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LET'S TALK APPLICATIONS

PLATFORMS & INTEGRATION

SWISS MULTI–NATIONAL PHARMACEUTICAL COMPANY CREATES VALUE THROUGH HCL'S GLIMS

GLOBAL LABORATORY INFORMATION MANAGEMENT SYSTEM (GLIMS)

CUSTOMER DESCRIPTION

One of the world's largest pharmaceutical companies is based in Switzerland, ranking high among the worldwide industry in 2013. The company had a market-cap of around USD 280Bn, making it the largest healthcare company by this metric. It manufactures various high quality drugs and agents such as, Clozapine (Clozaril), Diclofenac (Voltaren) and more. The organization is a full-time member of the European Federation of Pharmaceutical Industries and Associations **(EFPIA)**, the International Federation of Pharmaceutical Manufacturers and Associations **(IFPMA)**, and the Pharmaceutical Research and Manufacturers of America **(PhRMA)**

BACKGROUND

LabWare LIMS is a strategic GxP application used by TRD to allow for the global harmonization of the TRD business process. It has been in operation since 1999 and has undergone different version upgrades since then.

GLIMS is a full-featured Client/Server Laboratory Information Management System utilizing current generation Graphic User Interface (GUI) within a Windows environment.

CURRENTLY, THE NEXT UPGRADE HAS BEEN INITIATED I.E. LABWARE VERSION 7.

GLIMS (Global Laboratory Information Management System) system is used by TRD, Biologics, and Ophtha concerning regulatory, legal, and information security topics.

GLIMS is a shared laboratory system for the management of analytical data and QA release information throughout the worldwide TRD organization. The system is designed to harmonize business processes, improve laboratory efficiency, and facilitate laboratory compliance with US and European GMPs.

The key application of GLIMS is to support all analytical activities from sample login through batch release. The system covers analyses of raw materials, excipients, chemical intermediates, drug substances, and bulk drug products. In addition, the system can flexibly support early development non-QA approved samples while also rigidly enforcing GMP requirements for late phase development samples which do require QA approval.

BUSINESS CHALLENGES/ PROBLEMS FACED/ PAIN AREAS

Some of the problem areas included:

- Inspection lot mapping performed manually

- Material master mapping performed manually

- Lack of business user knowledge increased the ticket ratio

- Performance issues which increase the turnaround time for business user
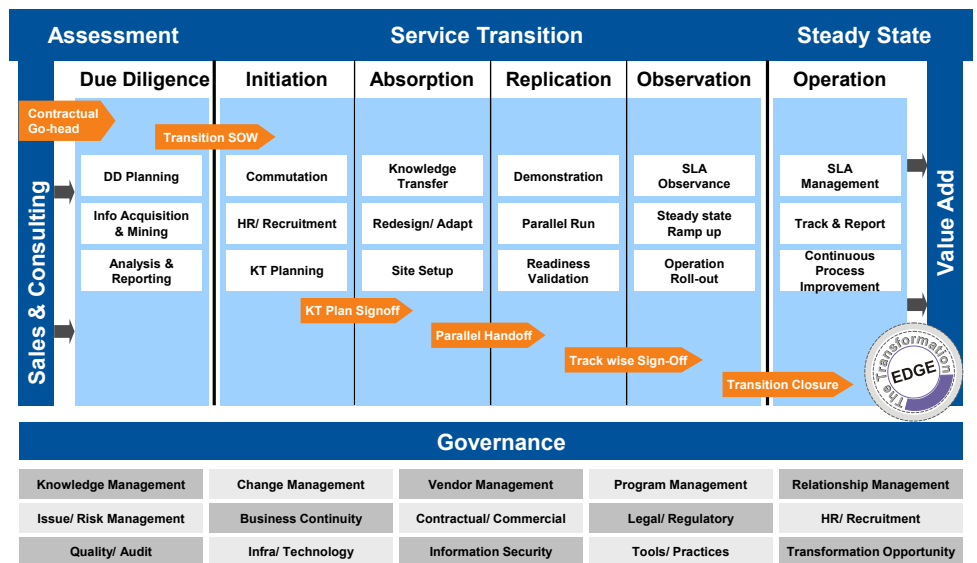
ENTER HCL

HCL Technologies delivered the following services to the client:

- Provide seamless support to GLIMS application (Admin activities, support request, incident: L1, L2, L3)

- Develop and implement change requests by business based on prioritization of workload of resources

- Implement a continuous improvement program to identify and implement agreed-upon improvements

- Provide weekly/ monthly status report

TRANSITION METHODOLOGY:

The transition of support activities of the LIMS platform was performed through HCL's proven ASSeT™ methodology. The model for transition and achieving steady state was in three stages, namely Assessment, Transition, and Steady State for five work streams evolving through life cycle or three stages.

Assessment	Service Transition				Steady State
Due Diligence	Initiation	Absorption	Replication	Observation	Operation

Contractual Go-head → **Transition SOW**

Due Diligence	Initiation	Absorption	Replication	Observation	Operation
DD Planning	Commutation	Knowledge Transfer	Demonstration	SLA Observance	SLA Management
Info Acquisition & Mining	HR/ Recruitment	Redesign/ Adapt	Parallel Run	Steady state Ramp up	Track & Report
Analysis & Reporting	KT Planning	Site Setup	Readiness Validation	Operation Roll-out	Continuous Process Improvement

Sales & Consulting

KT Plan Signoff

Parallel Handoff

Track wise Sign-Off

Transition Closure

The Transformation EDGE

Value Add

Governance

Knowledge Management	Change Management	Vendor Management	Program Management	Relationship Management
Issue/ Risk Management	Business Continuity	Contractual/ Commercial	Legal/ Regulatory	HR/ Recruitment
Quality/ Audit	Infra/ Technology	Information Security	Tools/ Practices	Transformation Opportunity

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THE SOLUTION

- Automated inspection of lot mapping

- Automated material master mapping

- Created a knowledge base for each user

- After investigation, HCL purposed to install an extra physical server in load balance to reduce turnaround time that affected performance

KEY ENGAGEMENT HIGHLIGHTS

- HCL seamlessly implemented direct GLIMS Secure reports search functionality for non-GLIMS user via SharePoint

- HCL successfully upgraded Crystal report 8.5 to 10; all old reports were also migrated to Crystal report 10 without any business interruption

- Implemented long pending business requirements

BUSINESS BENEFITS

- Inspection Lot mapping was performed manually:- HCL implemented the Automation which decrease Business workload by 80%

- Material master mapping was performed manually:- HCL implemented the Automation SAP-GLIMS) whcih decrease Business workload by 90%

- Lack of business user knowledge:- Create the knowledge base case basis which helps user to perform the day to day effectively which decrease ticket ratio significantly

- Performance issue which increase the turnaround time:- After investigation HCL purpose to install one more physical server in load balance and the turnaround time has improved significantly

SCOPE

GLIMS, just like the GxP application, includes comprehensive security features to manage individual access and functions within the system. These include user group assignments, functional privileges, and audit tracking of key steps in the software.

The TRD Global LIMS application consists of the following environments:

- Production

- Qualification

- Test

- Development

Currently GLIMS is being used in the labs in the below given countries:

- India

- San-Carlos (US)

- Basel (Switzerland)

- China

Interface: GLIMS has an interface with SAP (via PI) for importing product specification and linking inspection lot.

TECHNOLOGY SPREAD

Specific components of the software include:

- Sample login
- Product specifications management
- Stability protocol design
- Stability study tracking
- Stability inventory control
- Results entry
- Sample review
- Sample release
- Report generation
- Data acquisition interface
- eLab functions with eWorksheets
- Instrument calibration and maintenance
- Reference standard administration
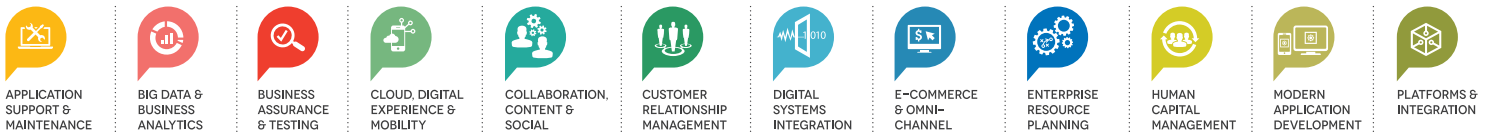- Retention sample administration

ON SHORE/ OFF SHORE RATIO

100% off shore

CUSTOMER ACCOLADES

Implementation of critical supply interfaceLiam

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