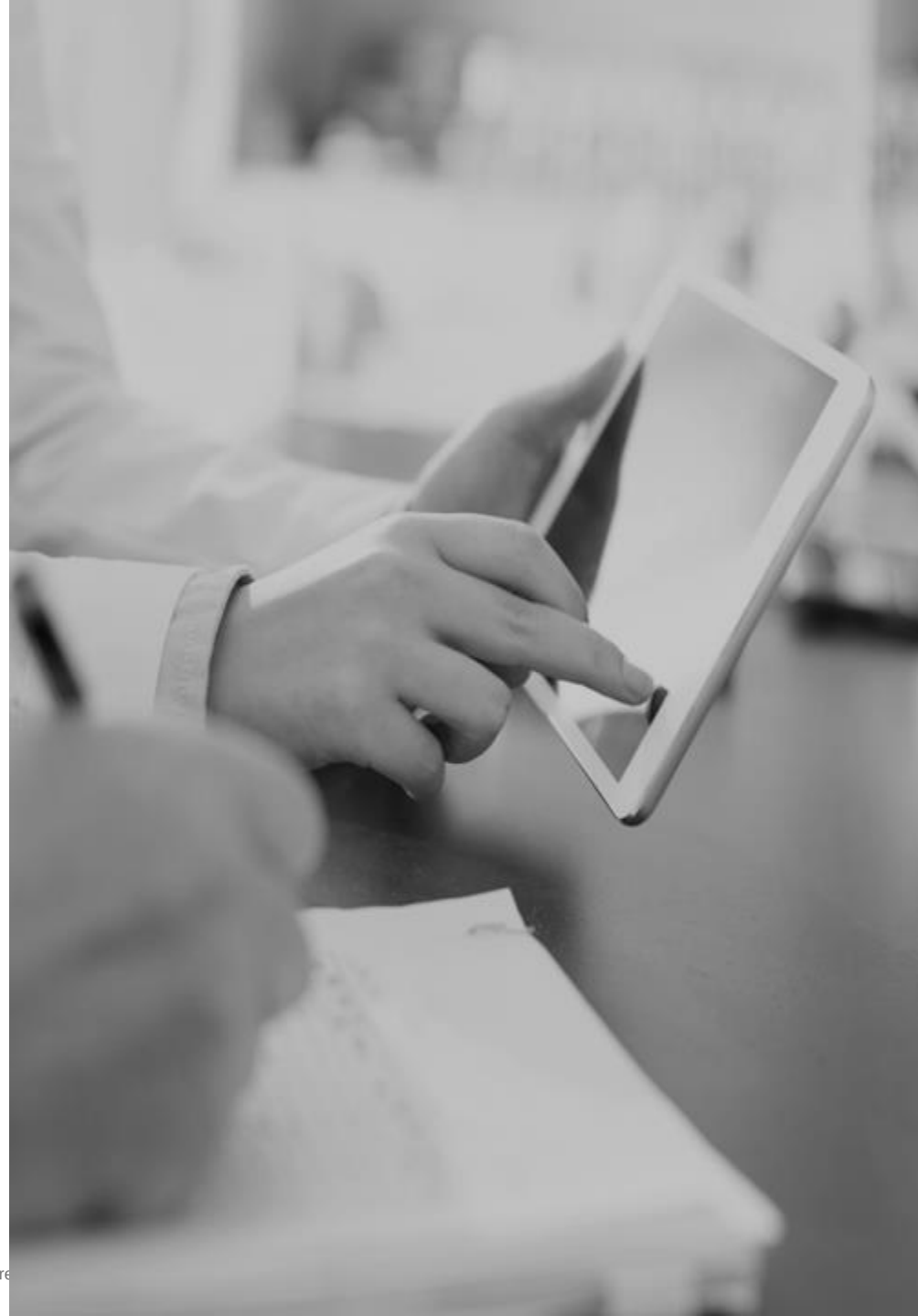


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QMR CHALLENGES

While QMRs are crucial for maintaining high standards in pharmaceutical manufacturing, there are several challenges:





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DID YOU KNOW?

ENHANCING THE QMR

FACT 1:
On average, a single site QMR contains 20-50 slides

FACT 2:
Preparing for a review takes the Quality team 2 months, often stretching to ~ 3 months.

FACT 3:
Typically, 15-30 individuals from multiple departments are involved in the entire review process.

FACT 4:
Manual processes and disparate systems lead to data inaccuracies, delays, and rework in greater than 5% of reviews.

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TRACKWISE QUALITY MANAGEMENT REVIEW



Honeywell Quality Management Review leverages digital technologies to ensure consistent effectiveness, suitability, and performance of your QMS and monitor KPIs to drive continuous improvement and maintain a competitive edge in the market.

Shift the Quality Management Review paradigm from a regulatory requirement to proactive quality management with Honeywell Quality Management Review.

1000s

Hours per site per year

100s

of employees

> *QMR's are conducted quarterly. They take **hundreds of people** and **thousands of hours** to prep.*

> *Want QMR roll-up views but currently there isn't an efficient way to do so. **Spend ~770 hrs / site / yr preparing and conducting ~100 QMRs globally***

> *QMR is **very manual** using excel spreadsheets and PowerPoint. It's now a checkbox exercise*

IMPROVE EFFICIENCY & DECISION MAKING

Automatically conduct complex analysis of quality data, and collaborate with cross-functional groups

MULTI-SITE ROLLUP

Consolidate and summarize data and findings from different sites to create a high-level overview for senior management

QUALITY INSIGHT

Automated Data Collection using Native Data Connectors; Quickly obtain data to increase operational efficiency

TRACKWISE QUALITY MANAGEMENT REVIEW

1 Collect

2 Analyze

3 Collaborate

4 Consume

API Connectors

Automated Data Collection & Analysis

Modern Interface & Ease of Use

Collaborative Reviews

Proactive Quality Insight

Electronic Signature

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BENEFITS: QUALITY MANAGEMENT REVIEW

Honeywell QMR leverages digital technologies to ensure consistent monitoring of the suitability, adequacy and effectiveness of a quality management system.



PROCESS AUTOMATION

Gather data across all quality processes quickly and efficiently



CROSS-FUNCTIONAL COLLABORATION

Review data across groups to monitor, correct, and improve the quality function



IMPROVE EFFICIENCY & DECISION MAKING

Streamlined processes, intelligent workflows and automation for faster, more informed decision making



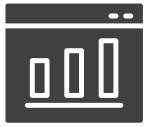
QUALITY INSIGHT

Monitor the suitability, adequacy, and effectiveness of the QMS in near real-time and anticipate trends.



REGULATORY COMPLIANCE

Manage regulation guidelines with a fully validated and digital solution



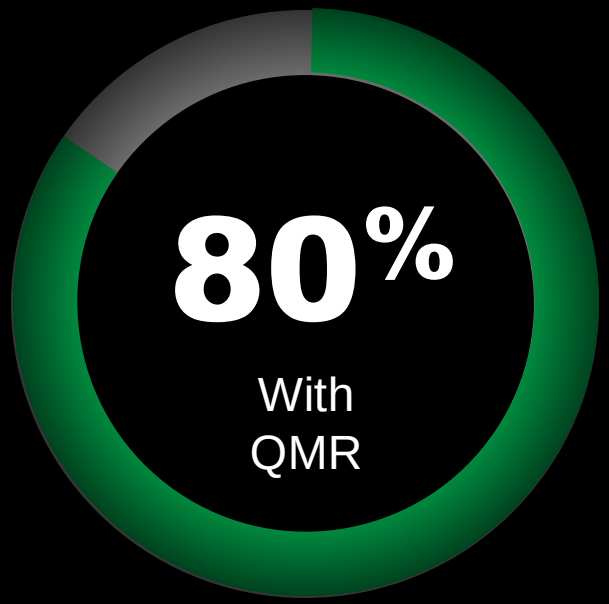
DYNAMIC DATA VISUALIZATION

Interactive dashboards for presenting complex information in a comprehensible and actionable format.

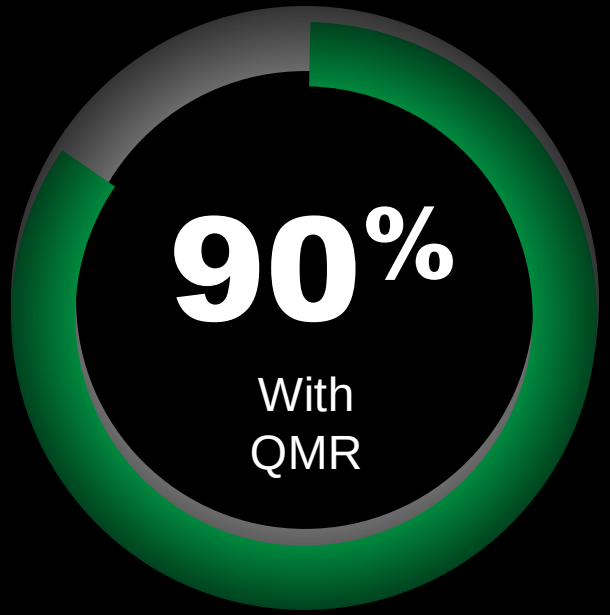
Modern Approach to Quality Management Reviews

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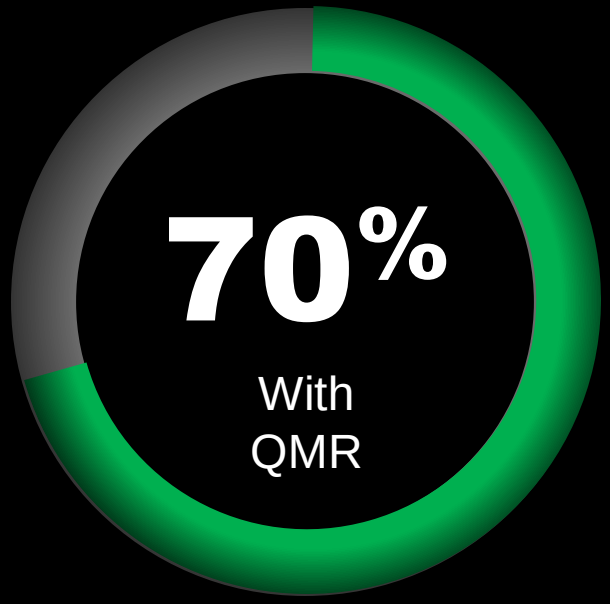
UNLOCK THE POWER OF PROACTIVE QMR



Information retrieval



Report Preparation



KPI's Review and Approval

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Q&A



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THANK YOU.



Abhishek Hiremath
Product @ Honeywell



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Industry Innovator | Business Development | Continuous Improvement

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