

## HAVE CONFIDENCE IN YOUR DATA As Bio/Pharma Advances, So Must Our Data Integrity

Bio/pharma development and manufacturing processes have been evolving at a rapid pace. The pharmaceutical industry has grown from simple aspirins to IV delivery, antibiotics and, most recently, cell and gene therapy. Products are more complex, tailored and varied than ever and the associated amount of data is growing - which requires a new level of attention to detail. As covered in the Life Science Leader article "[How to Avoid Data-Integrity Woes in Pharma](#)", the situation is exacerbated by data dispersed among various proprietary systems and disparate teams across global manufacturing networks. This framework also complicates compliance with the FDA's requirements for data integrity in development and manufacturing operations.

"With the advent of personal medicines and unprecedented scrutiny in drug manufacturing and drug product quality, the industry needs to improve data integrity and operational transparency," commented Robert Di Scipio, CEO of informatics software company, Skyland Analytics.

While data integrity is critical to building confidence in the supply chain and product quality, as well as meeting FDA compliance obligations, many organizations remain highly reliant on [spreadsheets](#), manual data entry, paper records and email which create numerous opportunities for error and can result in FDA warning letters, fines or recalls.

Large life science companies who have invested in systems to manage development and manufacturing data may experience integrity challenges as systems tend to proliferate with acquisitions, new IT staff and evolving user requirements. This problem is further exacerbated as in-house built solutions age due to technology obsolescence.

### What are the latest solutions that address data integrity issues?

New cloud-based data management systems not only collect data from digital systems with intuitive workflows that improve data integrity but provide new levels of data transparency to all constituents in the supply chain. These systems can be rapidly deployed at low cost to enable the establishment of a digital data spine early in the product and process life cycle. This provides the foundation of a persistent, dynamic knowledge library relied upon by sponsors and CMOs throughout clinical and commercial manufacturing operations. New digital data management tools provide controls for data entry, storage, analytics, reporting and sharing.



### POOR DATA QUALITY COSTS

Research firm Gartner has found that the average cost of poor data quality on businesses amounts to anywhere between \$9.7 million and \$14.2 million annually. At the macro level, bad data is estimated to cost the US more than \$3 trillion per year.

## Today's Data Integrity Challenges

- More complex processes and data
- Multiple teams and partners
- Paper and spreadsheets
- Disparate systems
- Regulatory scrutiny

According to the [Harvard Business Review](#), improving the data health of your enterprise entails following a core set of principles:



### Your data must be:

- Transparent
- Thorough
- Timely
- Trending
- Telling

### Choosing the right tool.

Look for the following features when choosing a data management system to establish compliant data visibility across teams, sites and partners and establish data integrity throughout the product life cycle.

**21 CFR Part 11 Compliant** - Designed, developed and tested to comply with FDA 21 CFR Part 11 and meet other user requirements (Electronic approvals and signatures • Full audit trails • Comprehensive validation kit)

**CPV-Ready** - Captures all critical quality and process data (CPPs, CQAs, etc.) on a batch by batch basis; manages changes to target control limits and process specifications with automatic contextualization of this data; and seamlessly generates required outputs for CPV including control charts for trending and process capability.

**Supports Intuitive Workflows** - Controls and verifies data entry across operators, manufacturing managers and QA groups. Contextualizes data in relevant time. Delivers batch quality alerts to selected team members to accelerate troubleshooting and timely batch release.

**Comprehensive Data Capture** - Captures and contextualizes all types of data – digital, paper, manually-entered, queried and calculated. Incorporates attachments and URLs to dynamically accumulate knowledge throughout the product lifecycle to transform the enterprise's knowledge management with persistent, digital information accessible across the supply chain.

**Cloud-Based** - Centralized, single source of data truth with targeted transparency through secure data access based on specific roles and user permissions for internal and external teams dispersed across complex networks of manufacturing sites.

**Scalable** - From development to clinical and through commercialization, provides a flexible, intuitive and validatable system that requires no coding. Ability to adopt as the first digital data tool - to move away from paper and Excel – and serve as the digital data hub for efficient aggregation and analysis as your IT landscape matures.

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Skyland PIMS® was designed for the life science industry by the developers of the very first product-process data information solution. Enhanced and cloud-based, PIMS™ is the industry leading data management tool which orchestrates the aggregation, analysis and sharing of product and process data in a Part 11-compliant, validatable workspace. With Skyland PIMS, your team will improve data integrity, remain compliant and make better, more rapid product and process decisions with confidence.