



PaperLess GMP

Pharma ERP With QMS

CP/PR/DOM/ -22-23

India's Most Economy and Complete Pharma ERP With advance
Technology Support with QMS

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1.0 Introduction: Cyclone Pharmaceuticals Pvt. Limited

Cyclone India Group is established by PHARMA TECHNOCRATS. We offer more than 25 years of experience in the international field and of these more than 20 years in pharmaceutical consulting. We are dedicated mainly to the Quality, Technical, Regulatory and Training Consultancy to Pharmaceutical Industry. We aim at helping small to medium size pharmaceutical companies in complying to the regulatory norms by providing and assisting them in their technical Matters. We are providing services like compilation of regulatory files, DMF, Dossiers, Internal Audits, Preaudits, Preparation for Regulatory or any other Audits, Professional training programs for skill development and Personality development for Pharmaceutical staff and technical Professionals. On site GMP and Technical Training is also our expertise and we believed in concept clearance for smooth and Quality Functioning of Pharmaceutical Industry.

Group Companies

Group Company	Website
Cyclone Pharmaceuticals Pvt. Limited	<u>www.cyclonepharma.com</u>
GMP Software Pvt. Ltd	<u>www.gmpsoftwareindia.com</u>
Paperless GMP ERP Software	<u>www.paperlessgmp.com</u>

Promoters Vision: Pharmacist Mr. Sachin Bhalekar is Promoter of Cyclone Pharmaceuticals Pvt. Ltd Pune. He is expertise in Quality Assurance, GMP and Regulatory sector with a great track record and served many multinational companies. With highest quality approach and transparency in every deal he is willing to take up this company as world's best Pharmaceutical Consultancy company. Need based cost-effective solution to small scale Pharma Manufacturers is his aim and motive for excellence.

As a dream Project Cyclone Pharmaceuticals Pvt Ltd had taken up PaperLess GMP Software and its subsequent like PaperLess GMP ERP

2.0 Introduction: GMP Software Pvt. Limited

GMP Software Pvt Ltd is established by PHARMA TECHNOCRATS. GMP Software Pvt. is subsidiary company for most reputed pharmaceutical consultants of India. Cyclone Pharmaceuticals Pvt. Ltd is established with a vision of making pharma industry Paperless and the dream project has been introduced as 'PaperLess GMP' under the guidance of GMP software Pvt. Ltd.'s experienced technocrats and experts.

Promoters Vision:

Sachin Bhalekar, Pharma graduate and Management PA; A professional technocrat who is known for his experience in GMP and Regulatory Operations. He is a person with crystal clear knowledge of Quality Assurance and other Pharma operations. He has developed the 'PaperLess GMP' concept and promoting it as a director of Cyclone Pharmaceuticals Pvt. Ltd. and GMP Software Pvt. Ltd



3.0 OUR SERVICES

Cyclone Pharmaceuticals Pvt Limited is having devoted and dedicated team to serve all kind of Technical Needs of Pharmaceutical Industry.

CYCLONE PHARMACEUTICALS PVT. LTD.

REGULATORY SERVICES

- US DMF compilation
- EU DMF compilation
- Excipient DMF
- Packing Material DMF
- Dossier Compilation
- ACTD / CTD Dossier
- Dossier for Herbal and Nutraceutical
- Variance Filing

TURN KEY PROJECTS

- API Plant Setup
- Formulation Plant Setup
- Cosmetics Plant Setup
- Ayurvedic and Herbal Plant Setup
- Injectable Facility Setup
- Veterinary Plant Setup
- Documentation Development for any GMP Inspection
- USFDA/MHRA Compliant Documents development

REGISTRATION SERVICES

- DMF Registration Services for US, Europe and ROW
- Dossier and Product Registration Services
- Query Support
- Review and Registration of Dossiers/DMF
- Ayurvedic and Herbal Product Registrations

TECHNOLOGY TRANSFER

- Development of New Methods
- New Formulation Development
- Technology transfer
- Validation Batches Execution
- Technology correction

PHARMA QA

Inspection Conventions (PICS) :

- Team of Experienced Auditors
- Gradation/Accreditation as Per International GMP Norms
- Certification of Facility
- Evaluation of Unit against different World GMP Norms
- Quality System Up-gradation

FORMULATION DEVELOPMENT

- New formulation development
- Established database of about 10000 different formulations
- Technology transfer/ Method Transfer
- Well equipped Research Facility
- Formula Verification

VALIDATION

- Process Validation
- Analytical Method Validation
- Analytical Method Verification
- Volumetric Solution Validation
- TLC Method Validation
- Well Equipped Analytical Lab

QUALITY INTEGRATION SERVICES

- Cost Assessment
- Packaging Material Cost Saving Solutions
- Onsite Cost Evaluation
- Minimizing Quality System Errors
- Single Quality System Implementation for Multiple Audits
- Formulation Loss analysis and Solution

VALIDATION PROJECT

- Equipment Validation
- Facility Validation
- AHU/HVAC Validation
- Water System Validation
- Utility Validation

AUDIT SERVICES

- New Plant Audit
- Contract Manufacturing Audit
- Regulatory, WHO, MHRA pre-audit
- Internal Audit (Self Inspection)
- Vendor Audit
- Consignment Audit
- QA & Documentation Audit
- Energy Audit
- API Plant Quality System Audit
- Assistance to Overseas client to monitor quality

SUPPORTIVE SERVICES

- BA/BE study
- Clinical Trial
- Pharmacovigilance
- Pharmacological Services
- Analytical Services
- Stability Study

TRAINING

- On job GMP training
- QA & Quality System training
- Audit Training
- Technical Training
- Refresher Training
- Quality Seminars



QUALITY

COST

COMPLIANCE

4.0 OUR SERVICES- GMP Software Pvt Limited


GMP Software Pvt. Ltd is subsidiary company for most reputed Pharmaceutical consultants of India. Cyclone Pharmaceuticals Pvt. Ltd is established with a vision of making pharma industry Paperless and the dream project has been introduced as 'PaperLess GMP' under the guidance of GMP software Pvt. Ltd.'s experienced technocrats and experts.

WHAT WE DO

Our amazing features & services and others listed below.

Paperless GMP (Pharma Manufacturing)

Paperless GMP takes care of each step with dual authentication and checker is basic concept of the GMP and we covers the same.



Digital HR

A Payroll system is software designed to organize all the tasks of employee payment and the filing of employee taxes.

Retail Medical Software

Pharmacy Software with Easy GST Billing & Filing. Have full control over inventory, billing & accounting, information about store items, suppliers & customers.

B2B for Pharma

Pharma Business Portal for Buyer & Sellers of Medicine and Pharmaceutical products and medical Devices.

Wholesale Pharmacy Software

It is designed with high level of care at every point so that the chances of manual mistakes are minimized. It manages all aspects of wholesale operations quickly and accurately.

VeriPharma Software

India's First Exclusive Pharma Recruitment Portal with Employee Verifications System.

OPD/IPD Management (Small Clinics)


OPD / IPD covers Appointment, Reception, OPD, IPD, TPA etc. Hospitals and nursing to manage and monitor patient data.

Regulatory Software

The hotel and restaurant management degree prepares students for supervisory position in hostels, restaurants, and other hospitality-related organization.

eCTD Software

PAB International has developed eCTD compilations and conversion Software. Cloud based software with highest security. Software is having reserved rights for admin & users.



Pharma ERP

Inventory Management, Material Management & Distribution Management Software for Pharmaceutical Management.

5.0 STAFF AND MANAGEMENT

Sr. No	Name of Person	Qualification	Designation	Experience
01	Mr. Sachin Bhalekar	B. Pharm MBA	Director and Chief Consultant	20 Years of Industrial Experience
02	Megha Ganage	B. Pharm	Head Bussiness Development	Software and Pharma Division
04	Dr. Sachin Zaware	Pharm D	Clinical Expert	Clinical Experience andExpertise
05	Ms. Sharmila Kulkarni	B. Pharm MBA, ClinicalDiploma	Clinical And Pharmacovigilance Expert, Head UKOperations	20 Years of Quality Experience
06	Ms. Prajakta Chemte	B. Pharm	Regulatory Executive	10 Industrial QA RA Experience
07	Mr. Santosh Pimparkar	B Pharm MBA	Quality Assurance and GMP Auditor	20 Years Industrial QA
08	Ramesh Lamkhede	MCS	Director GMP Software	20 Years of Software Development Experience
09	Deva Raju Ratnal	BCS /MCS	Director GMP Software	15 Years of Software Development Experience
10	Dedicated Staff for QA Total 15 Numbers			
11	Dedicated Staff for RA 10 Numbers			
12	Core Software Developers: 15 Nos Software Server Management: 5 Software Testing Team: 05 Software Testing Pharmaceutical Forms :05			

GMP Software Pvt Limited Team:

Above mentioned are Key personnel of Cyclone Pharmaceuticals Pvt. Ltd Pune and GMP Software Pvt Ltd apart from this we have following Technocrats team associated with us.

Associated Free Lance Consultants	No	Associated CRO Centers	No
Associate Regulatory Consultants	25	Clinical and BE Study Centers	03
Associated GMP Auditors	12	Quality Control laboratories	05
Associated Engineers	5	Analytical Validation Center	02
GMP Trainers	5	Formulation Development CRO	02
IT Infrastructure Partners	02	IT Support Companies	02

Offices:

1. Corporate Office Pune

2. Development and Server Management Office: GMP Software Pvt Ltd: Pune

3. Development and Server Management Office: GMP Software Pvt Ltd: Hyderabad

7.0 Software Description and Modules:

S	Features	PaperLess GMP Pharma ERP	
		GOLD	SILVER
1	Human Resource and Admin	Recruitment Employees Attendance Joining and Appointment Medical Checkup Training Labour Management User Management Resignation and Relieving	✓
2	Management	Product List HR Admin Production Report Dispatch report Purchase Report Analytical Status Batch release Status Shortage Report Product Costing Inventory Management Review Meeting	✓
3	Accounts	Challan Expense Assets Management Stock Regular Accounting	✓
4	Marketing	Client Management Lead Management Quotation PO from client Market Complaint Handling Customer Feedback Commission Agent	✓
5	Planning	Sales order from Marketing Consolidated Requirement Production Plan Plan Tracking Stock Book Batch Formula Unit Formula	✓
6	Purchase	Indent Quotation Purchase Order Stock Book Reports Vendor Registration	✓
7	Security	Material Inward-Outward Employee, Labour entry-exit Digital Gate Pass Security round Fire Extinguisher Vehicle Entry First Aid	✓
8	Stores/Warehouse Inventory Management	Challan Verification Receiving Dedusting Weighing GRN Dispensing Return and Rejection Management Bin Card Label Printing Stock Book and Issuance	✓
9	Quality Control	Sampling Testing: Result Entry Module Specification Control Sample COA Retest Management Water Analysis Control Sample Retest Management Inventory	✓

10	Quality Assurance	Batch approval FP Sampling IPQA Batch Release Training Rejection Management Stereo Management Vendor Management	NA
11	Microbiology	Sampling Testing Reports	✓
12	Production	Partial BMR: Dispensed Material Receiving IPQC Sample and release panel for technical Information Sheet Yield Reconciliation entry Additional Material Requisition	✓
13	Packing	Dispensed Material Receiving Yield reconciliation of Packing Material Stereo Management	✓
14	Engineering	Maintenance Note Breakdown Intimation Indent	✓
15	Engineering Stores	Inward Receiving GRN Preparation Issuance Stock book Outward Gate Pass Indent Material Requisition	✓
16	Masters	QA Masters QC Masters HR Masters and other department wise masters	✓

8.0 Additional Offerings (Complementary):

1	Plan	Pharma ERP GOLD	Pharma ERP SILVER
2	Users	Unlimited	Unlimited
4	Training	Online/Offline	Online
7	OS Requirement	Windows Licensed Copy Microsoft word PDF Reader	✓
8	Hardware	Laptops PCs Tabs Android Phones Wi-Fi or wire Lan	✓
11	Database	MySQL	✓
12	Development Platform	Angular JS	✓
15	Data Backup	Online Offline as per Realtime basis Auto	✓
16	Query Backup /Support	Immediate 24 x7 Support for Minor Queries Major Queries within 4 hours	✓



9.0. CPPL Approach to GMP Software Implementation

1. CPPL Responsibility:

Cyclone Pharmaceuticals Private Limited will be Technology Partner for GMP Software Private Limited and entire software Sales, support and technical responsibility is of Cyclone Pharmaceuticals Pvt Limited

2. CPPL Compliance and Monitoring system:

CPPL provides close watch on Implemented system through its strong follow-up and strong monitoring system. Distance is not the matter for us. We visit our client's site frequently as per given schedule and discuss the issues in implementation. Also, we provide 24 x 7 Quality support for all kind of queries raised by client on documents. Till perfection and satisfaction is our responsibility

3. GMP Software Private Limited's Responsibility:

GMP Software Private Limited is responsible for technical Development of software and after sales support and is bounded to give continuous support to our client till the relationship goes on. GMP Software Private Limited is legally liable for the legal and technical Aspects of the Software.

4. CPPL Training Methodology:

Training to the Clients Staff is responsibility of Cyclone Pharma team, we will train every person related to the modules upto their satisfaction level

5. CPPL\GMP Consultants capabilities:

We believe in positivity and knowledge. People trust on us for our knowledge and for our perfection Level

6. CPPL Integrity towards Work:

We never GIVE UP on our work until satisfaction of Client. Cost, Time and Knowledge are important parameters in our growth

7. Regulatory Approach:

We assure continuous support to our client in their regulatory approval procedures wherever required relevant to our products

10.0 SUMMARY OF CHARGES: Financial Plans
Plan I: PHARMA ERP GOLD

Sr. No.	SAC Code	Particulars of Service	Amount INR	Qty	Total Amount INR
1.	99831	PaperLess GMP - Pharma ERP System with QMS (Gold)	250000.00	1	250000.00
2.	99831	Shared Cloud SERVER With Limited Space (Additional Space with Additional Charges)	40000.00	1	40000.00
3	99831	Software License Charged Per Unit	25000.00	1	25000.00
Amount Payable INR					3,15000.00
TAX 18 %					56,700.00
Total					3,71,700.00
Training Online Free /Offline onsite training Travelling Lodging Boarding charges applicable + 50000.00 Offline or On Client Server Installation Server Charges will be deducted If Software is Installed on Client Server					
Payment Terms: 50% Advance: 40% On Activation and Format Customization (Max 15 Days), No Fees for PDF Format customization for first time , 10% on Live					
Annual Maintenance: Every Year 7.5% On Completion of First year On Basic Cost of Software					

OR

Plan II: Rented Pharma ERP: Annual Rental Plan

Sr. No.	SAC Code	Particulars of Service	Rate INR Annually	Monthly INR
1	99831	PaperLess GMP -Pharma ERP System with QMS (Gold)	100000.00	10000.00
For ANNUAL Rental Plan No Offline Installation, 25000/- One Time License Cost Per Plant is applicable Special Benefit: Software License Ownership will be transferred to Buyer on Completion of 36 Months there after Only 40000.00 Per ANNUM as annual Maintenance charge and Server Cost				
2.	NA	Shared Cloud Server (Per Year Charges)	20000.00	2000.00
GST 18% Applicable				

Please Note: 1. In Monthly plan only cloud subscription is available No Offline Installation
2. Training Online Free /Offline onsite training Travelling Lodging Boarding charges applicable no other fees
3. Payment Terms: 1. Annual Rental Plan: 25000/- One time Cost for each unit +50% of ANNUAL Rental Plan +100% Server Cost along with PO Remaining on completion of Installation and Software Live (Not Exceeding one Month)
Annual Maintenance: Not applicable for rental Plan

Plan I: PHARMA ERP SILVER:

Sr. No.	SAC Code	Particulars of Service	Amount INR	Qty	Total Amount INR
1.	99831	PaperLess GMP (Without QMS) Pharma ERP- Silver	100000.00	1	100000.00
2.	99831	Shared Cloud SERVER With Limited Space (Additional Space with Additional Charges)	20000.00	1	20000.00
3	99831	Software License Charged Per Unit	25000.00	1	25000.00
Amount Payable INR					145000.00
TAX 18 %					26100.00
Total					171100.00
1. Training Online Free /Offline onsite training Travelling Lodging Boarding charges applicable + 50000.00 Offline or On Client Server Installation					
2. Server Charges will be deducted If Software is Installed on Client Server					
3. Payment Terms: 50% Advance: 40% On Activation and Format Customization (Max 15 Days), No Fees for PDF Format customization for first time, 10% on Live					
4. Annual Maintenance: Every Year 7.5% On Completion of First year On Basic Cost of Software					

OR

Plan II: Rented Pharma ERP :Annual Rental Plan

Sr. No.	SAC Code	Particulars of Service	Rate INR Annually	Monthly INR
1.	99831	PaperLess GMP -Pharma ERP System without QMS(Silver)	75000.00	8999.00

For ANNUAL Rental Plan No Offline Installation, 25000/- One Time License cost Per Plant is applicable

Special Benefit: Software License Ownership will be transferred to Buyer on Completion of 36 Months there after Only 30000.00 Per ANNUM as annual Maintenance charge and Server Cost

2.	NA	Shared Cloud Server (Per Year Charges)	20000.00	1500.00
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GST 18% Applicable

Please Note: In Monthly plan only cloud subscription is available No Offline Installation

Training Online Free /Offline onsite training Travelling Lodging Boarding charges applicable no other fees

Payment Terms:

1. Annual Rental Plan: 25000/- One time Cost +50% of ANNUAL Rental Plan +100% Server Cost along with PO Remaining on completion of Installation and Software Live (Not Exceeding one Month)

Annual Maintenance: Not applicable for rental Plan

BANK ACCOUNT DETAILS

Cyclone Pharmaceuticals Pvt. Ltd.

Branch Name:

**Bund Garden
Pune**

Bank Name:

ICICI Bank Ltd

IEC Code .:

AAECC2908E

Account No.

000505021182

Pan No.:

AAECC2908E

RTGS/ NEFT IFSC

ICIC00000005

GST NO:

27AAECC2908E

TERMS AND CONDITIONS

1. Validity of Proforma: 15 Days.
2. **If Visit is required for training or Requirement collection Traveling, Lodging boarding and food arrangements shall be done by client.**
3. Advance Once transferred will not be refunded if Software Copy has been created
4. Customization's list shall be provided by Client in time so we can do the same
5. Software Developer company or Cyclone pharma does not transfer ownership rights of the software to client its License and user agreement
6. Misuse of Data or wrong interpretation of systems is not our responsibility.
7. Payment Shall be completed before 1 Month from Installation of software.
8. Additional Modules suggestion will attract additional charges per module other than the list given in software details

Timeline for Implementation:

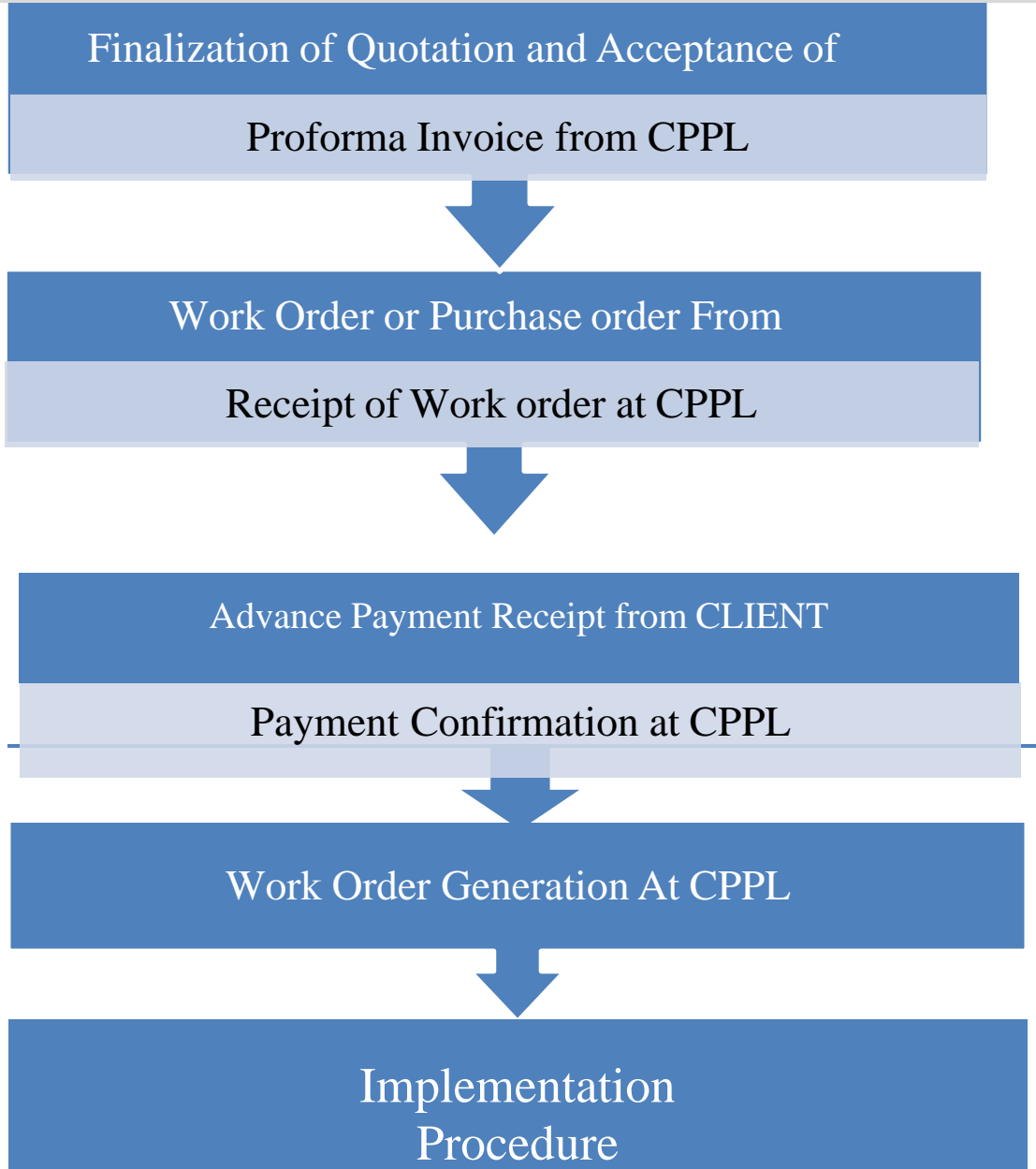
Sr. No	Activity	Timeline Required
01	Creating Copy of Software	Within 4 Working days from Advance
02	Customizations as Per Clients	15-20 Working days depend on requirement
03	Final Upload on server	7 Days From complete Customization
04	Training and Making LIVE	7-10 Days from Upload
05	Continuous Training	Online

12.CONFIDENTIALITY

Cyclone Pharmaceuticals Pvt. Limited is bounded to keep our contract and deal confidential. No data will be used for any other purpose which is not related to client by any time. Every document and every technical thing will be kept confidential which is received from client.

Confidentiality non-disclosure agreement and Software acquisition agreement will be signed before going ahead with our contract.

13.0 ROAD MAP FOR INITIATION OF WORK



Contact:

Mr. Sachin Bhalekar

Chief Consultant

Cyclone Pharmaceuticals Pvt. Ltd.

104 Garnets Bay, Near Sheraton Hotel, Nagar Road, Viman Nagar 411014

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