# GMP Pro

New Generation GMP Compliance System

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# What is GMPPro?

- GMPPro is a Specialized Software Application for Pharmaceutical Industry.
- Innovative concepts to achieve Quality compliance through built in cGMPs.
- User-friendly, Fast to Implement & Easy to Use.
- An end to end solution for Material management, Manufacturing, Quality Control, Quality Assurance and Engineering requirements.
- In-depth functional scope in each procedure and customizable to company's SOPs.
- Well defined connectivity between departmental activities.

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# Features at a glance

- ✓ QMS Dash board.
- ✓ Reduced Paper Documents.
- ✓ Reporting Features.
- ✓ Data Management.
- ✓ 21 CFR Compliance.

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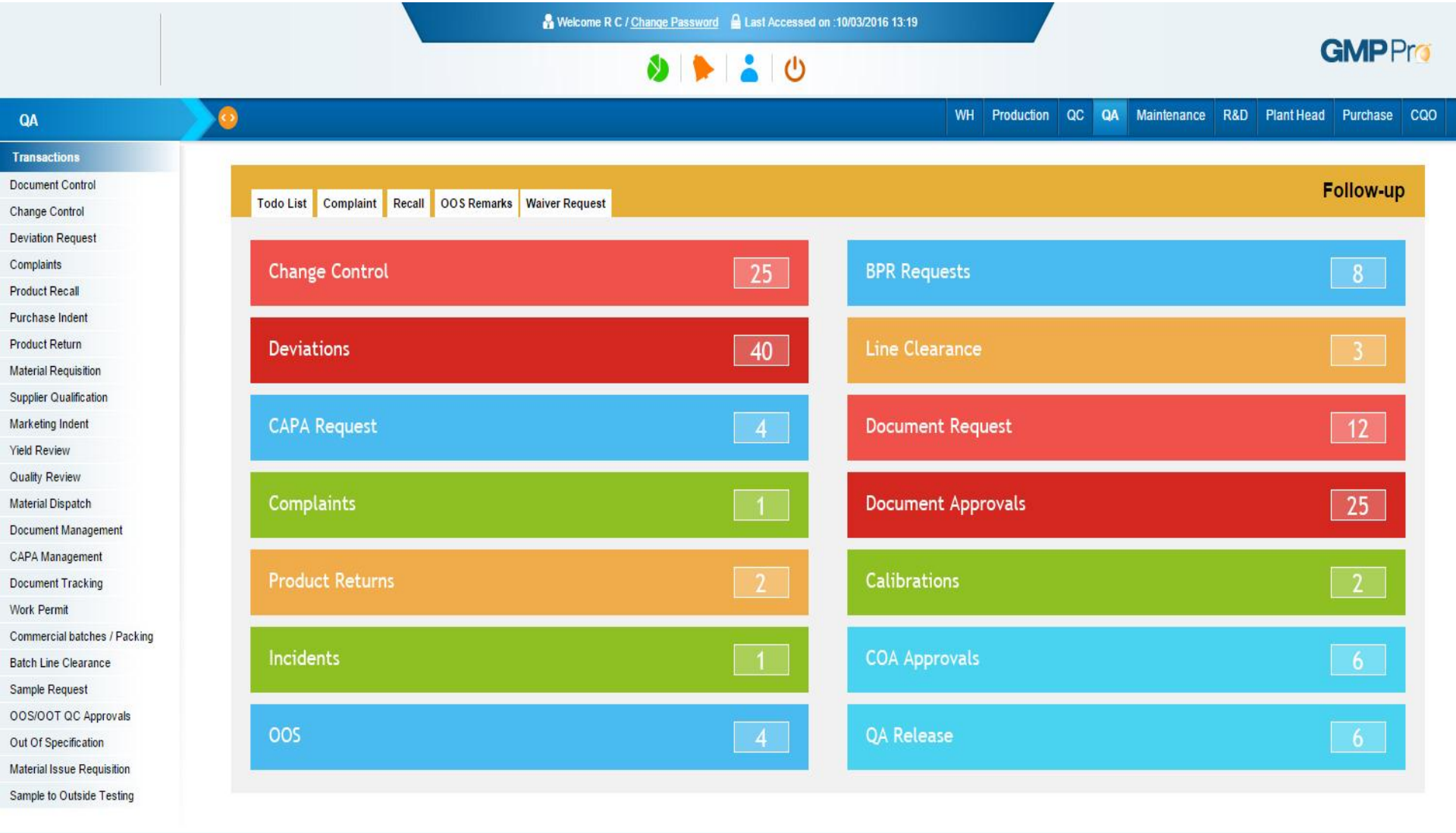
# QMS Dash Board

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# Benefits of QMS Dash board

- Easy to trace out tasks, assess workloads & act on…
- Interactive dashboards will provide instant status on many follow-up activities.

- **User Level**: Treat like a work diary .
- **Middle Management**: Smart way of Analyze – Act – Escalate – Close.
- **Top Management**: Better Business In sight.

**Bottom Line**

Makes works simpler and decisions faster

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# How GMPPro reduces paper documents?

- GMPPro provides 100+ electronically generated reports as per 21 CFR guidelines & cGMP standards.
- GMPPro comes with dynamic process handling mechanism, which eases the process of documentation and manual transfer of data.
- Reduced chances of data errors, manipulations & data redundancy.
- Improved employee performance by reduced workload of paper based tasks.
- GMPPro provides dynamic data trending which saves time and resources.
- It provides convenience of simple data entry - Generate forms automatically - Accelerate the data and process information under the conditions that we can control.

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# Sample Reports

**Motto Systems Pvt. Ltd**
**Unit-4**

## STOCK REGISTER

**Material Name** : TETRABUTYLAMMONIUM HYDROGEN SULFIDE
**Material Code** : RCHLRG00001
**Category** : Raw Material
**Usage UOM** : gr.

| Date & Time | Receipt B. No. | Supplier | Received Qty | Opening Balance | Issued Qty. | Issue B.No. | AR. No. | Prod B.No. | Closing Balance | Remarks |
|---|---|---|---|---|---|---|---|---|---|---|
| 05/22/2015 17:34 | DRCHLRG00001-15001 | CAMBRIDGE SOFT ASIA-PACIFIC | 100000 gr. | - | - | - | DRM15050004 DRM15080003 | - | 100000 gr. | |
| 05/22/2015 18:09 | - | - | - | 100000 gr. | 0.1 gr. | DRCHLRG00001-15001 | DRM15050004 DRM15080003 | DRMIW/15-0004 | 99999.9 gr. | |
| 05/25/2015 14:42 | DRCHLRG00001-15002 | HYSEL INDIA PVT LTD | 100000 gr. | 99999.9 gr. | - | - | DRM15050010 | - | 199999.9 gr. | |
| 05/25/2015 14:42 | DRCHLRG00001-15003 | HYSEL INDIA PVT LTD | 60000 gr. | 199999.9 gr. | - | - | DRM15050011 | - | 259999.9 gr. | |
| 05/25/2015 14:42 | DRCHLRG00001-15004 | HYSEL INDIA PVT LTD | 40000 gr. | 259999.9 gr. | - | - | DRM15050012 | - | 299999.9 gr. | |
| 05/25/2015 14:45 | - | - | - | 299999.9 gr. | 3 gr. | DRCHLRG00001-15002 | DRM15050010 | DRMIW/15-0010 | 299996.9 gr. | |
| 05/25/2015 14:49 | - | - | - | 299996.9 gr. | 2 gr. | DRCHLRG00001-15003 | DRM15050011 | DRMIW/15-0011 | 299994.9 gr. | |
| 05/25/2015 14:58 | - | - | - | 299994.9 gr. | 3 gr. | DRCHLRG00001-15004 | DRM15050012 | DRMIW/15-0012 | 299991.9 gr. | |
| 05/25/2015 17:19 | - | - | - | 299991.9 gr. | 1 gr. | DRCHLRG00001-15001 | - | DMBM15001B | 299990.9 gr. | |
| 06/19/2015 19:44 | DMSPL/RM-0002-15001 | HYM BROTHERS ANALYTICAL SOLUTIONS | 120 gr. | 299990.9 gr. | - | - | DRM15060004 | - | 300110.9 gr. | |
| 06/19/2015 19:48 | DMSPL/RM-0002-15005 | KEVIN TECHNOLOGIES P LTD | 1000 gr. | 300110.9 gr. | - | - | DRM15060005 | - | 301110.9 gr. | |

Form No :
Rev.No.:
This is an auto generated and electronically signed Document / Record
Effective Date:
Page 1 of 3
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Generated On : 03/10/2016 19:34

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**Unit-4**

## CORRECTIVE AND PREVENTIVE ACTION FORM

**CAPA No. : CAPA-D-GL-15-001** **Date of Initiation : 05/22/2015 19:18**

**1 . CAPA INITIATION:**

**Department / Block / Area name** : Production
**CAPA Type** : General
**Source of CAPA** : Break Down Maintanance
**Source reference number** : DJO/15/00001
**Type of activity** : Corrective Action
**Short description of quality issue :**

As discussed during the audit, we are in the processing of making necessary arrangements and to upgrade the infrastructure for auto back-up of electronic records that are being generated in QC.

**Description of the Corrective Action / Preventive Action :**

Corrective Actions

**Justification :**

The Server and the back up system is now under testing and which will be completed by the end of April 2015

**Proposed Target Date** : 05/27/2015
**CAPA Owner Name** : Sai

**NOTE: Attach all data and files needed to support the source of CAPA, investigation and root cause.**

**Reference Documents** : 1_01.doc

| | | | |
|---|---|---|---|
| **Initiated By** | Admin Admin | **Reviewed By** | Admin Admin |
| **Department** | Production | **Department** | Production |
| | N / A | **Designation** | N / A |
| | 05/22/2015 19:18 | **Date** | 05/25/2015 16:48 |

Effective Date : 10-06-2014
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Page No : 1 of 4

Report

**Unit-4**

## PACKING MATERIAL ALERT AND ANALYTICAL REPORT

| | | | |
|---|---|---|---|
| **Name of the Packing Material** | TRIPLE LAMINATED ALUMINIUM BAGS CAPACITY : 15 kg | | |
| **Manufacturer Name** | HYSEL INDIA PVT LTD | **Requested By** | Admin Admin |
| **Supplier Name** | PRAMA ANALYTICS PVT LTD | **Date of Request** | 05/22/2015 17:36 |
| **Mfg./Supplier Batch No.** | M-001 | **Sampled By** | Admin Admin |
| **In-house Batch No.** | DPMPMSMSC00001-15001 | **Sampled Quantity** | 100 gr. |
| **Total Quantity** | 100 Kg | **Expiry Date** | N / A |
| **No.of drums/bags/cylinders** | 5 | **Sample / Operation No.** | DMSPL/PM-0001 |
| **Analysis Category** | Packing Materials | **Sampling Date** | 05/22/2015 18:00 |
| **Retest Date** | N / A | **MRR Number** | DDPM150001 |
| **Spec & STP Number** | SP/TLA-001 | **AR Number** | DPM150001 |

| S No. | Parameter | Acceptance Criteria | Results |
|---|---|---|---|
| 1 | Appearance Color (Descriptive) | White Color Powder | White or almost white color |
| 2 | Indentification by IR | The frequency and relative intensity of the absorption peaks in the sample spectrum correspond to those in the reference spectrum | Complies |
| 3 | Loss on drying by TGA | Not more than 0.2 | 0.02 |
| 4 | Sulfated ash, %w/w | Not more than 0.3 | 0.1 |
| 5 | Organic Impurities by HPLC, % w/w | | |
| 5.1 | Total Impurities | Not more than 2.0 | 1% w/w to 1.3 |
| 5.2 | Potency | Not less than 97.5 | 98.5 |

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# Reporting Features…

- **Different Types of Reporting tools in GMPPro.**
  - Dynamic Data Reporting on activity performance.
  - It generates reports into PDFs to avoid manipulations.
  - Provides alerts on follow-up tasks via e-mails.
  - Generates trends for Quality & Yield.
  - Provides comparison charts to assess competitive advantages on Suppliers & Customers data.
  - Scheduling of tasks for maintenance & calibration activities.
  - Export data for various data analysis requirements.

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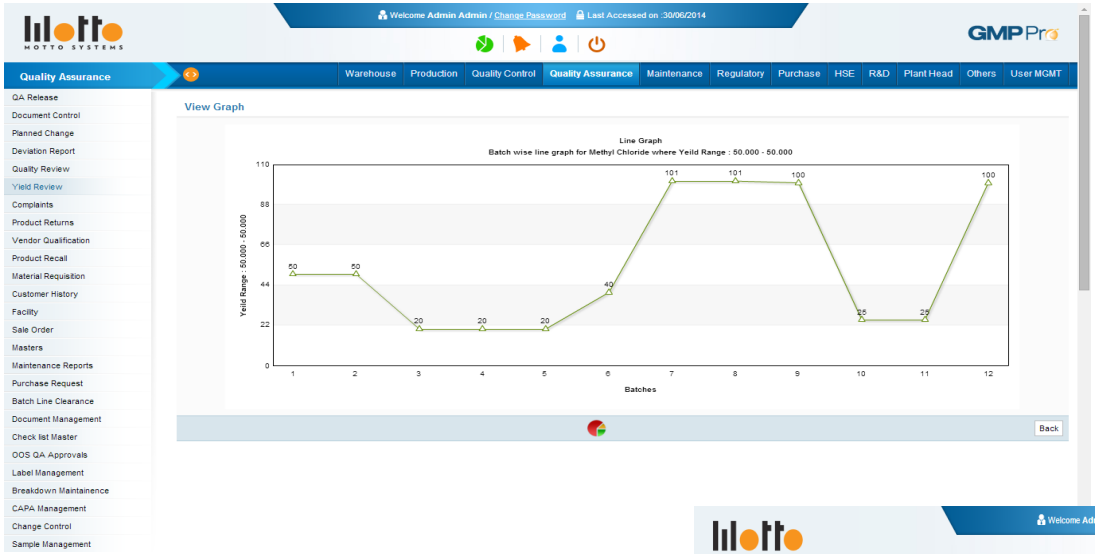
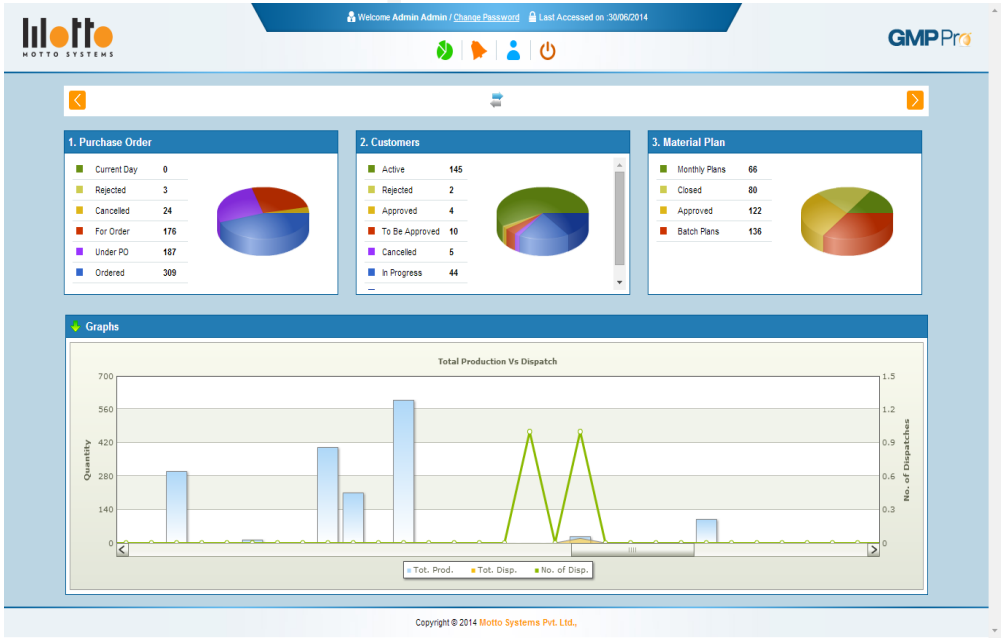
# Sample Data Screens



# Data Management

**Communicative architecture design of GMPPro** makes the operations quick while keeping **information consistent, safe and secure**.

GMPPro provides 3 different types of document management

1. **System data management** – Authenticity of data is completely controlled by the system through built in Audit Trail. It provides data on demand with instant and accurate reports.

2. **Historic data management** – Upload all historic documents into a centralized and secured data location of the system.

3. **Electronic data management** – System & process controlled data architecture to Create drafts – Review – Proof Reading – Approvals – Distribute - Version control.

GMPPro has automated data back up facility which runs based on defined time intervals.

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# 21 CFR Compliance

GMPPro is compliant to **21 CFR Part-11 guidelines** and various **Regulatory requirements.**

Following standards available in GMPPro.

1. **Electronic Signatures** – All GMPPro procedures enabled with Electronic Signatures with secured user credentials.

2. **Data Integration** – Data communication and integration between activities are completely controlled through cGMPs and Good Data Management practices.

3. **Data Authenticity** – GMPPro has complete Audit Trail and it ensures authenticity of data in every level through innovative data validation procedures.

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# GMPPro Modules Scope

## Quality Assurance

- » QA Release
- » Change Control
- » Deviations & Investigation
- » Incidents
- » Document Control
- » Supplier Qualification
- » Complaints
- » Product Returns
- » Product Recall
- » CAPA Management
- » Quality Review
- » Yield Review
- » Electronic Document Management

## Quality Control

- » Specifications
- » Sample Inward & Analysis
- » Reserve Samples
- » Working Standards
- » Reference Standards
- » Volumetric Solutions
- » Lab Chemicals
- » OOS Investigation
- » Out Of Trends (OOT)
- » Stability Protocols & Process
- » Certificate Of Analysis (COA)
- » Re-test Analysis
- » Instrument Calibration
- » Third Party Testing Samples
- » Samples Destruction

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# Organizational Benefits…

*GMPPro quality management system promises the best means for reducing the cost of quality and to improves quality compliance.*

Reduces

1. Reduces man hours by making process automation.
2. Reduction in problem recurrence.
3. Reduction in waste and unnecessary expenses.
4. Reduction in unused man hours by making auto work generation.
5. Reduces drafting / prototyping efforts.
6. Reduces non productive hours during document access & approval.
7. Reduces manual dependencies on many activities.

Increases

1. Promotion of consistent and proper record keeping
2. Increase in customer satisfaction.
3. Increase in employee awareness.
4. Improvement in communication.
5. Improves in decision making.
6. Improves better sense of responsibility and ownership.
7. Provides constructive approach to uphold Quality practices.

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# Few examples…

**Change Control:**
The whole process becomes a lot easier as once requested it instantly gets circulated for reviews, approvals until it gets closed. In turn saving man hours lost due to manual circulations.

**CAPA management:**
Corrective and preventive actions generated from different sources of activities are centralized and maintained for Activity follow ups, implementations, authenticity verifications till it gets closed.

Manual process is very tedious as it requires consulting different team members, gathering corrective and preventive actions status and closing them.

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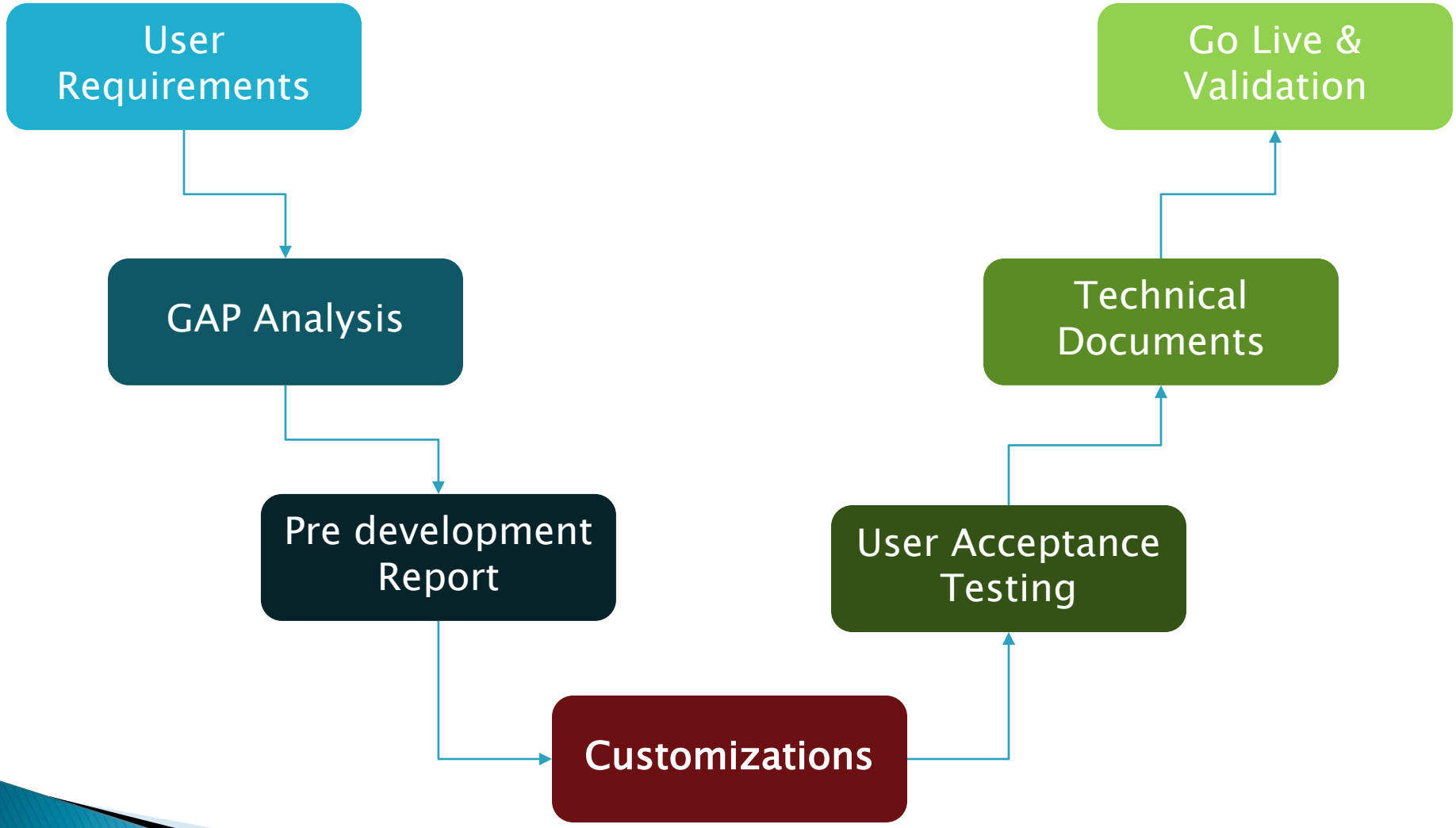
# Implementation



# Thank You…

GMP Pro
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