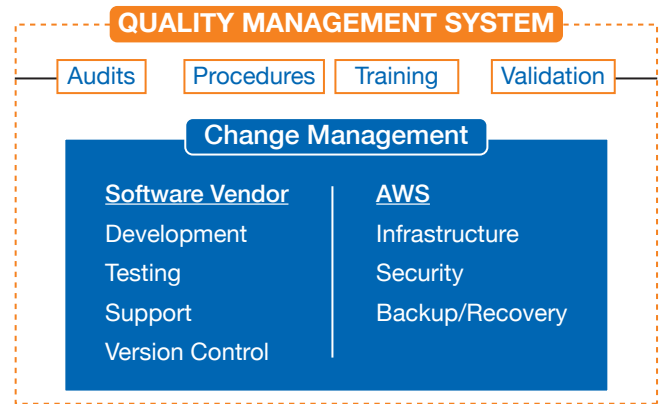**HCL**

# CLINICAL PLATFORM **COMPLIANCE** IN THE CLOUD

# APPLICATION SERVICES AND INFRASTRUCTURE

HCL's Clinical Platform as a Service (CPaaS) is the first GxP compliant clinical information management platform hosted on a public cloud. Industry concerns regarding security and confidentiality are many and well known. That is why HCL has partnered with Amazon Web Services (AWS) for state of the art application and infrastructure services. A thorough audit of AWS has demonstrated that the CPaaS infrastructure is highly secure, thoroughly tested and under a state of control governed by policies and procedures as per GAMP V guidelines. Data integrity and confidentiality is assured through 256 bit encryption "at rest" and "in flight" in compliance with HIPAA and supports three environments (Development, Test, Production).
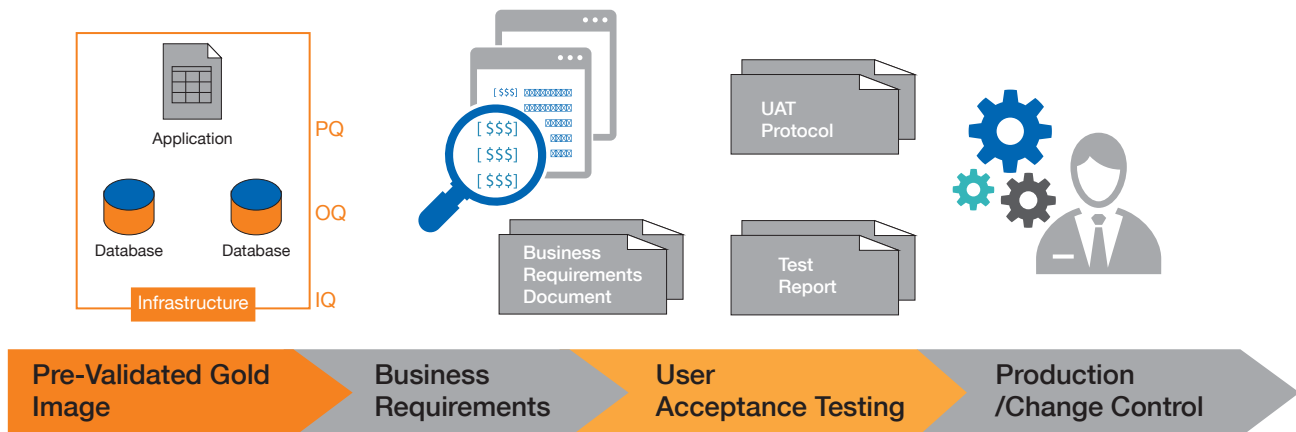
## QUALITY MANAGEMENT

System operation and maintenance is governed by a formal Quality Management System in compliance with FDA regulations 21 CFR 820.70(i) and EU Annex 11. Staff training and qualifications are managed through an electronic Learning Management System. Standard Operating Procedures and Policies are audit-ready and accessible through controlled access of our eQMS platform.

**QUALITY MANAGEMENT SYSTEM**

| Audits | Procedures | Training | Validation |

**Change Management**

| Software Vendor | AWS |
|---|---|
| Development | Infrastructure |
| Testing | Security |
| Support | Backup/Recovery |
| Version Control | |

## VALIDATION

HCL's CPaaS platform consists of an integrated suite of clinical data management systems including; EDC, CTMS, eTMF, etc. All software development is performed by HCL's partner Edetek, while support and maintenance is performed by HCL. In order to support the compliant delivery of these systems on the AWS cloud, HCL has developed a complete System Development Lifecycle (SDLC) in compliance with 21 CFR Part 11, CFR Part 820.70(i). The SDLC includes a full validation process for each of the modules as well as the integration points between internal and external systems with full traceability.
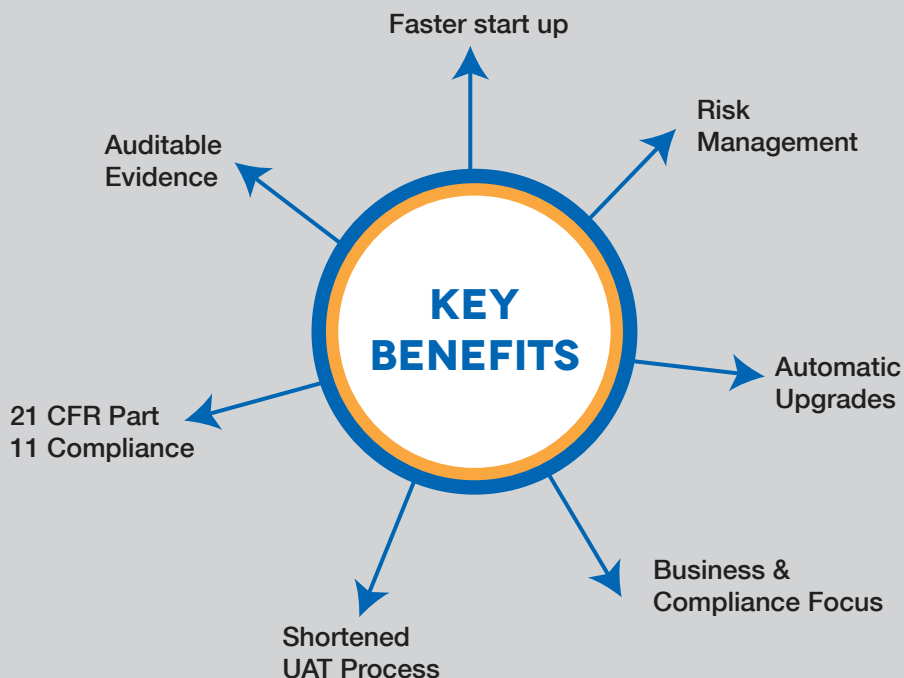
Application

PQ

Database    Database

OQ

Infrastructure    IQ

[ $$$ ]
[ $$$ ]
[ $$$ ]

UAT Protocol

Business Requirements Document

Test Report

| Pre-Validated Gold Image | Business Requirements | User Acceptance Testing | Production /Change Control |

**Validation Process:**

1.  Pre-validated core system (IQ/OQ/PQ) deployed on AWS

2.  Client specific configuration documented in Business Requirements Document

3.  User Acceptance Test planned, executed, documented

4.  Client configuration released into production, managed under change control

All system upgrades are tested and validated in HCL's UAT environment with full regression testing of client's configurations. Client's receive system upgrades upon successful validation of the core system.

## OUR REGULATORY COMPLIANCE ASSETS INCLUDE:

- Vendor Audits
- User & Installation Manuals
- IT Governance Policies
- Standard Operating Procedures
- System Development Lifecycle
- Master Validation Plan
- Testing Evidence

- Validation Reports
- Employee Training Records
- Document Management System
- Electronic Quality Management System (eQMS)
- Training System
- Change Control

Faster start up

Risk Management

Auditable Evidence

**KEY BENEFITS**

Automatic Upgrades

21 CFR Part 11 Compliance

Business & Compliance Focus

Shortened UAT Process

# HCL LIFE SCIENCES & HEALTHCARE

HCL is a leading provider of Life Sciences and Healthcare Business and Technology services. We are the chosen service provider for enabling new growth drivers for our clients, providing them with industry leading best practices, taking care of their compliance needs and ensuring goldstandard process cycle times. Our clientele includes seven of the top ten global pharmaceutical companies, seven of the top ten medical devices companies, six of the top ten health plans, three of the top five CRO's and two of the top three data providers. Equipped with certified technology experts and domain specialists, HCL offers services in critical areas of the life sciences and healthcare eco system such as drug discovery, clinical development, drug safety, regulatory compliance, manufacturing and plant automation, commercial, Healthcare analytics, Population Health Management [PHM], mHealth, member experience management [MEM], fraud, waste and abuse management [FWA].

Let's connect:

Please feel free to write to us at contact.lsh@hcl.com

# ABOUT HCL

## ABOUT HCL TECHNOLOGIES

HCL Technologies is a leading global IT services company working with clients in the areas that impact and redefine the core of their businesses. Since its emergence on the global landscape, and after its IPO in 1999, HCL has focused on 'transformational outsourcing', underlined by innovation and value creation, offering an integrated portfolio of services including software-led IT solutions, remote infrastructure management, engineering and R&D services and business services. HCL leverages its extensive global offshore infrastructure and network of offices in 31 countries to provide holistic, multi-service delivery in key industry verticals including Financial Services, Manufacturing, Consumer Services, Public Services and Life Sciences & Healthcare. HCL takes pride in its philosophy of 'Employees First, Customers Second' which empowers its 105,000 transformers to create real value for customers.

HCL Technologies, along with its subsidiaries, had consolidated revenues of US$ 5.8 billion, for the Financial Year ended as on 31st March 2015 (on LTM basis). For more information, please visit www.hcltech.com

## ABOUT HCL ENTERPRISE

HCL is a $6.5 billion leading global technology and IT enterprise comprising two companies listed in India – HCL Technologies and HCL Infosystems. Founded in 1976, HCL is one of India's original IT garage start-ups. A pioneer of modern computing, HCL is a global transformational enterprise today. Its range of offerings includes product engineering, custom & package applications, BPO, IT infrastructure services, IT hardware, systems integration, and distribution of information and communications technology (ICT) products across a wide range of focused industry verticals. The HCL team consists of over 100,000 professionals of diverse nationalities, who operate from 31 countries including over 505 points of presence in India. HCL has partnerships with several leading global 1000 firms, including leading IT and technology firms. For more information, please visit www.hcl.com

NOTES

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