

PaperLess GMP

future of Pharma Industry,
advancement towards Pharma 4.0

*the pharmaceutical
PaperLess Technology*



Cyclone Pharmaceuticals Pvt. Ltd.

Cyclone Pharmaceuticals Pvt Ltd is a renowned pharmaceutical GMP and technical consultant company in India, with a strong track record of serving the pharmaceutical industry for the past 12 years. As experts in regulatory and GMP consulting, CPPL has successfully assisted numerous pharmaceutical companies in enhancing their GMP practices and documentation to ensure regulatory compliance.

GMP Software India

GMP Software India, a subsidiary of Cyclone Pharmaceuticals Pvt Ltd in India, was established with the objective of transforming the entire pharmaceutical manufacturing process into a paperless system. The company benefits from the expertise and reputation of renowned pharma technocrats, who provide guidance in the development of digital solutions.



Sachin Bhalekar

is currently the Director at Cyclone Pharmaceuticals Pvt Ltd, where he holds an esteemed position. Alongside this role, he also serves as the promoter at GMP Software India. Mr. Bhalekar's valuable guidance has played a significant role in the development of the world's first end-to-end PaperLess GMP Software. This software is known for its sophistication, practical solutions, and precise operations, all of which are made possible due to Mr. Bhalekar's extensive expertise in pharma manufacturing, QMS, and regulatory affairs. Under his guidance, we have a unique opportunity to enhance our services to the pharma industry and contribute to a meaningful digital transformation within the sector.

Sachin Bhalekar

CEO/ Director GMP Software Pvt. Ltd.

Cyclone Pharmaceuticals Pvt. Ltd.

Product Catalogue

PaperLess GMP

PaperLess Pharma ERP

PaperLess HR / Admin

PaperLess QMS. (LMS/DMS)

PaperLess eBMR / eBPR

PaperLess F&D R&D

Management



Management



Marketing



Human Resource



Admin



Account



Finance



Project



Sales Force



vendor



Purchase



Store



FG Store



Engineering Store



Planning

Material Management

Manufacturing



Production



Packing



Log Books



IPQA



Quality Control



Quality Assurance



External Training



Microbiology

Quality Management:

Research & Development



Research and Development



Technology Transfer



Engineering



Preventive Maintenance



Water System



Equipment Qualification

Utility

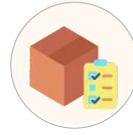
Quality Assurance and QMS Module highlights



Batch Approval



IPQA



Finish Product Sampling



Batch Release



Control Sample



OOT



Deviation



Training



Incident Reporting



Complaint



CAPA



Change Control (Permanent)



Stability Management



Audit / Self Inspection



Rejection Management



APQR



Document Management



Product Recall



Equipment Qualifications



Risk Management



Stereo Management



Label Control



Personal Qualifications



Environment Management



Vendor Management



Technical Document



GMP Monitoring



OOS



Art Work Management



Temp. / Pressure Diff. Reading

Product Highlight:

Perfection And Accuracy

- GMP and QMS needs perfection, Accuracy and Quality and PaperLess GMP is delivering the same
 - Zero human error System.
 - Backed up with incident reporting and Deviation Management at every stage.
 - Highest Security, Validated modules, access control.
 - eBMR with complete process flow.
 - All modules covered.
 - Perfection And Accuracy
-

Features of PaperLess GMP

Cost Saving for Stationary

One Click Report

Manpower Reduction
by 30%

Track and Trace
all Activities

Minimum Error

Follows all GMP and
QMS Concepts

Zero Investment
on Backup

Access Control and
Level Management

Compliance with System
and QMS Requirement

Control with Deviation
and Incident Management

Inhouse Trainers **External Trainers**

Training Announcement/Attendance:

- Training Need Identification
- Training Schedule
- Training Attendance
- Trainer Certification

Training Activity:

- Need Based
- On Job Training
- Document Training
- QMS Training
- Refresher Training
- Daily Training
- Self Certification
- Induction Training

Training Evaluation And Records:

- Training Evaluation
- Individual Training Record
- Training Log / Record
- Training Feedback

Specifications, Methods

- Specifications
- Method of Analysis

Laboratory

- Sampling
- Testing
- Vendor Sample Testing
- Water Analysis
- Control Samples
- Reagent Management
- Volumetric Solution
- Standard Management System
- HPLC Column Management
- Calibrations

Inventory

- Chemicals
- Reagent
- Glassware Management
- Equipment Inventory
- Indent

Reports

- Sampling Reports
- Specification Report
- Analytical Status

Inward / Outward:

- Charan Upload
- Raw Material
- Packing Material
- Finish Goods
- Outward Material
- Balance Calibration

Stock Book:

- Stock Book
- Material Status
- Bin Card
- Opening Stock
- Dumping
- Rejection
- Returned & Rejected Goods
- Common Log
- Log Books
- Receipts
- Additional Material Requisition

Other:

- Racks Master
- Maintenance
- Temp. & Humidity Control

Operations:

- Batch Approval
- Finish Product Sampling
- IPQA
- Batch Release
- SOP Management
- Control Sample
- Deviation
- Change Control (Temp)
- Change Control (Permanent)
- Incident Reporting
- Lab Incident
- Complaints
- CAPA
- Training
- Stability Management
- OOS
- Document Management
- Audit / Self Inspection
- Rejection Management
- Risk Management
- Product Recall
- Equipment Qualifications
- Personal Qualifications
- Label Control
- Environment Management
- GMP Monitoring
- Vendor Management
- Technical Document
- Temp. / Pressure DIR, Reading
- Important Document
- Software Restrictions

General Administration / Management:

- Management
- Human Resource
- Admin
- Account
- Sales (Force)
- Marketing/BD
- Export Sales
- PPC/Planning
- Purchase
- Auto Purchase
- Masters

Factory / Operations:

- Security
- Store/Warehouse
- Production
- Packing
- FG Store

Quality Management:

- Quality Control
- Microbiology
- IPQC
- Quality Assurance

QMS:

- Incidents
- Deviation
- Change Control
- CAPA
- SOP's

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- Quality Control
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QMS:

- Incidents
- Deviation
- Change Control
- CAPA
- SOP's

IT/Engineering:

- Engineering Tools
- Engineering
- Calibration
- Temp. / Pressure DIR, Reading
- Important Document

Research and Development

- Research and Development

External Panel

- External Panel
- External Panel

Specifications, Methods

- Specifications
- Method of Analysis

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H I G H L I G H T S

Paperless GMP Plans

Sr No	Features	PaperLess GMP Platinum	PaperLess GMP Gold	Pharma ERP
		Regulated	Semi Regulated	Non-Regulated
1	Human Resource and Admin	Recruitment Appointment Training Shift Management Medical Check-up Payrollandsalary Usermanagement Appraisaland Promotions Resignationand Relieving	✓	Recruitment Employees Attendance Joiningand Appointment Medical Checkup Payroll salary Training / Labour Management/ Government Compliance User Management Leave Management Resignation and Relieving
2	Management	Management Review Meeting Production Report Dispatch Report Purchase Report Yield Statement Analytical Report Product Costing	✓	✓
3	Marketing	Client and Lead Management Quotation and PO record market Complaint Handling Customer Feedback Transporters.	✓	Client and Lead Management Quotation and POREcord market Complaint Handling Customer Feedback Transporters Commissionagent
4	Purchase	Indent Quotation Purchase Order Stock Book Reports Vendor Management Post Receiving status	✓	✓
5	Security	Material Inward-Outward Employee, Labour entry-exit Digital Gate Pass	✓	✓
6	Stores	Receiving Dedusting Weighing GRN Dispensing Return and Rejection Management Stock book and Inventory Bin Card Chart Equipment Usages and Cleaning Balance Calibration Label Printing	✓	✓
7	Quality Control	Sampling Testing MOA Specification Control Sample Digital AR, COA and Raw Data Sheet Retest Management Calibration Env. Monitoring WaterAnalysis Volumetric Solution Inventory	✓	Sampling Testing Specification Control Sample COA Retest Management
8	Quality Assurance	Incident Report Change Control Deviation Management SOP Management Stability Study Risk and CAPA Analysis IPQA Vendor Management Complaints Training OOS Document Management Auditor Self Inspection Rejection Product Recall Label Control GMP Monitoring Art Work Management Stereo Management (Applications for Formulation)	Incident Report Change Control Deviation Management SOP Management Stability Study Riskand CAPAAna lysis IPQA V e n d o r Management Complaints Training OOS Auditor Self Inspection Label Control Art Work Management Stereo Management	Incident Report ChangeControl Deviation Management SOP Management Stability Study Risk and CAPA Analysis IPQA V e n d o r Management Complaints Training OOS Audit or Self Inspection Label Control Art Work Management Stereo Management
9	Production	e BMR	✓	Bill of Material BMR Stages Production IPQC release Production-Dispensing BatchTransfer
10	Packing	e BPR	✓	Packing BOM BPR Stages IPQC Product Transfer
11	Dispatch/ FGStore	✓	✓	✓
12	PPIC	✓	✓	✓
13	Engineering and Engineering Stores	✓	✓	Inward Receiving GRN Preparation Issuance Stock book Outward Gate Pass Indent Material Requisition
14	Researchand Development	✓	✓	X
15	ExternalPanel s:Vendor/ Lab/Doctor etc	✓	✓	X



Advanced Software with Simplicity

Introducing the world's first and most advanced Pharmaceutical ERP solution with QMS. This software is not only simple to operate but also easy to understand, ensuring perfect and precise output. It has been meticulously designed to align with the actual flow of operations in the Pharmaceutical industry, with modules that include system restrictions while still maintaining simplicity and compliance.

21 CFR Compliance and Data Integrity

PaperLessGMP offers comprehensive documentation that complies with 21 CFR Part 11 and ensures data integrity. The software's standout feature is its ability to accommodate unlimited users, providing robust data security and integrity through its user interface. With no option for editing or deleting data within the software, it effectively prevents any unauthorized tampering or alteration of entered results. Corrections can only be made through a systematic approach implemented by the quality management system. Furthermore, there is no concept of a super administrator, ensuring that entered data remains integrated and safeguarded against any form of alteration. The software also includes an audit trail feature, enabling the tracking of all activities and ensuring compliance with current good manufacturing practice and GMP guidelines.



Manpower and Cost Savings

Digitalization through the use of paperless systems, like GMP software, offers significant cost and manpower savings. By eliminating physical documentation and repetitive data entry, over 70% of stationery expenses can be reduced. The software also reduces reliance on manual labor, resulting in savings in manpower or man hours. Infrastructure costs are also reduced, as fewer operating instruments such as computers, printers, and networking infrastructure are required. The software can be easily operated on simple mobile tablets or mobile phones within your factory.

Validations and Change Management

Paperless GMP is more effective than fully validated software in the pharmaceutical industry. The software validations follow industry guidelines such as GAMP, ICH, and international standards for software validation. CPPL provides comprehensive documentation including User Requirement Specifications (URS), Design Qualification (DQ), Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ), and Site Acceptance Test (SAT), along with detailed test cases. The change management system for this software is highly stringent, particularly for minor or major changes. All modifications require procedural authorizations before they can be made. After the changes are completed, the modified forms and fields go through additional testing and validation.

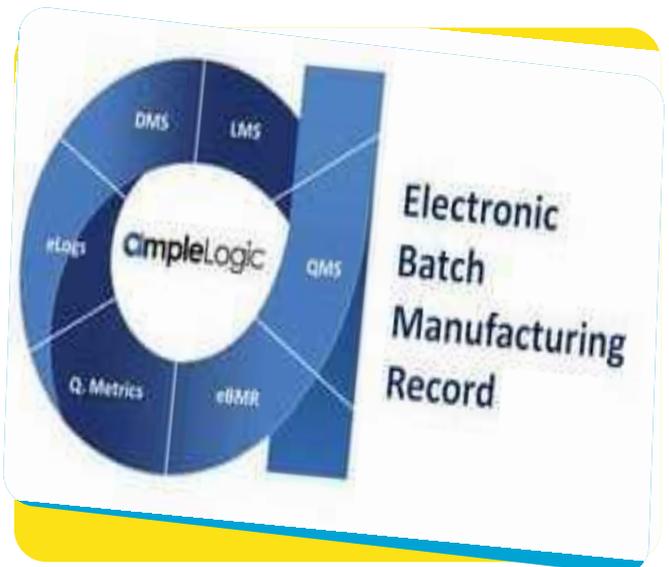


No Need of Add on Software

PaperLessGMP offers a broad solution for the Pharmaceutical Manufacturing industry. It effectively addresses multiple areas, including marketing, CRM, Human resource administration, Purchase, Accounts and Finances, Salesforce management, Security, Warehouse management, Quality control, Quality assurance, production, Packing, Dispatch, Engineering, Stores management, utility management, EHS (Environment, Health, and Safety), research and development, and microbiology. This comprehensive platform encompasses all essential operations within a manufacturing unit, eliminating the necessity for companies to acquire supplementary software or tools.

Amazing eBMR, eBPR, and Raw Data Sheet management.

PaperLessGMP offers a unique and comprehensive solution for the pharmaceutical industry. It provides customised Electronic Batch Manufacturing Record (eBMR), electronic Batch Packing record (eBPR), and well-established raw data sheet management in the quality control department. While only a few software developers have been able to successfully create software with these features, PaperLessGMP has successfully developed a customised ebmr and ebpr solution that helps manufacturing units save valuable time in their process and analytical documentation.



Quality Assurance with QMS

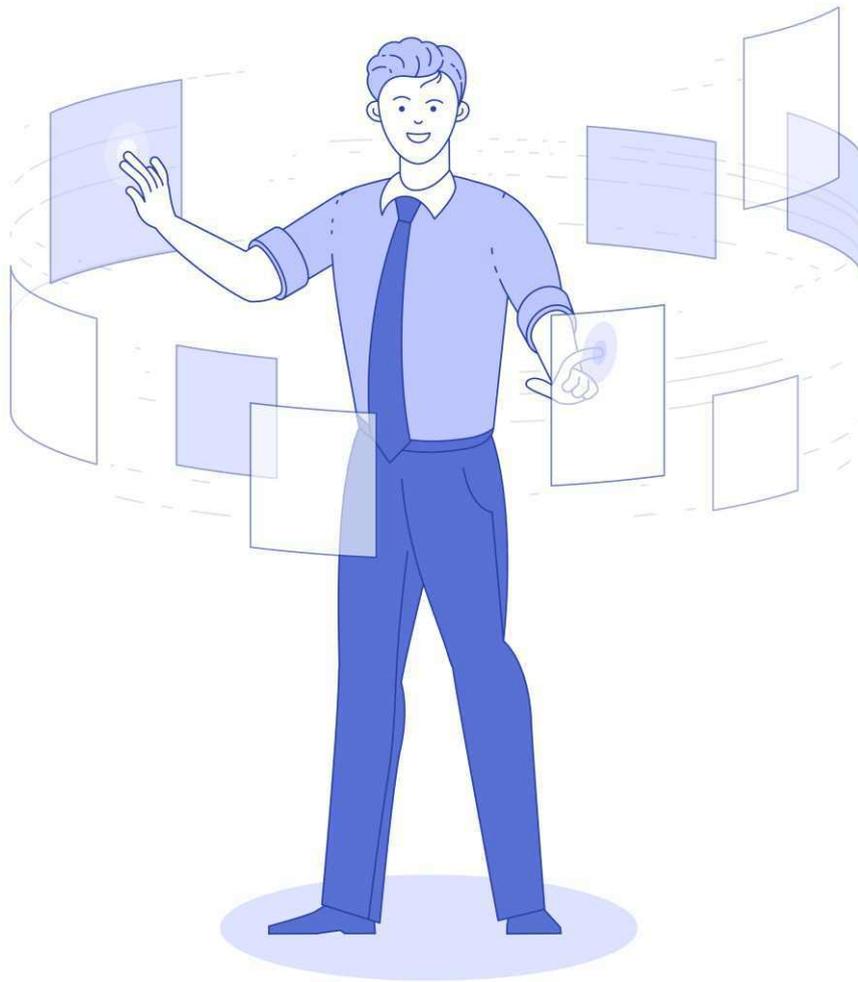
PaperLessGMP offers the world's first integrated quality management system. The quality assurance module is comprehensive and includes all the necessary components of quality assurance and quality management. It encompasses deviation management, change management, risk management, SOP management, and training management, all of which are equipped with impressive features and operate with a fully automated management system.

Secure and Safe

Paperless GMP is a cloud-based secure software developed using the angular JS platform and my SQL database, which are recognized as the most secure platforms and databases in terms of cyber security. Additionally, CPLL offers excellent cloud services and recommends clients to acquire secure servers to ensure data protection and cyber security.



Android Support for all modules



◀•• Other Products ••▶

- ▶ PaperLess GMP
- ▶ PaperLess HR
- ▶ PaperLess QMS
- ▶ PaperLess LMS
- ▶ eCTD Conversion
- ▶ PaperLess ERP

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