
"Quality begins with the intent,
which is fixed by Management."
Dr. W. Edwards Deming
GMP Pro
www.quickgmp.com

Pharma
a vital factor for life

Human life has various aspects – Physical, mental and emotional, all are very important. If any of these disturbed, life becomes miserable. In this contest "Pharma" comes as a "Great saver of life". The pharmaceutical industry is playing a vital role in the human life.

Pharmaceuticals are not ordinary "goods". The concern towards quality in the pharmaceutical industry has become an important aspect. Since the world has gathered together to harmonize its practices and guidelines and launching of the current good manufacturing practices – the cGMP, there has been a growing awareness for the significance of the quality of the pharmaceutical products.

ISSUE: The inconvenient truth is that unless we ensure that pharmaceutical systems are institutionally robust we risk limiting the results of pharmaceutical process. Decision makers need to be familiar with the potential areas where noncompliance can occur in the pharmaceutical system.

Requirement: It is imperative that pharmaceutical and life science industries comply with globally accepted standards, guidelines and rules of cGMP, which are based on directives from authorities like FDA, WHO, ICH, TGA, MHRA and regulatory bodies.

An *idea* is all it takes to change the way you work..!

The proposed **GMPPro** system aims to increase transparency and accountability in the regulation, procurement, process, testing and distribution processes of drug manufacturing companies.

PHARMA
ANALYTICAL
BULK DRUG
R&D
NUTRACEUTICALS

What is GMPPro

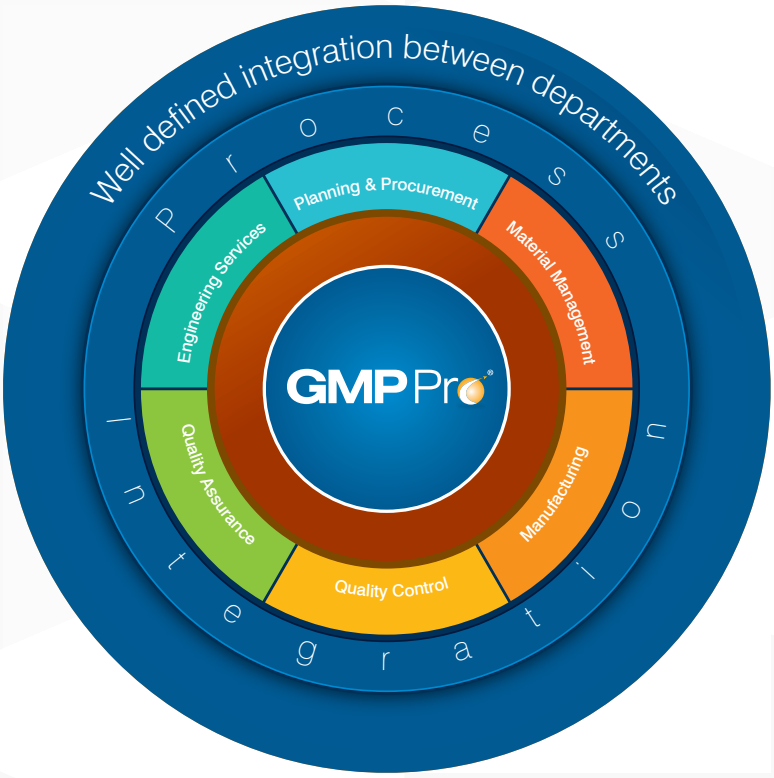
GMPPro is a software product specifically designed and developed for the life science and pharmaceutical industries to manage day to day compliance requirements.

GMPPro has been specifically designed to meet the requirements demanded by regulatory bodies. It provides the ability to control every aspect of the pharmaceutical processes, activities and operations through the flow of compliant document management. It incorporates ICHQ7 guidelines and inbuilt cGMP features in every aspect of the process.

The process requirements from the existing Standard Operating Procedures (SOP) frameworks are incorporated into the GMPPro database. This makes GMP compliance fully automated and seamless.

Additionally, it has a user friendly interface with intuitive controls making it easy to learn and use. It encompasses all production processes starting from raw material procurement to finished product dispatch.

GMPPro has been developed by experts in this field, utilizing the latest technology platforms.



Increases Productivity

Increases productivity and reduces product inventory by quickly evaluating bottle neck stocks, product quality attributes and deliverables.

Saves Time

Modern, user-friendly navigation control relieves complications in data retrieval. Saves lot of time in activity follow-ups through user defined dashboard alerts.

Cost Reduction

Minimizes wastage of hard copy documentation by getting desired reports in electronic data formats.

Improved Compliance

Reduction in errors and deviation from accepted norms by automated task follow-up and by effective data review. Quick turnaround of historic data during product investigations & CAPA.

Ease of Administration

Real-time status on each stage with instant alerts and follow-ups. Centralized access of data from multiple locations, any time, anywhere.

Planning & Procurement

- Project Plan
- Material Plan
- Production (Batch) Plan
- Purchase Enquiry
- Purchase Requisition
- Purchase Order
- Material Inward
- Material Pre-Inspection
- Supplier Masters
- Auto Re-order Process

Material Management

- Material Masters
- Material Inventory
- Stock Reports
- Material Transfers
- Indents as per FIFO/FEFO
- Vendor Control
- Sales Orders
- Dispatches as per QA Release
- Batch Tree Structures
- Comparative Statements
- Customer History Reports
- Water Management

Production / Manufacturing

- Batch Process Records
- Master Batch Records
- Batch / Lot Process
- Online BPR
- Recovery & Reprocess Batches
- Recovery Consumption
- Product & Process Master Data
- Integrated Change Control & Deviation Process
- Batch Line Clearance
- Commercial Batches (Blending & Packing)
- Dispatch Requisition to QA

Quality Assurance

- QA Release
- Change Review
- Deviation Review (Planned & Incident)
- All Document Control & Approval
- Supplier Qualification
- Complaints, Investigation & CAPA
- Product Returns & Handling
- Online Change Control Process
- Numbering System & Log Reports
- Audit & Training
- Audit Trail
- Recall Process
- CAPA Management
- Annual Product Review
- Quality Review
- Yield Review

Quality Control

- Specifications
- Auto / Manual Sample Inward
- Sample Analysis
- Raw Data & Calculations
- Sample Management
- Standard Solutions
- Label Management
- Lab Chemicals
- Integrated OOS Process
- Stability Process & Control
- Out Of Trend Reports. (OOT)
- Certificate Of Analysis (COA)
- Re-test Samples & Auto Inward
- Instrument Calibration & Reports
- Primary / Ref. Standards

Engineering Services

- Equipment Masters
- Instrument Masters
- Calibrations (Schedule & Reports)
- Preventive Maintenance
- Periodic Maintenance
- Service Request & Reports
- Qualifications (IQ, OQ & PQ)
- Utility Reports
- Integrated Change Control & Deviation Process
- Breakdown Maintenance
- Equipment Occupancy

Key Features

- 21 CFR Part 11 & ICH Q7 quality compliant system.
- Easy application of enforced guidelines by USFDA, MHRA, TGA and other regulatory bodies.
- Auto generated customized reports.
- Guides users towards cGMP compliance.
- Auto escalation of tasks, reports and complaints.
- Helps to manage activities during audits.
- Provides reference guidelines to obtain high quality results.
- Generates multiple data reports which suites for several Regulatory needs.
- Reduces the burden of hard copy management and re-work.
- E-mail and dashboard alerts.
- User friendly navigation and controls.

Advantages at all levels in the organization

- Automated communication between departments for immediate, effective & responsive tasks.
- Secure & reliable data reports for error free audits.
- Harmonized procedures for better performance.
- Easy and Control access on documents.
- Complete control over the Company's quality practices.
- Clearly defined and controlled procedures for consistent performance.
- Unique repository for all quality management system documents.
- Saves time for employees during document preparation, handling, archiving & retrieving.
- Dynamic data reporting to generate Annual Product Reports.
- Data backup system which can be retrieved and saved.
- Powerful User Management System.

RECOMMENDATIONS TESTIMONIALS

It has got the additional distinction of having been developed by personnel who had hands on experience in regulatory affairs and quality assurance in transnational companies.

We at GMP Pharma Consultants vouch for the capability of the software to deliver, as we have scrutinized the same diligently and are fully satisfied.

Mr. S. R. Parthasarathy
GMP Pharma Consultants

For the first time, we have full control over the entire business operations all from my desk. All our Purchase, Warehouse, Production, QA, QC & Engineering departments are now completely automated and the paperwork in these departments are less than one fourth of what it was prior to GMPPro.

Mr. Sujan D
Director Operations
Venkateswara Ayurveda Nilayam Ltd.

During this course of implementation and support, we found Motto Systems is committed and delivered best quality. We are happy to recommend M/s. Motto Systems Pvt Ltd., for any one whom so ever interested in implementing GMPPro for their business.

Mr. Rahul
Director Strategic Business
Posh Chemicals Pvt. Ltd.,

More...

GMPPRO IMPLEMENTATION PLAN

Business Process Study & Gap analysis — **Step 1**

Step 2 — Trial Installation & Preliminary Training

Customization & End User Reports — **Step 3**

Step 4 — GMPPro installation & User Acceptance Testing

End User Training — **Step 5**

Pre-Production Validation & Go Live

Advanced Quality Management System (QMS) for commercial processes with inbuilt cGMPs

GLP compliant integrated Laboratory Information Management System (LIMS)

Electronic Lab Note book (ELNB) for advanced R&D and Drug discovery studies.

MOTTO SYSTEMS

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