Skyland PIMS
Smarter Drug Manufacturing Process Data Management

Skyland PIMS IDBS

Still relying on spreadsheets, paper records and disparate data systems? Enterprise systems too costly?

Introducing Skyland PIMS process information management system

PIMS serves as a single source of data truth for life science organizations developing and manufacturing clinical and commercial-stage therapeutics. Designed for all biopharma products — small molecule, biologics and cell and gene therapies alike — PIMS allows for more efficient gathering, analysis, reporting and sharing of product, process, batch and patient data across internal and external teams, sites and partners.

Centralized, persistent and dynamic data library

PIMS coheres and contextualizes all types of data — digital, paper, manually entered, queried and calculated. Integrated workflows ensure critical data is captured at every stage of development and manufacturing while enabling the inclusion of comments, links to URLs and attachments of batch records, flowcharts and other documentation for additional process and product knowledge and context. PIMS provides a complete audit trail of data entries, including authorship, change justifications and time stamps, and meets the strict requirements of 21 CFR Part 11.

Simplify
Data acquisition & management

Expedite
Batch release

Accelerate
Scale up & tech transfer

Enhance
Process monitoring & understanding

Elevate
Data visibility & integrity

Streamline
Business & regulatory reporting

Improve
Operational efficiency

Lower
Cost of compliance

Embedded analytics

PIMS preserves the process context of data needed for analysis. Its Data Cascade feature enables data to be digitally retrieved or entered once for auto-generation of segmented control charts, correlations and analysis across lots, processes and products. PIMS provides ready access to CPPs and CQAs, raw material attributes and historical limits and specifications data for analysis and regulatory reporting (e.g., CPV, APQRs, CMC).

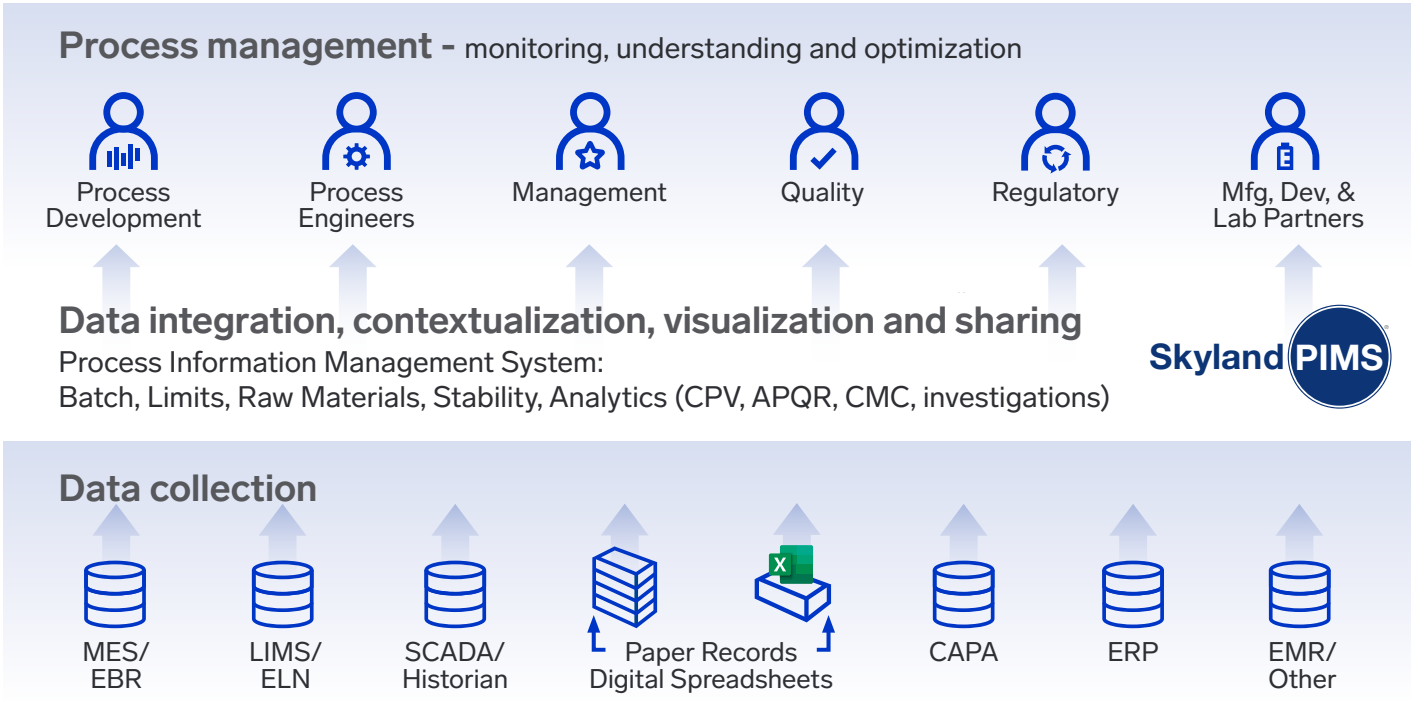
Secure data sharing across the supply chain

PIMS' collaborative workspace bridges the information gap across development and manufacturing and internal and external teams, sites and partners. It was designed for secure and timely data access by authenticated users whose permissions for data access, entry and approvals align with business needs and SOPs. PIMS ensures data visibility and knowledge sharing that are critical to driving fast and effective scale-up and tech transfer and provides seamless operational transparency, thereby reducing costs and enabling compliance for all supply chain teams.

Scalable, low-cost digital platform

Cloud-based, PIMS is deployed in two hours, requires no IT infrastructure or coding, and is easily configured by subject matter experts. From development through clinical and commercial manufacturing, PIMS provides a flexible, intuitive and validatable system that efficiently addresses growth needs regardless of the existing landscape. The first digital tool to move away from paper and Excel — and a springboard or complement to other systems — PIMS serves as the digital data backbone of your IT infrastructure.

Manufacturing process information management



PIMS consists of modules that can be licensed as a suite to provide an end-to-end manufacturing and quality data repository, or individually with the ability to scale to meet operational and IT needs.

PIMS Batch

Establish visibility into the status of all batches with PIMS' centralized batch data repository. Manage batch data verification settings that can be pre-configured to flag out-of-range values. Use approval workflows and dashboards to monitor critical data entry and batch release status.

PIMS Limits

The industry's first platform to centrally manage product and process specifications and target control limits. PIMS Limits provides an audit trail of changes, authors, approvers, date and rationale, and contextualizes data to feed analysis and reporting for regulatory compliance and business requirements.

PIMS Analytics

Seamlessly transform data into shared, actionable insights by generating charts, reports and alerts. PIMS Analytics supports improved understanding and control of process and product performance with its charting tools, including segmented control charts and process capability, intra-batch overlay plots with chromatogram, golden batch and graphical display of batch genealogy.

PIMS Raw Materials

Unlimited raw materials (and intermediates) definitions for CoA storage, trending and analysis. Quickly track, trace and compare unlimited raw material quality and performance across vendors, lots, processes and products. Provides genealogy tracking of material components in intermediaries and solutions through final product.

PIMS Stability

Centralize data from different steps in the drug development process and forecast product expiration dates and shelf life for the drug approval process. Enter stability table parameters and set up analysis and model options. Output overlay plots with expiration age, pooling and dating analysis, and generate summary table slopes, intercepts, p-values, expiration ages and more.

"We needed to move fast on our COVID-19 vaccine and replace Excel data management and scale/accelerate CMO data sharing, PIMS was the perfect product."

Director of Data and Analytics, Novavax

PIMS meets requirements for development, manufacturing, quality, compliance, supply chain and IT operational needs.

- **Streamlined processes:**

  Data Cascade for auto-generated analytics, pre-configured review/approval workflows, customized alerts, cloud platform, deployed in hours, easily configurable, managed by process experts/scientists, no IT infrastructure, simplified licensing, low TCO

- **High-quality data:**

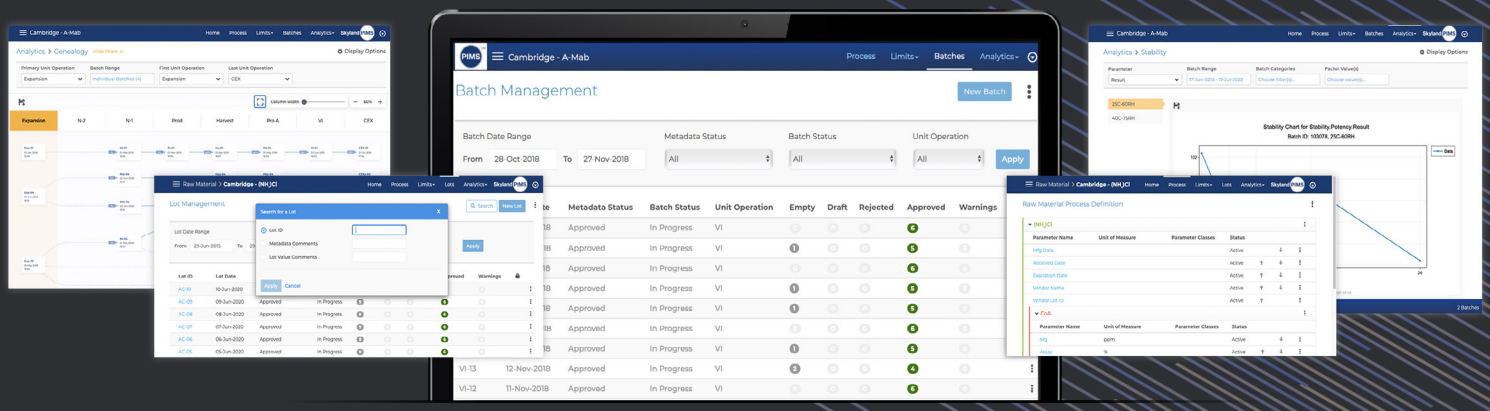
  Persistent knowledge base, data contextualization, 21 CFR Part 11 compliant, complete audit trail, data integrity controls, easy validation

- **Secure collaboration:**

  Centralized data hub, controlled and secure data sharing

Drive a successful CPV program

CPV-ready PIMS 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.



Evaluate PIMS today.

Experience first-hand the power and ease of managing manufacturing process data in PIMS with a **FREE** demo.

Find out more about smarter drug manufacturing process data management.

About IDBS

IDBS helps life science organizations accelerate the discovery, development and commercialization of products and therapies that transform the lives of populations worldwide. From lab through manufacturing, IDBS uses its 30+ years of experience working with a diverse list of customers - including 22 of the top 25 global pharma companies - and deep expertise in scientific informatics and product and process data management to tackle today's most complex challenges. In addition to E-WorkBook for R&I, IDBS offers an innovative software platform for BioPharma Lifecycle Management (BPLM). The unique capabilities of its cloud-based IDBS Polar and Skyland PIMS process solutions serve as a digital data backbone for quick access to critical information and key insights across the supply chain.

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