

QUALITY MANAGEMENT

Transforming Biopharma Quality through an AI-driven Approach

CHALLENGES

Manual Data Entry

Constant Change Management

High Volume Critical Data

High Risk Impact Analysis

Data Buried in Documents

Unstructured Form Data

Disconnected Data Model

Inaccessible Data

EXCELLENCE IN QUALITY MANAGEMENT REQUIRES MORE THAN HUMANS

INDUSTRY SAYS

"We submitted incorrect data to the FDA 3 times on the same tables (despite repeated human review of data)." *

"We cannot prioritise work on quality events as it takes too long for humans to triage (over 6,000 per year)." *

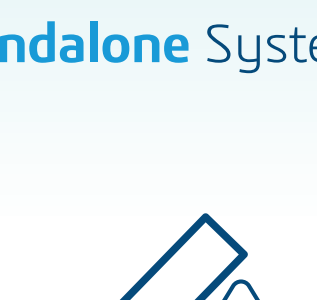
"We completed all planned changes and still failed to fix the problem (due to unanticipated consequences)." *

***TOP 20 BIOPHARMA**

WHAT IS NEEDED?

Companies need to **MOVE**

YESTERDAY



Standalone Systems



Document and **Forms** Based



Manually Operated



Weak and **Isolated** Data

NEXT GEN



Fully **Connected**



Embedded **Next Gen** Process



AI Assisted



Data Driven and **Model Based**

BIOVIA QUALITY MANAGEMENT MAKES A DIFFERENCE

1 FULLY CONNECTED

Accurate analysis without human reliance

2 EMBEDDED NEXT GEN PROCESS

Proven processes for optimal outcomes

Deep industry expertise
Regulatory aligned
AI embedded

3 AI ASSISTED

Prevent rather than correct problems

AI and ML go beyond human capabilities in scale and volume



Correlate



Predict



Recommend

THE BIG ANSWER

Patient

Product

VIRTUAL

REAL

Plant

Process

Enterprise

Why Choose BIOVIA Quality Management?

50%

Reduction in Data Verification*

99%

Success Rate in Predicting CAPA Severity*

70%

Reduction in Human Review Time for Quality Triage*

100%

Accuracy in Identifying Similar Historical Deviations*

*Dassault Systemes internal analysis from customer experiences

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