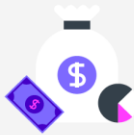# The Digital Quality Transformation Journey

## From Paper to AI

Rosalind Beasley, VP Digital Innovation, Dot Compliance

**MYTH**

As a life science company, you need a costly and complex quality management system (QMS) that cripples you financially, takes months to configure and implement, and continuously surprises you with hidden fees for updates, upgrades and validation.

**REALITY**

Within weeks you can be up and running with a ready to use, cloud-based QMS that is preconfigured based on industry best practices to support the quality and compliance processes you need when you need them.
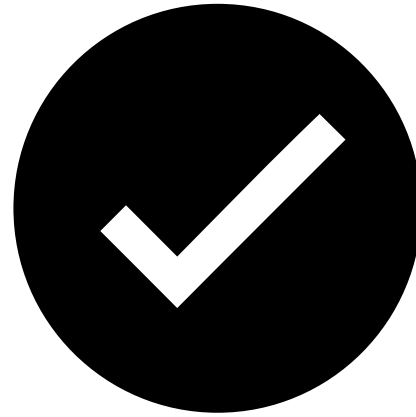
**What does it take to be a successful quality organization in today's business climate?**

2

# Agenda

TRANSITION FROM PAPER AND FILE-BASED SYSTEMS TO AUTOMATED QUALITY

THE ATTRIBUTES AND ADVANTAGES OF A MODERN QUALITY MANAGEMENT SYSTEM

OVERCOMING CHALLENGES DURING THE TRANSITION

LAYING THE FOUNDATION FOR AI

# Transitioning from paper & file-based quality

Where are you now?

" A recent survey indicated that of the surveyed businesses, only 22% use a cloud-based QMS and more than half use either Excel (27%) or paper-based systems (26%). "

Survey by DOT Compliance

# Transitioning from paper & file-based quality
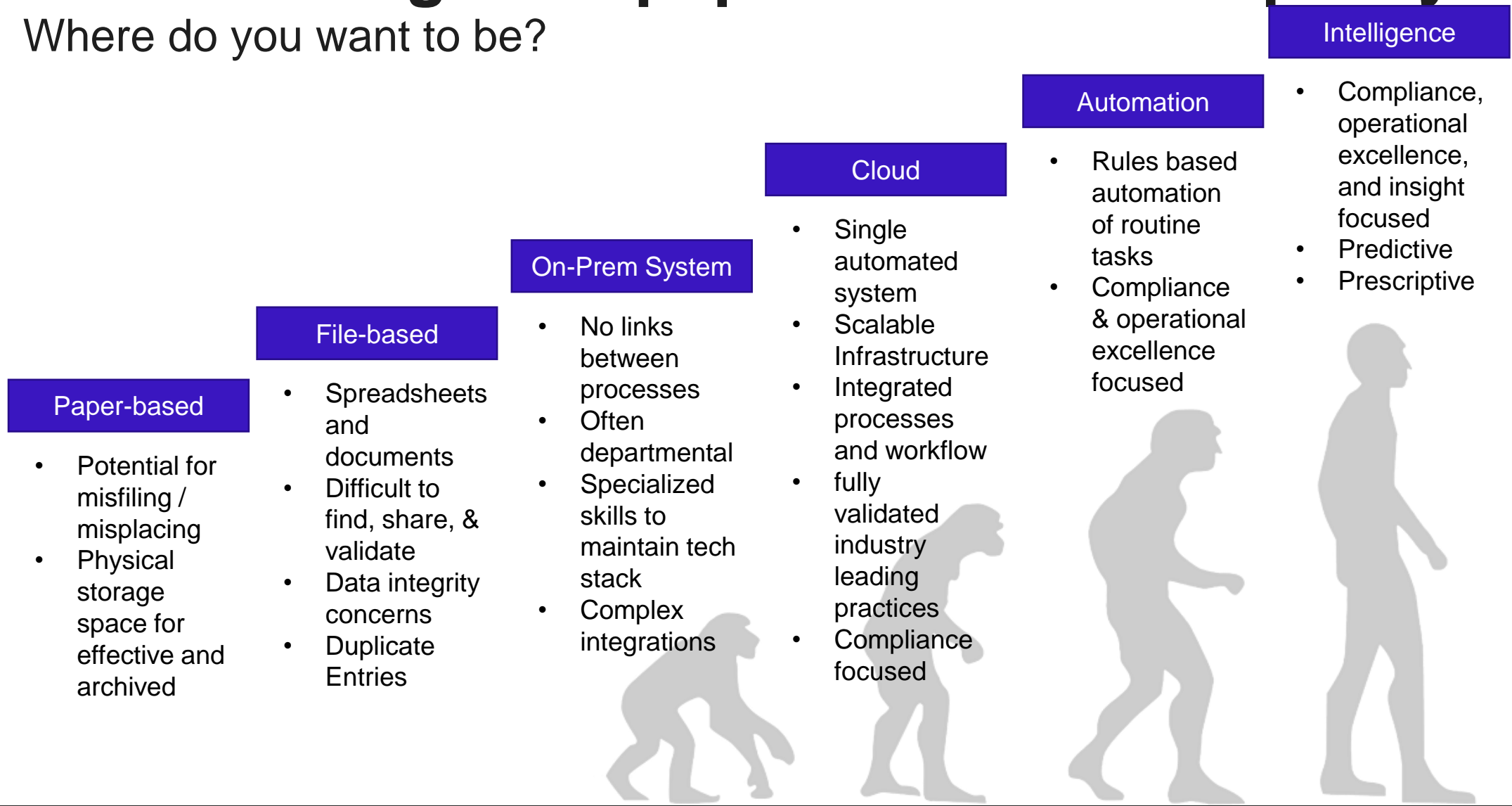
Where are you now?

**"** More than half of office professionals spend more time searching for documents than they do working. **"**

Wakefield Research & Elastic

# Transitioning from paper & file-based quality

Where do you want to be?

**Intelligence**

- Compliance, operational excellence, and insight focused
- Predictive
- Prescriptive

**Automation**

- Rules based automation of routine tasks
- Compliance & operational excellence focused

**Cloud**

- Single automated system
- Scalable Infrastructure
- Integrated processes and workflow fully validated industry leading practices
- Compliance focused

**On-Prem System**

- No links between processes
- Often departmental
- Specialized skills to maintain tech stack
- Complex integrations

**File-based**

- Spreadsheets and documents
- Difficult to find, share, & validate
- Data integrity concerns
- Duplicate Entries

**Paper-based**

- Potential for misfiling / misplacing
- Physical storage space for effective and archived

# Poll #1

- What level of maturity is your quality organization currently in?
    - Paper-based
    - File-based
    - Legacy On-Prem
    - Cloud
    - Cloud + Automation
    - Cloud + Automation + Intelligence

# Transitioning from paper & file-based quality

## What are the capabilities and benefits of a modern Cloud QMS?

- Accessible & Secure
  - Accessible to any authenticated user at anytime from anywhere
  - Built in collaboration tools
- Continuous Improvement
  - Metrics at your fingertips to quickly assess quality & compliance
  - Pre-validated and compliant processes and validated upgrades
- Aligned with Industry Standards
  - Industry standard processes
  - Role based workflows
  - Automated routing
  - Approval Matrices
- Built in Data Integrity
  - Guardrails to ensure data is Attributable, Legible, Contemporaneous, Original, and Accurate
- Regulatory Compliance
  - Easier to meet regulatory requirements for reporting, record keeping, and access control.
- Employee Motivation
  - Less time spent on unnecessary tasks, duplicating work, running around to get signatures, searching for documents makes for happy employees
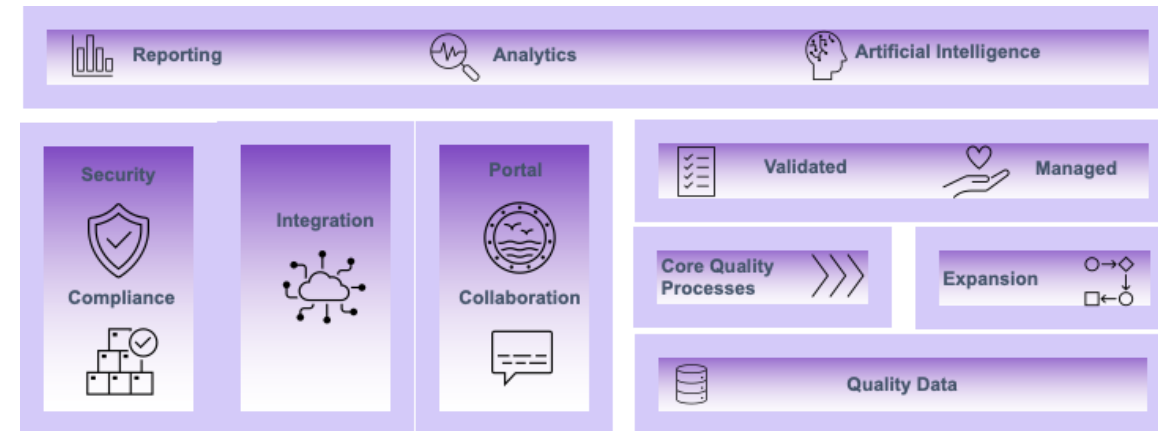
# Transitioning from paper & file-based quality

How do you get there?

**INITIATION**
Engage aligning and leveraging leadership to support change: Assign stakeholders & project team.

**BUSINESS & OPERATIONAL READINESS**

**DESIGN** (Optional)
Prepare environment strategy, migration plan, interface requirements

**ADOPTION & OWNERSHIP**

| What's changing and impact analysis | Readiness Action Plan & Tracking | Validation Package Acceptance |
|---|---|---|

**SYSTEM REVIEW & ADOPTION**
System walkthrough: layouts, lifecycle, permissions, reports and dashboards. Practice sessions.

| Operating Procedure Updates | Admin & End User Training | Proficiency and practice sessions |
|---|---|---|

**LEADER & END USER ENGAGEMENT**

| Readiness Assessment | Go-Live & Hypercare | Post go-live Optimization |
|---|---|---|

# Transitioning from paper & file-based quality

What are the obstacles?

- Managing change
  - The biggest challenge is understanding how much change your company can adopt within a period of time.
- Preparing initial data
  - You will want to start preparing list of data that are core to your business
    - Products
    - Customers
    - Vendors
    - Employees
    - Users
    - Sites
    - Departments
    - Training Plans
- Migration from excel or another system
  - Original Source Documents
  - Signed Effective Documents
  - Do you want to migrate all prior versions?
  - Do you have the metadata for the documents
  - Do you want to migrate prior training records?
  - Do you want to migrate change controls, complaints, deviations, etc.?

# Transitioning from paper & file-based quality

How did they get there?

**UNIPHARM**

**Challenge:**  Needed to streamline paper based and semi automated quality and compliance processes to assure high quality standards, faster change management, operational efficiency and business continuity **during the COVID-19 crisis.**

**Solution:**  Adopted SaaS solution with pre-configured core quality process, on-line training sessions, sample SOPs, data migration tools.

**Industry:** Pharmaceutical
**Location:** EMEA

**30% Reduction in process time for document control and training**

Improved performance following deployment of automated workflow for document review, approval, content distribution, and training compliance

**3 Month rollout: Deployed over 10 ready-to-use processes, data migration**

# Poll #2

- Where in the maturity matrix would you like to be within a year?
    - Paper-based
    - File-based
    - Legacy On-Prem
    - Cloud
    - Cloud + Automation
    - Cloud + Automation + Intelligence

# Laying the foundation for AI
Guiding Principles

| | | |
|---|---|---|
| Implementing AI won't be immediate | It requires lots of data | It requires clean data |
| The more data validations there are in the QMS the better | Stop entering data into large text fields | Define reference and master data |

# Laying the foundation for AI

## What problems are you trying to solve?

### Remove Quality & Compliance Barriers

**Soaring costs of quality, safety and related risks**

**+20%** of operating budget

Automated processes reduce business and non-compliance risks

Over **50%** of supply shortages are related to quality & compliance

### Enhance Decision Making

**Exponential growth in structured and unstructured data volume.**

The ability to make informed fact based quality and regulatory decisions is becoming increasingly challenging.

Life Science organizations will shift focus to resolution of root causes aided by technology.

### Increase Productivity

**Lack of transparency into processes hinders productivity gains.**

80% of Life Sciences CEOs expect to see ROI for AI, RPA and other digital technologies in the next 1-3 years [a] - KPMG

# Laying the foundation for AI

How will you use it?

## Descriptive Analytics

" utilizes the current data, real-time data, historical data produced by users, applications and machines throughout the organization. "

**what has happened**

## Predictive Analytics

" A process that applies mathematical and statistical models to descriptive data to predict future outcomes. "

**what could happen**

## Prescriptive Analytics

" A process that analyzes data and provides instant recommendations on how to optimize business practices to suit multiple predicted outcomes. "

**what should happen**

# It all culminates in automation & adaptiveness
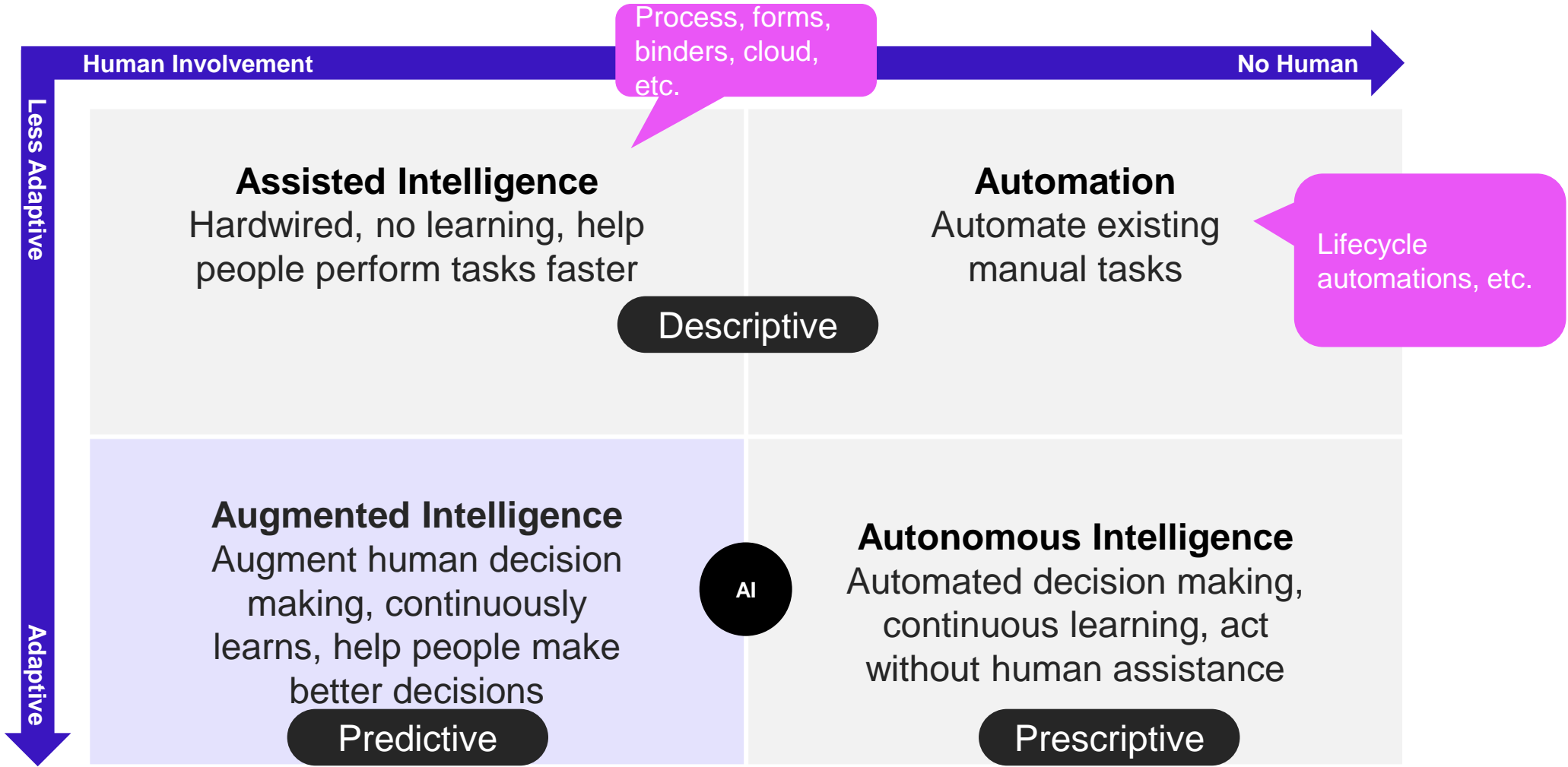
# Key Take Aways

- Know where you are in your journey today.

- Assess where you want to jump to.  (Remember there are rules to how far you can leap).

- Start preparing the data in advance.  This will save you time during adoption.

- Remember its an adoption not an implementation.

- Look out for our follow-on webinar where we will discuss AI use cases for quality management!

# Thank You!

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**www.dotcompliance.com**

**Dot Compliance** offers a holistic, innovative, end-to-end Quality and Compliance Solution powered by the **Salesforce.com** platform.

## Good to Know     We are designed for fast deployment, flexibility and minimal implementation effort.

✓ Includes all core quality assurance processes, training, regulatory compliance, and document control

✓ Dot Compliance ready to use solutions helps you mitigate device manufacturing risks, while ensuring compliance with regulations such as 21 CFR Part 11, 21 CFR Part 820, GMP, ISO13485, ISO9001, and others

✓ Ensures your organization and outsourced suppliers get the required visibility in real-time from early product development – design history files (DHF) and device master records (DMR), manufacturing – to post-market surveillance.