Skyland Analytics

Life Science Product & Process Data Intelligence

# THE EXCEL PROBLEM:

## Picking the Right Tool for Product-Process Data Management

In the life science industry, like many sectors, Excel is a proverbial hammer. However not all problems are nails. Launched by Microsoft in the 80's, Excel has become ubiquitous as a tool for every department and workflow imaginable, ad hoc analyses, back-of-the-envelope calculations, and more.

Excel is on most of our desktops and devices. Ease of access, perception of no-cost and the user-friendliness of spreadsheets drive its adoption for more use cases than it is truly suited.

## Limitations and Risks of Using Excel

Although it has its place in the pharm/biopharma sector, it is important that drug sponsors and development and manufacturing partners (CDMOs/CMOs) realize the limitations of Excel and the potential risks it can create if relied upon for certain data management needs.

### Manual Data Entry

Spreadsheets are an inferior platform for storing and analyzing life science data subject to compliance requirements. Spreadsheets create data quality issues, as it is easy to input incorrect data – almost 90 percent of all spreadsheets have errors[1] – and they do not integrate with digital data sources such as electronic batch records (EBR), Lab systems (LIMS) and Manufacturing Execution Systems (MES).

### Validating Data

Validating data is often a matter of manually verifying, using conditional formatting to find duplicates, sorting/filtering, and performing find and replace. Not only is this time consuming, all too often the result is a pattern of data errors.

### Capturing Data Complexity

Spreadsheets are not designed to manage custom time-dependent data or contextualize disparate data types (i.e. replicate, continuous, discrete).

### Versioning and Collaboration

Even with auto-saving and cloud-based access, collaborating using a spreadsheet often involves saving, downloading, re-saving, and uploading versions. Teams typically rely on emailing files with variable attention paid to file names that try to lock down version with dates and initials. This can lead to confusion and possibly working from wrong information.

[1] 12 of the Biggest Spreadsheet Fails in History, Christiane Soto, October 21, 2019

### Advanced Analyses

Spreadsheets limit users to logic-based functions, basic arithmetic, and summary statistics. This forces users to spend valuable time getting creative with their Excel solutions and find workarounds for critical analyses.

### CFR Part 11 Compliance

Excel is not designed to be compliant with FDA 21 CFR Part 11 guidelines and validation requirements. An Excel file is easily transported and hard to track. With no audit trail functionality or user-based controls, an employee can accidentally or maliciously email it to an outside address, print a copy to take out of the building, or upload it to a shared drive like Dropbox or Google Docs, all without traceability.

## The True Cost of Using Spreadsheets to Manage Life Science Data

Use of spreadsheets in life science development and manufacturing carries high tangible costs that may not be so obvious: manual data entry, competing data sets entered by different users, version control, security, delayed data migration to Part 11 compliant systems.

### Highly Paid Staff Perform Manual and Repetitive Data Management

Spreadsheets take time to setup and maintain. Often, it is highly paid and skilled SMEs that spend time building them, creating formulas, formatting cells, and much more. Managing spreadsheets takes up time and resource availability, accruing high costs for your organization.

### Spreadsheet Errors Create Financial Risk and Liability

Monumental spreadsheet blunders are more common than you might imagine. Organizations who rely on Excel in ways that are poorly suited for its use create potential for failure and even disastrous results. In 2008, Barclays Capital acquired 179 bad contracts from Lehman Brothers because of a spreadsheet that included hidden rows containing contracts intended to be excluded from the deal. In 2014, Trans Alta, a Canadian power generator, lost $24,000,000 in a contract purchase after a copy and paste error in a spreadsheet mistakenly increased sales pricing. Many other costly examples abound.

## 4 Signs You Need to Move Off of Excel

1. Multiple users rely on spreadsheets to analyze like data
2. Spreadsheets store sensitive patient data
3. Spreadsheets are not securely version-controlled
4. Excel is used to store/ analyze batch information

If your team relies on spreadsheets for any of these tasks it's time to move off of Excel-based solutions to Skyland PIMS process information management suite.

**Gartner estimates that inaccurate and incomplete data cost organizations $14,200,000 on average every year. Spreadsheets are the biggest source of data quality issues.**

### Corporate Knowledge Suffers When Spreadsheet Builders Leave

Excel spreadsheets are often assembled with little thought to maintaining them. They make their way into ongoing business operations where they proliferate without the proper document management and/or change control measures. Over time, the individuals who built the spreadsheets make changes, and then they revise their changes. Eventually, the person responsible for creating and maintaining the spreadsheet leaves for another department, takes another job, or retires.

## Accelerate Business Performance, Reduce Risks, Cut Costs

Spreadsheet-based workflows have their place, however there are other solutions that are easier to use, scale across the enterprise and are purpose-built for the complexities of life science manufacturing. Skyland PIMS® offers drug sponsors and CDMOs/CMOs an easy-to-use, single-source-of-truth process data collaboration platform that ensures Part 11 compliance, data transparency and data integrity throughout the product lifecycle and across the supply chain.

### Data Contextualization

Skyland PIMS provides or preserves the context of disparate data needed for analysis. Based upon the framework of your process definition (process map or hierarchy), the platform's Batch, Limits and Analytics modules enable data to cascade throughout the application to seamlessly generate charts, reports and alerts without manual data transfers and the creation of custom formulas.

### Data Integrity

Skyland PIMS enables customers to cohere paper, spreadsheet and digital data throughout the supply chain with controlled data entry and fewer human errors. Easy batch data entry form creation and alerts, automatic derived values and querying of data directly from disparate data systems (LIMS, MES, EBR) increases the data fidelity.

### Collaboration and Compliance

Skyland PIMS cloud-based platform was designed for secure data sharing among internal and external teams establishing a single source of data truth. User roles and permission settings align data entry, transfer, viewing and approvals with business needs, SOPs and FDA guidelines.

### Persistent Knowledge Base Throughout the Product Lifecycle

Serving as a persistent product and process data library, Skyland PIMS ensures process knowledge is maintained across the global supply chain and throughout the product life cycle. PIMS supports document attachments, comments, URLs, and flowcharts for additional context and includes a complete audit trail of data entries including authorship, change justifications and time stamp.

Avoid the time, cost and risks of spreadsheets. Skyland PIMS was designed for the life science industry by the developers of the very first drug manufacturing informatics tool. 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.