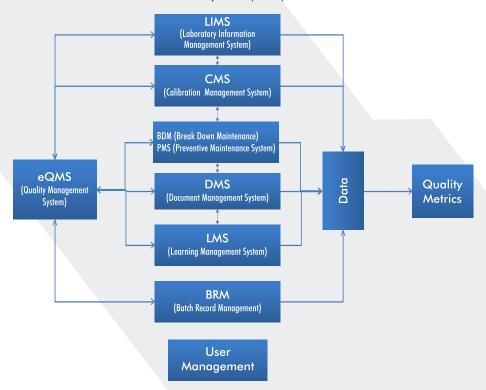




# AUTOMATION AND PAPER LESS PHARMA QUALITY COMPLIANCE SOFTWARE

- Pharma Compliance Software (PCS) which enables the electronic form with electronic signatures by Meeting the Regulatory Requirements.
- We provide Integrated Solutions for Quality Management Systems for planning and follow-up of action items to complete task within the time frame.
- Modules Available in the Pharma Compliance Software are :
  - Quality Management System (QMS)
  - Document Management System (DMS)
  - Learning Management System (LMS)
  - Laboratory Information Management System (LIMS)
  - Batch Record Management System (BRM)
  - Calibration Management System (CMS)
  - Break Down Maintenance (BDM)
  - Preventive Maintenance System (PMS)





# **Quality Management System**



- Change Control
- Deviation
- CAPA
- Market Complaint
- Risk Management
- Internal/External Audits
- Laboratory Incident

- Out of Specification
- Out of Trend
- Vendor Qualification
- Vendor Complaints
- Error Ratification
- Back Up & Restore
- Summary and Trends Reports
- Quality Metrics
- Dashboard

# **Document Management System**



- Document Types
- Document Templates
- Different Workflows for different Document Types

- Auto Generated Document Numbering
- Document Versions
- Periodic Revisions,
- Document Issuances and Retrieval
- Format Issuances and Retrieval
- Dashboard



# **Learning Management System**



- User Job Responsibilities
- Induction, Initial and Field Trainings
- cGMP Trainings
- Plan Adhoc, Refresher and External Trainings

- Web/Class Room /Offline Trainings
- Reschedule Trainings
   (Expired Schedules, Single Schedule and Re-Trainings)
- Offline Trainings
- Annual Training Plan
- Dashboard

# **Batch Record Management System**



- Master Batch Record Management
- Version Management
- Mother and Child stage Mapping

- Auto Batch Numbering Generation
- Issuance and Retrieval of Batch Records
- Reprinting for Additional copies as required
- Generation of Manufacturing and Expiry dates
- Dashboard



# **Laboratory Information Management System**



- Product Specifications
- Sample Requests
- Sample Sheet and Work Sheet Printing / Online
- Test Analysis Submission and Review

- Investigation Analysis
- COA Release
- Stability Management
- Working Standards
- Reference Standards
- Chemical Reagents
- Volumetric Solutions
- Dashboard

# **Calibration & Maintenance System**



- Instrument and Equipment Masters Management includes Versions, Replacement and Destruction /Termination
- Annual, Monthly External Calibration Plans
- Annual, Monthly Internal Calibration Plans

- In house and External Calibration Management
- Master and Measuring Instrument Usage
- Annual, Monthly Preventive Maintenance Plans
- Break Down Maintenance
- Work Order Maintenance
- Equipment/Instrument History
- Dashboard



# **Why Pharma Compliance Software is Required?**



### Compliant to Regulatory Requirements

 Ensure precise and efficient compliance with FDA, MHRA, EU regulations and Schedule M









### **Faster Decision Making**

• Analyzing the trends help your organization make quick, informed decisions.



#### **CAPA**

 Streamline the investigation of Deviations, Out of specifications, and Market complaints to facilitate effective CAPA implementation.



#### Security

Helps to Maintain the Data Integrity Principles.



#### Cost

- Affordable Pricing
- Reduce physical infrastructure costs with advanced software solutions.
- Integrated software requires low server configuration, further cutting infrastructure expenses.



#### **Human Factor**

- Enhances processes, boost employee productivity, improve product quality, and increase organizational margins and profits.
- Automate manual processes to enable efficient tasks performance and minimize human errors.



#### Time Efficient

- Reduce turnaround time for obtaining review and approval signatures.
- Enhance access and retrieval of records & information.



### REGULATORY COMPLIANCE FEATURES

VMTS Pharma Compliance Software solutions are compliant to meet the requirements of regulatory bodies like FDA's 21 CFR Part 11, EU Annex, MHRA etc.

### **Electronic Signatures**

### **Copies of Records**

#### **Access Control**

#### **Audit Trial**

### **Version Control**

### **View History**

# ePCS Special Features



21 CFR Part 11 Compliance



EU annexure 11 Compliance



User friendly Navigation



Central Repository



Trending Charts



Role base access with e-Signature & Audit Trail



Automated email Notifications, Reminders



Metrics Reports



24\*7 Web based Access



Modules Integration

# WHY Choose Us?

- Improve ROI.
- Improve Process Efficiency, Product Quality.
- Reduce Manual Errors.
- Increase Employee Productivity, Margins and Profit.
- Meeting Regulatory Compliance.

# Integrated Solution

Value for

Money Spend

- Streamline business processes with our seamlessly Integrated Application (ePCS), providing access to all modules through a single login.
- User friendly Application and easy to train all users
  - Centralized alerts (Escalations) and notifications to track all activities and ensure adherence to target dates.
- Centralized user management system helps to eliminate the overhead of maintaining and managing users across multiple applications.
- Secured single database backup for integrated application and eliminate the overheads of maintaining and managing backups and restoration procedures for multiple applications.

#### Real Time Support

- Quick assistance and increase satisfaction through real-time support.
- Release software updates and enhance application in timely manner.
- Friendly and approachable for the implementation and production support.
- Customization of software based client processes.

Fixed Cost

Leveraging expertise in the Pharma domain enables us to deliver solutions at a fixed cost with full transparency and no hidden fees.



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