DASSAULT SYSTEMES

BIOVIA

The FDA expects organizations to have full visibility and control over their processes - with shared responsibility for contract manufacturing

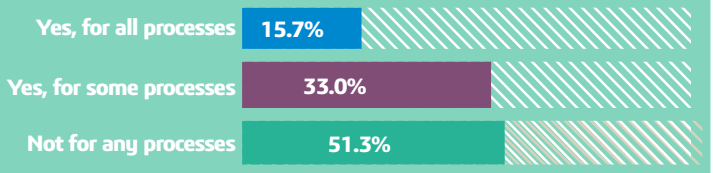
Expectations include:

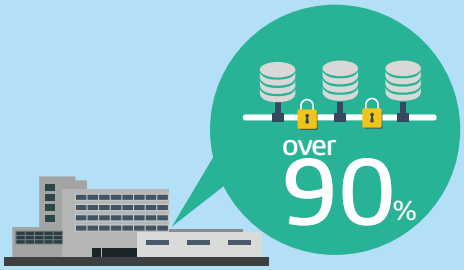
- Ensuring that processes are in a constant state of control
- Understanding products and processes in order to implement Quality by Design (QbD) into product development
- Delivery of quality metrics for risk-based inspection schedules as proposed by a new quality metrics program
- Shared responsibility for products manufactured by their Contract Manufacturing Organizations (CMOs)
- Drive improvements in manufacturing technology, product quality and safety - reducing recalls and mitigating drug shortages

PHARMACEUTICAL MANUFACTURING INDUSTRY CHALLENGES:

More than 50% don't use any software applications to manage their production processes

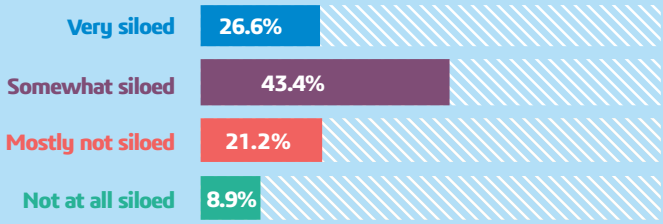
Over half of pharmaceutical manufacturing companies are not using software applications to manage or analyze any of their production processes

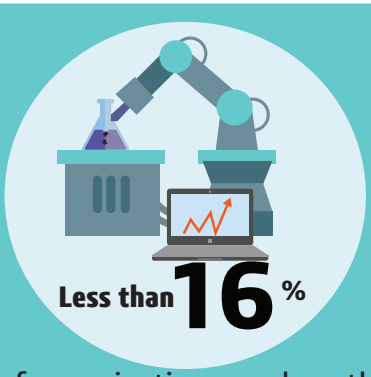




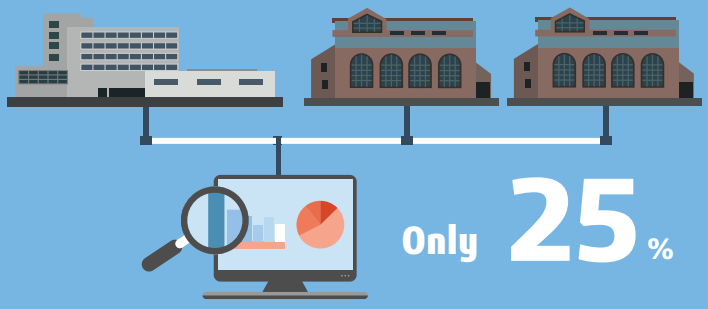
pharmaceutical manufacturing companies dealing with siloed data across their organization

Organizations reported that their data is:





of organizations analyze their production processes in real-time



Only 25% of pharmaceutical manufacturers use a software application for collaboration with contract manufacturers, or vice versa

Without software applications, companies have limited visibility into their quality and process data in order to:

- Gain full control of your processes
- Develop robust processes
- Deliver good quality metrics
- Share responsibility with outsourced manufacturing
- Reduce product variability to avoid recalls, FDA warnings and decrease patient risk

LEVERAGING BIOVIA'S SOLUTION FOR CPV, USERS REPORTED:

89 % Reduced time spent gathering and aggregating data

71 % Increased process understanding

66 % Improved visibility throughout the organization (i.e. reporting, dashboards)

66 % Decreased time producing standard reports

66 % Faster response to investigations

57 % Reduced time spent monitoring processes

BIOVIA Customer Testimonial

"Implementing BIOVIA Discoverant resulted in a big operational impact in terms of Continued Process Verification, process monitoring and process understanding."

Sr. DBA & Project Lead, Global 500 Pharmaceuticals Company

Learn about a maturity model to help companies navigate the major steps of implementing a global monitoring plan for Continued Process Verification (CPV), and why CPV is becoming increasingly critical for meeting the monitoring needs of life sciences organizations.

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