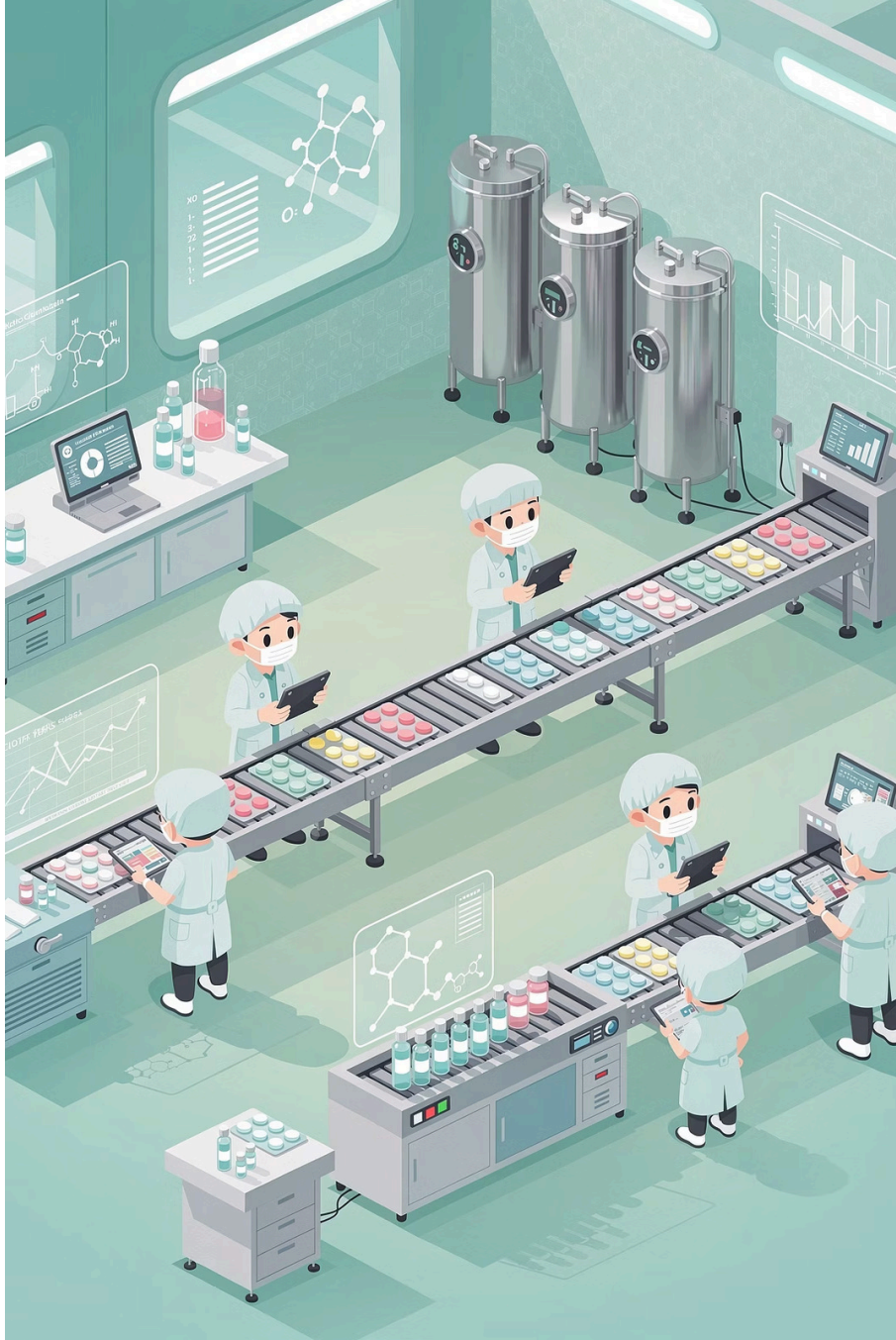
LIGHT PHARMA
consulting | technology

PI CPV

Digitized Continued Process Verification for Pharmaceutical Companies



OVERVIEW

The CPV Challenge

Continued Process Verification (CPV) monitors critical process parameters throughout the product lifecycle to ensure manufacturing processes remain in control. It identifies trends, anomalies, and variability to maintain compliance with regulatory standards.

However, organizations struggle with managing large datasets and adhering to structured guidelines consistently.

Introducing PI CPV

A state-of-the-art automation platform designed to digitize the entire CPV lifecycle

Statistical Analytics

Advanced data analysis capabilities for process monitoring

Seamless Integration

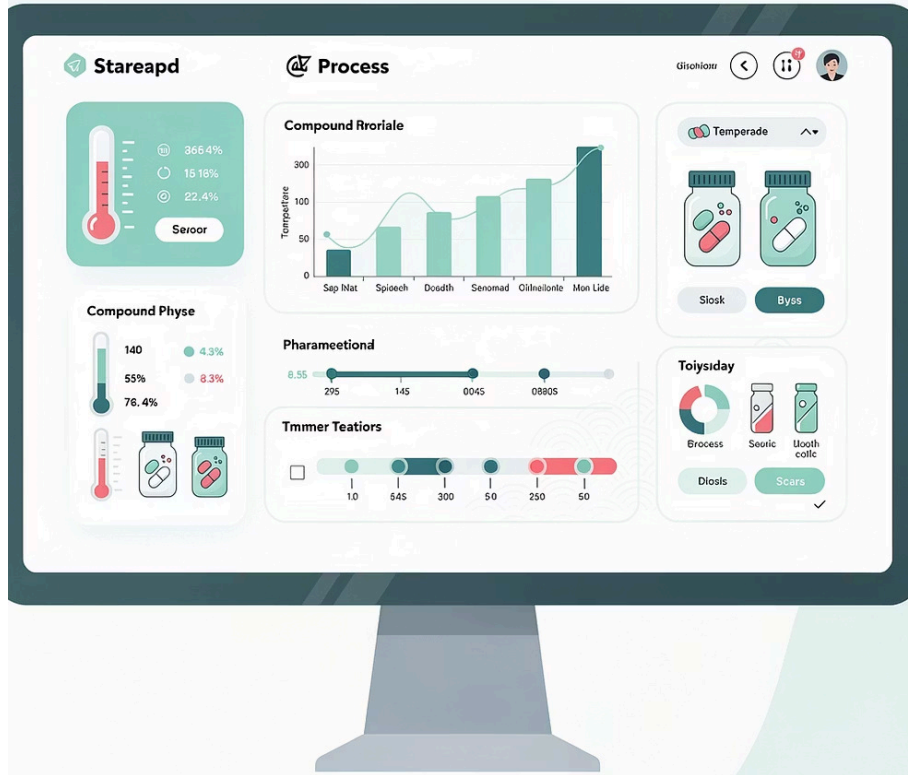
Connect with LIMS, SAP, TrackWise, and other systems

Customizable Reporting

Flexible templates tailored to your needs

Regulatory Compliance

Built-in adherence to global standards



FEATURE 1

Structured Workflow & Collaboration

01

Development

Create CPV protocols with built-in e-signature support

02

Review

Capture comments for transparency across teams

03

Approval

Track status visibility and ensure accuracy

04

Completion

Achieve timely collaboration and compliance

FEATURE 2

Centralized Data Repository

Unified Integration

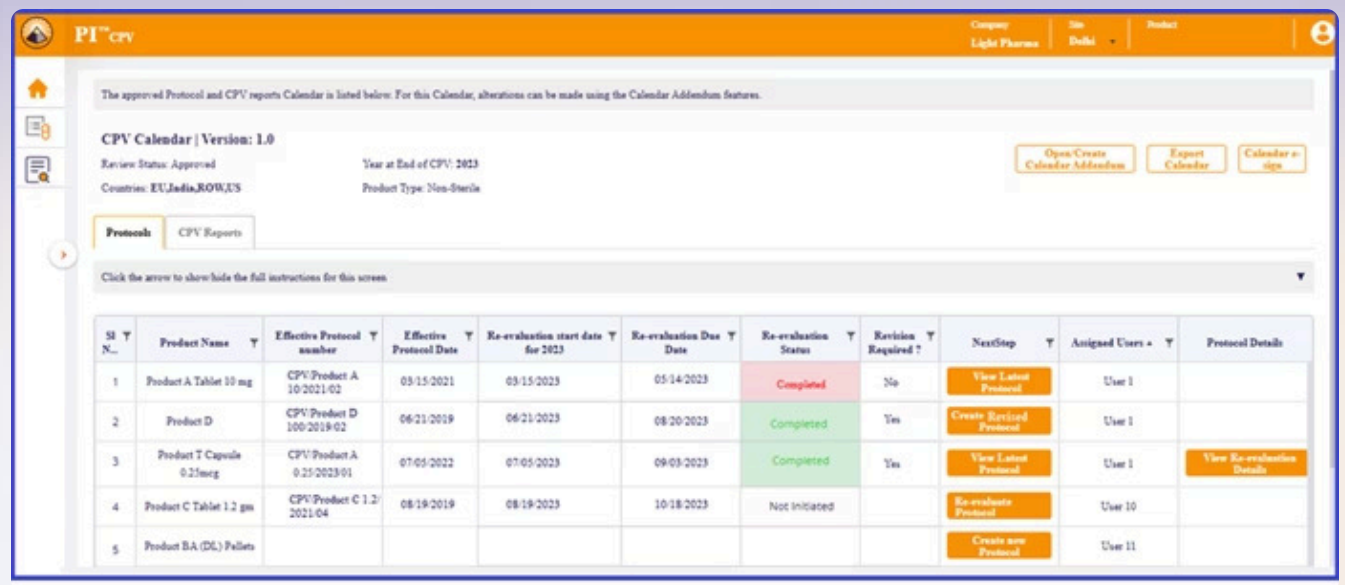
PI CPV integrates with key systems to unify data from multiple sources:

- LIMS
- SAP
- TrackWise
- EDMS

Real-Time Visibility

Centralized access enables:

- Batch information and materials tracking
- Analytical methods and process data
- Process deviations and recalls
- Investigations and corrective actions



FEATURE 3

Smart Scheduling & Tracking

1 Annual Planning

Schedule CPV protocol creation and re-evaluations

2 Periodic Reports

Organize report schedules and addendum creation

3 Management Tracking

Generate reports to monitor CPV statuses effectively

4 Notifications

Automated emails inform stakeholders of deadlines

Export options to Word or PDF formats simplify audits and archiving.

FEATURE 4

Automated CPV Protocol Management

Data Collection

Gather CPPs and CQAs from manufacturing processes

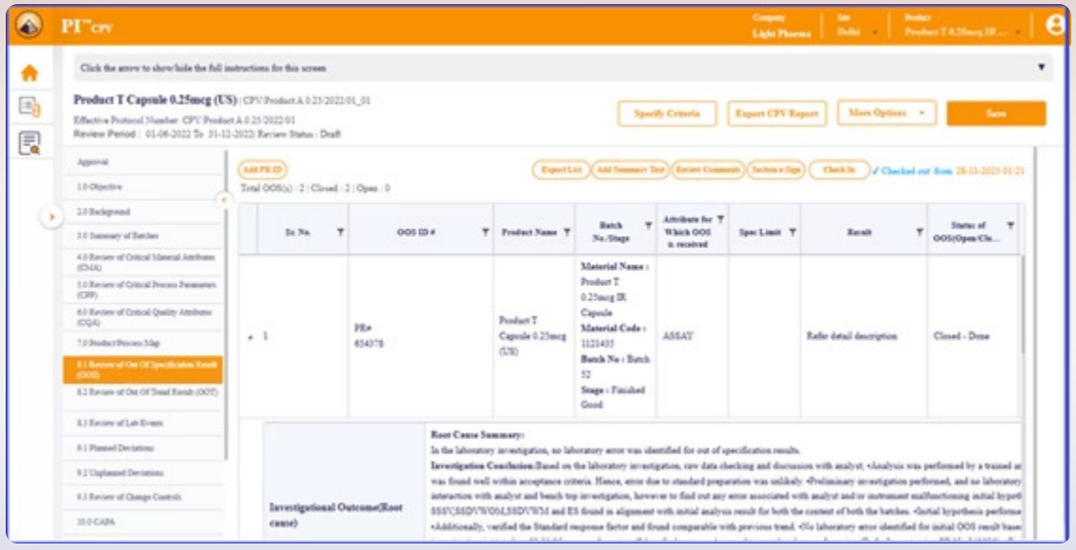
Data Analysis

Establish limits using SPC charts and trend analysis

Re-evaluation

Periodic protocol reviews maintain control standards

This structured workflow enables efficient protocol review and execution while maintaining compliance standards.



FEATURE 5

Streamlined CPV Report Generation

Configurable Templates

Support for single or multiple product strengths and markets

Flexible Import

Import standardized Excel files or enter data manually

Data Validation

Configurable rules ensure accuracy and consistency

Export Options

Generate Word or PDF formats for audits and archiving

FEATURE 6

Robust Role Management

Role-Based Access Control

PI CPV enables secure operations through precise privilege assignment:

- View, edit, approve, or export permissions
- Clear accountability across teams
- Minimized user errors
- Restricted access to sensitive data

FEATURE 7

AI-Augmented Summaries

Automated Intelligence

Generative AI creates summaries and recommendations based on CPV data

User Control

Override AI-generated content as desired to maintain accuracy

FEATURE 8

Data Security & Regulatory Compliance

Audit Trails

Secure tracking of all changes and approvals for complete transparency

E-Signatures

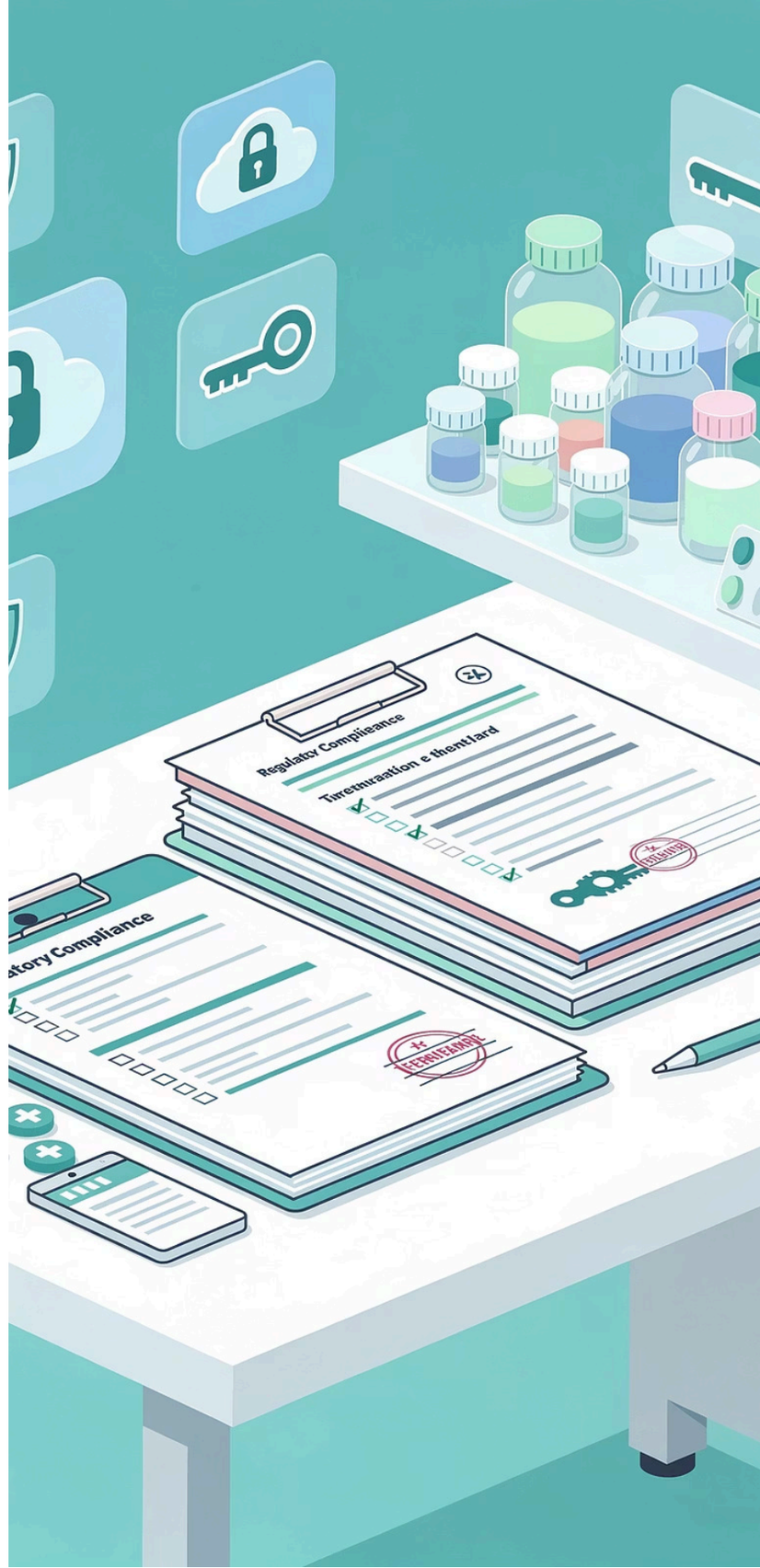
Embedded digital signatures ensure data integrity and authenticity

Global Standards

Compliant with CGMP, 21 CFR Part 11, and EU Annex 11 regulations

Inspection Ready

Exportable change histories prepared for regulatory inspections



The PI CPV Advantage

Transform your CPV process with complete digitization

↓

Minimize Manual Effort

Reduce errors through automation and streamlined workflows

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Enhance Capability

Improve process and product quality with advanced analytics

✓

Regulatory Readiness

Maintain compliance with embedded regulatory features