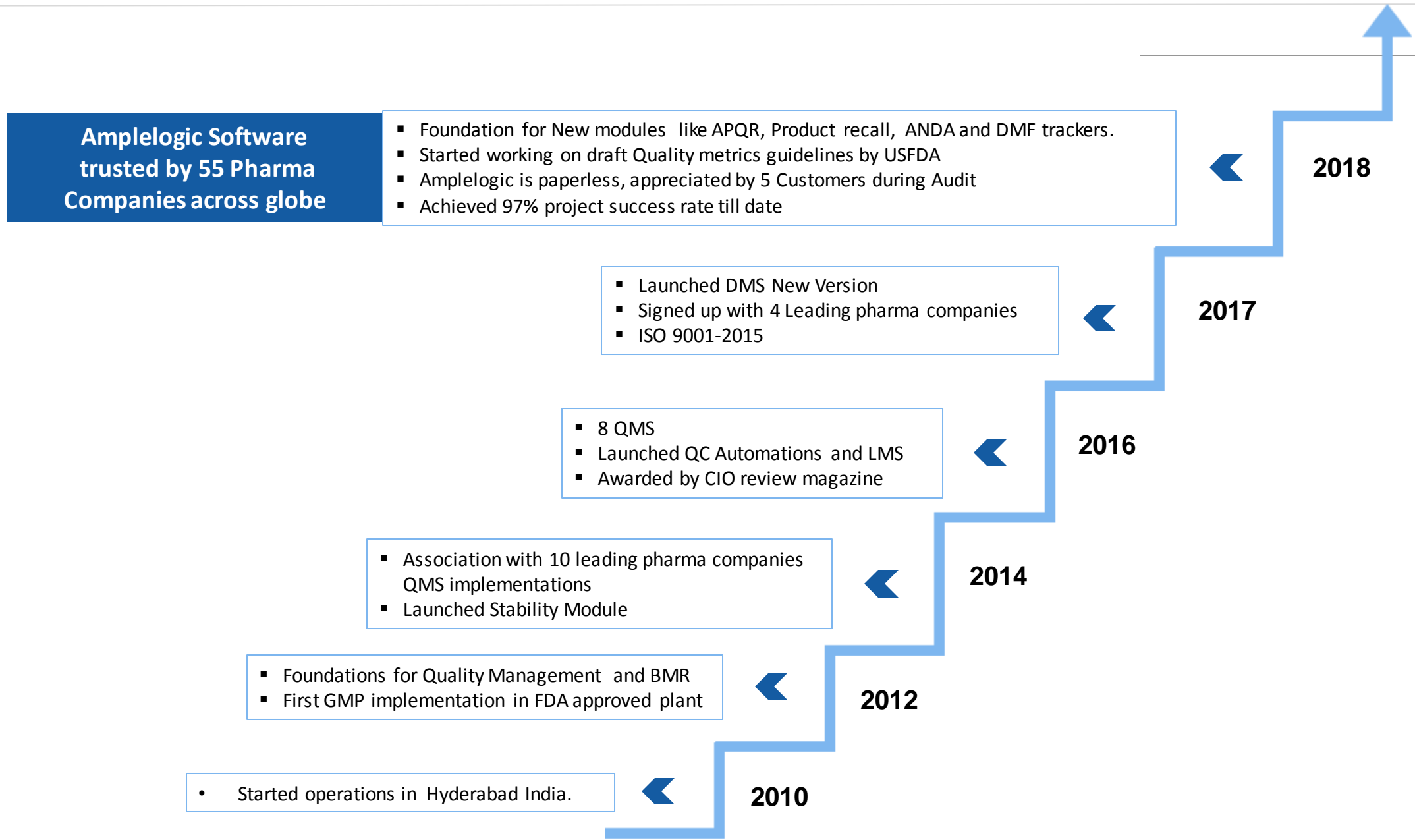
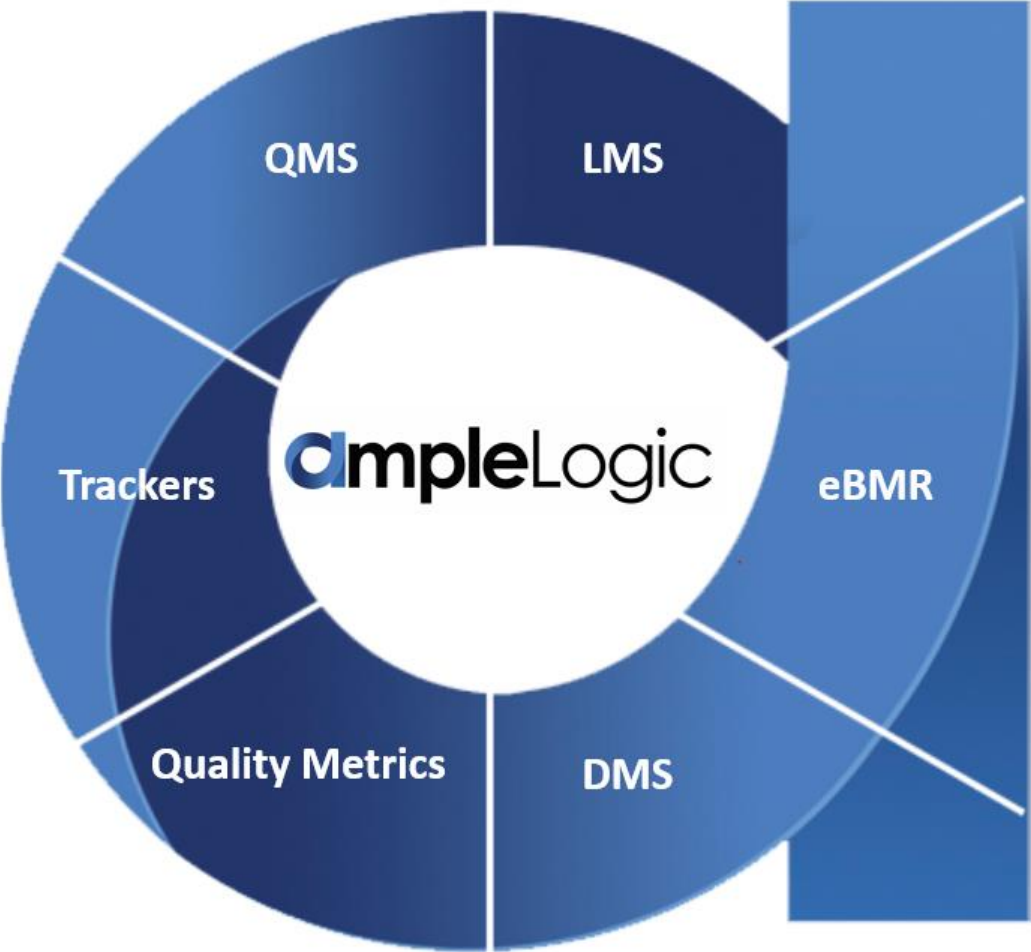


GMP Compliance Software for Quality Operations



Pharmaceutical Business Process - Ready to Use Modules



QMS

- Deviations
- CAPA
- Change Control
- Audits (Internal/External and Vendor)
- Market Complaints
- Vendor Qualification
- OOS
- OOT
- Product Recall
- APQR

LMS

- GMP and Non GMP Learning Management
- Skill Development
- Training Calendar
- Centralized training

Quality Metrics

- Quality Index and Metrics
- Facility Index and Metrics
- QMS Dashboards KPA wise
- Organization performance metrics

Trackers

- Calibration Schedules and Out of Calibration Management
- HPLC Column Management
- Standards (Primary/Reference and working) Trackers
- Stability Schedules
- DMF Tracker
- ANDA Tracker

DMS

- Documents Management
- Document Issuance
- Document Comparison
- Separate Workflows for protocols, SOP's, Templates and Annexures

Standard Features of the Modules



8 times faster than conventional approach, follow visual Modelling



21 CFR Part 11 Compliance



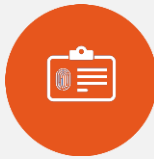
EU annexure 11 Compliance



Centralized data repository



Graphical, intuitive and analytical reports



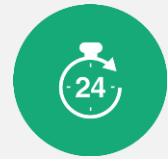
Role base access along with e-Signature and audit trail



Automated email notifications, reminder and escalations



Metrics Reporting and Analytical Trending

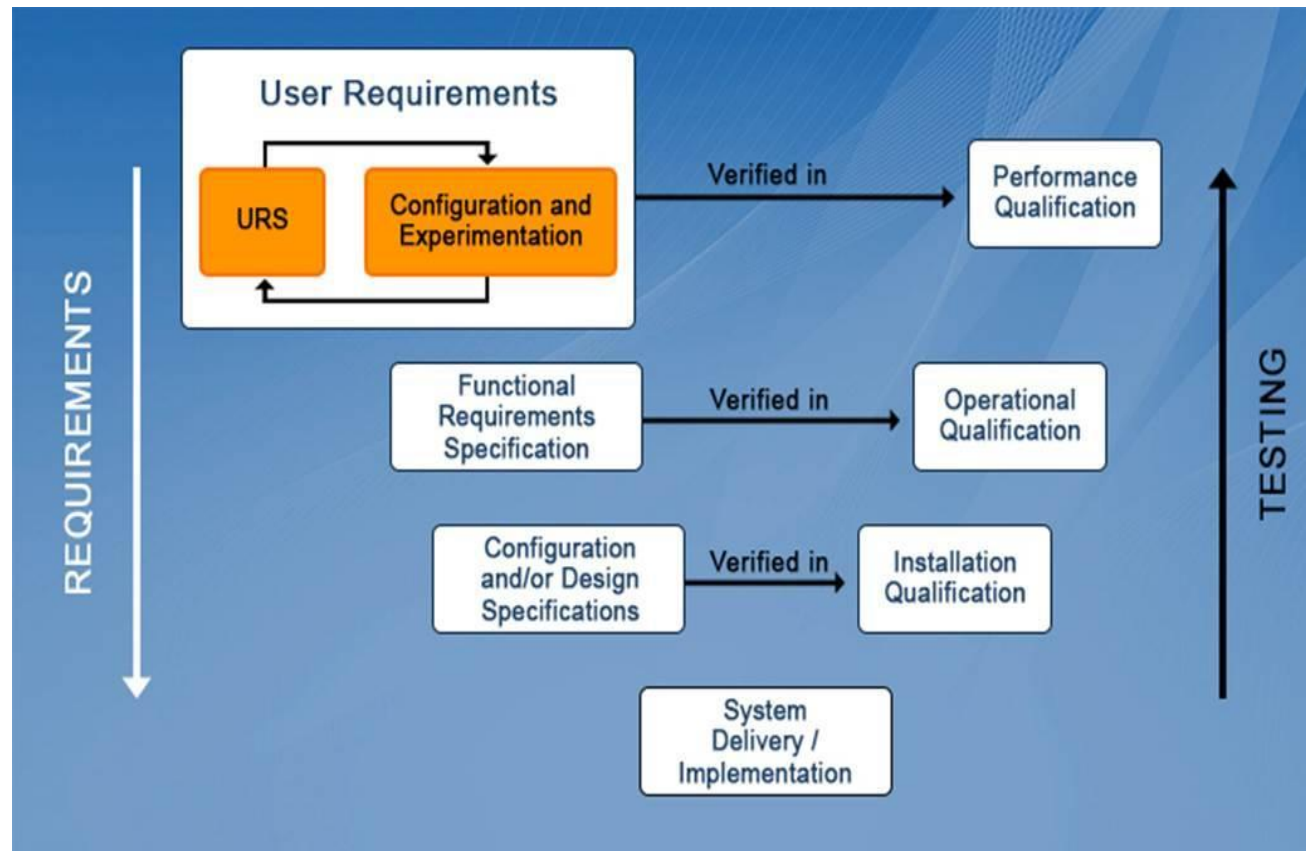


24*7 Web based access



Can be easily integrated with existing SAP, ERP and other systems.

Amplelogic - Our CSV Differentiation



AmpleLogic has tweaked traditional V Model to accelerate GMP Automations and address data integrity issues with unique No/ Low Code Platform by adding the Configuration and Experimentation phase in the implementation cycle which address regulatory audit observations related to revalidation, deviations and multiple release managements.



This approach helps in realizing requirements before the finalization of Functional Requirement Specifications, business user's will be clear on the Software Outcome.



Gaps can be easily identified during Configuration and Experimentation phase thus implementation time is reduced and allows to complete OQ in 25% of the total Project Time.



Configuration and Experimentation in the Implementation Cycle will address the Regulatory Audit Observations related to Revalidation, Deviations and multiple release managements and longer implementation times can be reduced by 70%.

Why to Choose Us?

No Code Development Platform

AmpleLogic No Code/low Code Platform offers pharma companies to automate and manage any quality and compliance processes with one software system

Unique Requirements

Every unique requirement from the client is treated as challenge, resulting in adding more component to our No Code Platform.

Customizable Reports

Powerful, easily customizable reporting allows to present information important in preferred format

Fixed Cost

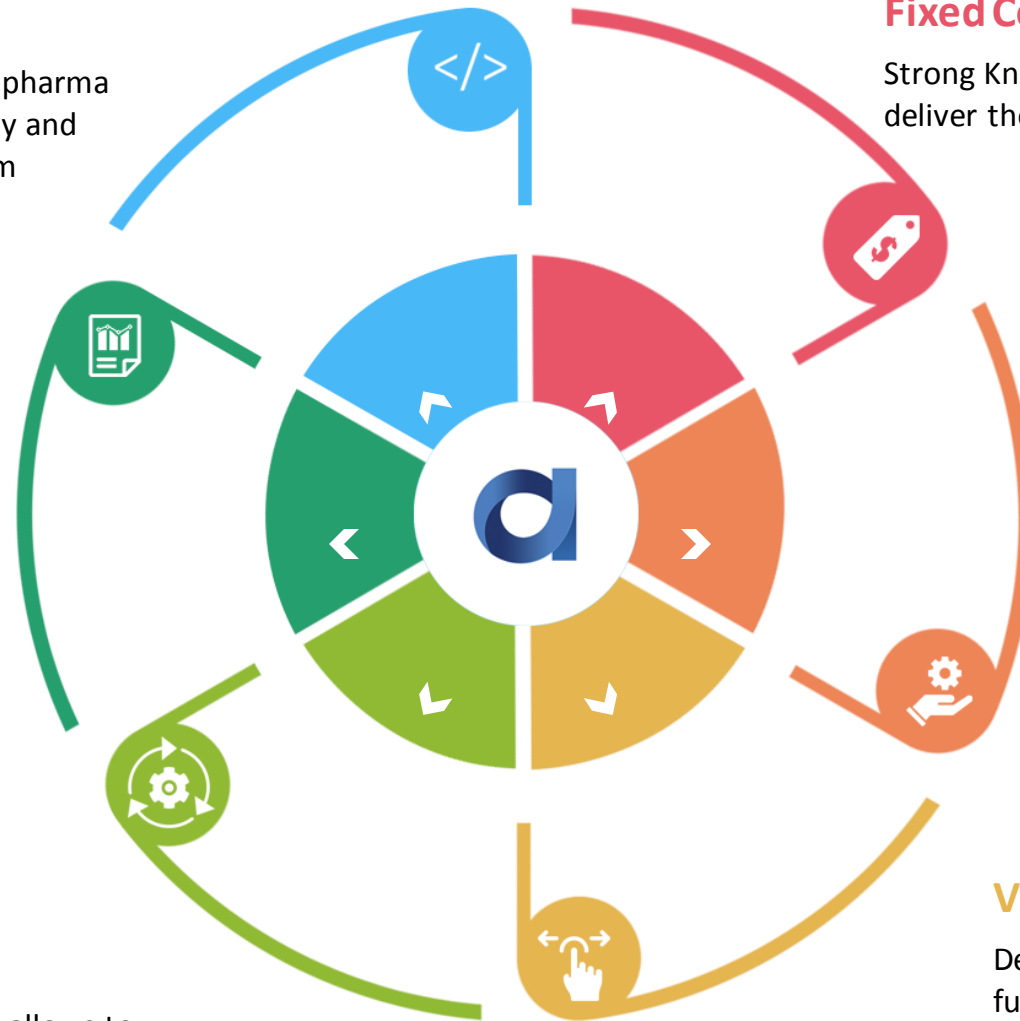
Strong Knowledge in Pharmaceutical domain allows us to deliver the solutions at fixed cost with no hidden charges.

97% project success Rate

Amplelogic Solutions delivery success rate is 97% against the IT industry average of 56%

Visual Modelling approach

Deliver with visual modelling, drag and drop functionality allows you to see the application development.



Amplelogic is paperless company. We automated ourselves before advising customers on automations.

Amplelogic Successful Engagement Approach

Initial Run

- Meetings with Business user's
- Initial Gaps finding during demo of Pre configured Application/Ready to use modules
- Configuration based on Initial Requirements/Gaps
- Software Installation
- User training
- Enter the current data
- Compare the System generated templates with Annexures

User Acceptance

- Requirements Finalization
- SOP Revision if Required.
- Re-Configuration to accommodate detailed Requirements.
- Reporting Requirements
- User Training
- Functional Requirements update.
- Validation Plan and IQ/OQ/PQ documents update and Approval
- UAT (User Acceptance Test) Sign off

Validation

- Re- Configuration based on Initial Phase inputs.
- Role and access rights definition
- Building Traceability across modules
- Reports customization
- User Training Manual update
- User Training
- Execution of Validation Activities (IQ/OQ/PQ)
- Closure of Validation Observations

Production Deployment & Support

- Final Version Installation
- Application Access to all Users
- User Training for 1 month
- Real time Data Entry
- Move from Manual to Automated System
- Support Definition

Our unique approach allowed us to achieve the Success Rate of 97 %

Our Pharma Customers

Julphar

الخليج للصناعات الدوائية
Gulf Pharmaceutical Industries

JULPHAR

Watson.

WATSON

TEVA
TEVA PHARMACEUTICALS

TEVA

Cipla

CIPLA

 **SANOFI**

SANOFI


RPG LIFE SCIENCES

RPG LIFE SCIENCES

Zydus
dedicated to *life*

ZYDUS

 **torrent**
PHARMA

TORRENT

 **PAR**
PHARMACEUTICAL

PAR PHARMACEUTICALS

Vimta
Driven by Quality. Inspired by Science.

VIMTA

Dr.Reddy's

DR REDDYS

nirlife **acULIFE**

ACULIFE

 **SUN**
PHARMA

SUN PHARMA

 **Bharat**
Biotech
Lead Innovation

BHARAT BIOTECH


Divis Laboratories Ltd.

DIVIS LABORATORIES LTD.

Alembic
Touching Lives over 100 years

ALEMBIC

 **LAURUS Labs**
Knowledge. Innovation. Excellence.

LAURUS LABS

 **HETERO**

HETERO

 **NATCO**

NATCO

 **CAPLIN POINT**
LABORATORIES LTD.

CAPLIN POINT

Thank You



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Any Queries?

Please Contact us: info@amplelogic.com