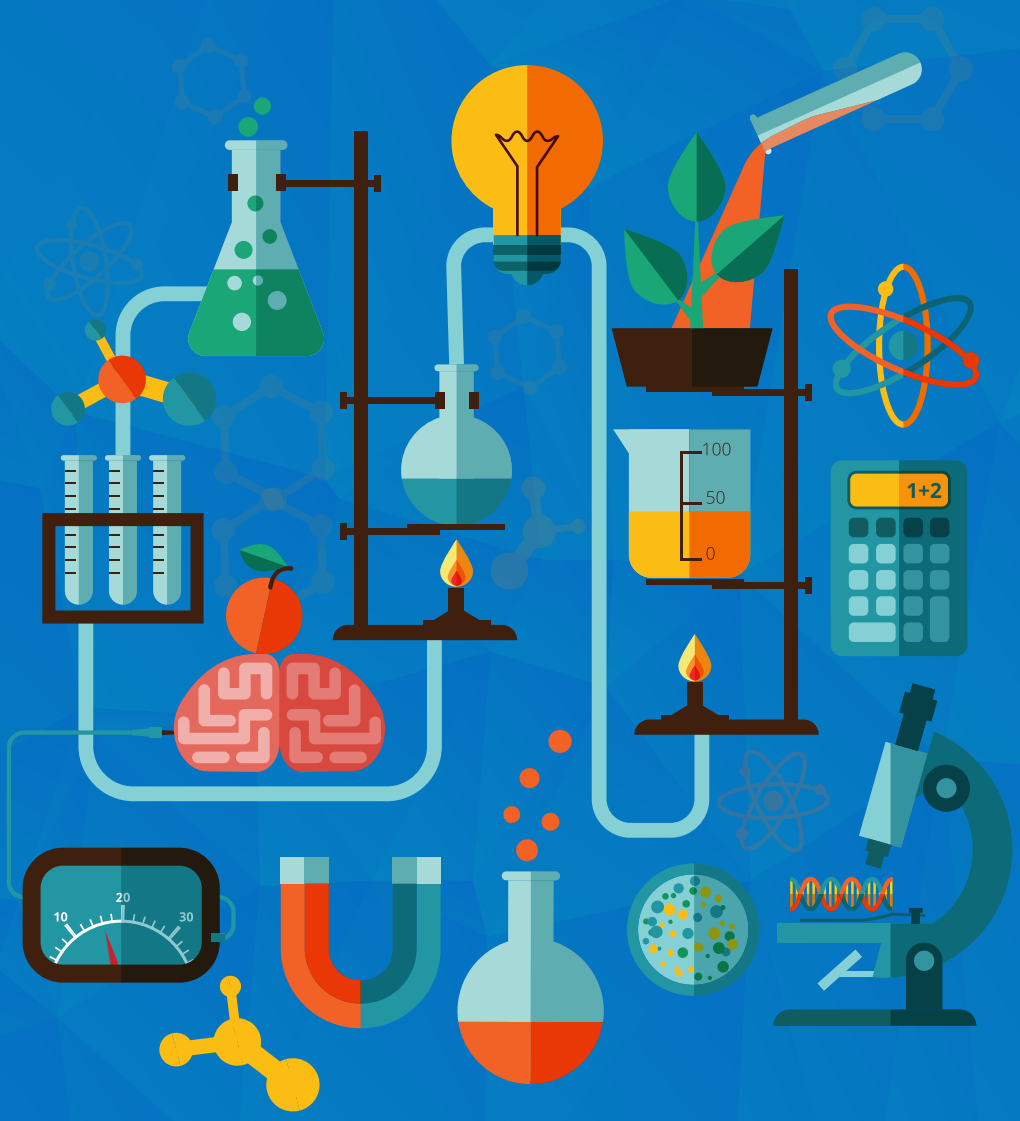


# DEMYSTIFY GOVERNANCE, RISK & COMPLIANCE FOR LIFESCIENCES

Competitive global markets, more-demanding patients, regulations from multiple regulatory authorities and high product development costs are forcing life sciences companies to deliver high quality products at low costs. Conformance to stringent requirements of global regulatory bodies is highly challenging. There is always an inherent product related and process related risks in any business process models.

There is a need for compliance at every stage of product development life cycle that has high relevance in reducing the inherent product and process related risks. Non-compliance may affect the business adversely, leading to loss of market and reputation.

Integrating the business process with the regulatory requirements has been the solution adopted by the companies to address the compliance requirements and the risk management. The regulatory bodies continue to raise the bar regarding the scope of compliance efforts required to manage the risks inherent in Product life cycle.

## RISK & COMPLIANCE MANAGEMENT REQUIREMENTS IN LIFE SCIENCE INDUSTRY

At every phase of the product life cycle, from R&D through manufacturing, distribution and marketing of products, life sciences companies must adhere to regulations from local, national and international authorities. Perhaps the most challenging element of mitigating compliance risk throughout the life cycle is ensuring compliance controls are appropriately integrated across the functional areas.

Some of the key agencies requirements with that company must comply are.

- Good Laboratory Practices (GLP)
- Good Clinical Practices (GCP)
- Good Manufacturing Practices (GMP)
- Good Automated Manufacturing Practices (GAMP)
- Electronic Records and Electronic Signatures (21 CFR Part 11)
- International Conference on Harmonization Requirements (ICH)
- Occupational Safety and Health Administration (OSHA)
- Sarbanes-Oxley Act
- Prescription Drug Manufacturing Act (PDMA)

## CHALLENGES IN ENSURING COMPLIANCE TO REGULATORY REQUIREMENTS

To ensure compliance to stringent regulatory requirements, enterprise may face the following hurdles.

Increasing external requirements for best practice, transparency and compliance

- Public / Community
- Governments
- Regulators
- Patients Investors / Creditors

Increasing efforts and costs for sustainability

- Documentation
- Projects
- Systems
- Interfaces

Growing complexity and scope of risks

- Globalisation
- "Multinational"
- Multi-factor approaches
- Regulatory expectations

## HCL SERVICE OFFERING HIGHLIGHTS

The HCL Governance, Risk & Compliance consulting division offers end to end consulting from discovery to clinical, manufacturing to sales, bringing consistency, efficiency and accountability to the compliance process. We leverage the experiences from our life sciences & healthcare industry thought leaders and GRC subject matter experts, to guide organizations through the process of defining their FDA compliance requirements.

HCL offers a comprehensive plan to guide clients on how to automate the internal controls and streamline all compliance activities. This approach significantly reduces the costs of compliance by providing auditors, the access to relevant processes, controls, test results and remediation and thereby saving time and effort with minimum disruption to client operations.

HCL with its extensive experience in the regulatory affairs offers consultancy services (cGMP, GLP & GCP, 21 CFR Part 11), submission services (INDA, ANDA, DMF, 510K etc), audit services (vendor, network, security), services in implementation and validation services comprising of COTS products, and custom development of regulated systems (Prospective validation), validation of legacy systems (Retrospective validation), Validation of migrated data, maintaining the validated State of Regulated Validated systems and data & business rules validation in Data Warehousing Projects.

HCL also provides solutions around industry specific needs in Pharma like e-CTD, SPL, LIMS, CrosSView, PAT, e-Pedigree, CAPA applications and CTSM.

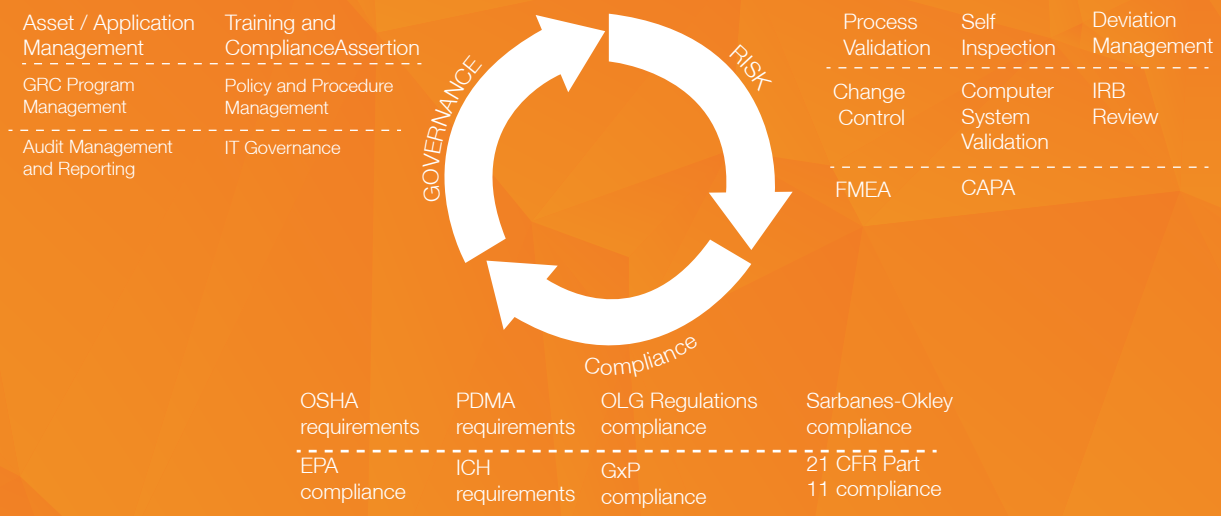


Figure 1, HCL GRC Solution Offering for Life Sciences

# FDA COMPLIANCE AUTOMATION AND MANAGEMENT WITH GRC PLATFORM

Life sciences organizations, today, have realized the far reaching benefits of automating their governance, risk management & compliance efforts. The HCL GRC practice has partnered with leading GRC vendors for providing the domain expertise in helping clients streamlining their GRC programs and helps the life sciences organization demonstrate compliance in an efficient & cost effective manner. This offering provide a centralized access control environment for automating the enterprise compliance processes, assessing associated risks and managing remediation efforts.

The automated solution offers features like risk based scoping of processes, conduct design & operational control test, managing audits & act as a single source of truth for audit evidences & organizational policies & procedures.

With deployment of this solution, life sciences organizations can create and manage a central hub of risk & compliance documentation, assessment, analysis & loss information from every part of business hence cutting the loopholes that exist in the silos compliance approach

The status of FDA-related along with other subjected regulatory risks, controls and the corresponding remediation projects are presented through a wide collection of personalized dashboards. This unified view helps executives in determining the current status of compliance activities and helps ensuring that emerging risks are identified and mitigated before they reach criticality beyond reprieve.

The GRC platform also allows easy integration with external systems to retrieve, store & deliver compliance specific data and hence assist collaborative and informed decision making.

The GRC solution for life sciences industry comes pre-packed with the standard operating procedures for implementing internal controls though out the complete lifecycle, through R&D to manufacturing, to distribution & marketing of products along with the procedures for Current Good Practices (CGXP). Besides this the knowledge store also incorporates control implementation guidance for cross industry regulations like SOX, Information Security and Data Protection. The standard risk management approach & guidance available in the solution is based on specific risk standards (1S014971, ICHQ9, ISOizt000) for Life sciences.

Compliance workflow automation, risk based scoping, integrated data collection and assessment, alert notifications workflow can further help increasing the process efficiencies and also reduce the compliance overruns.

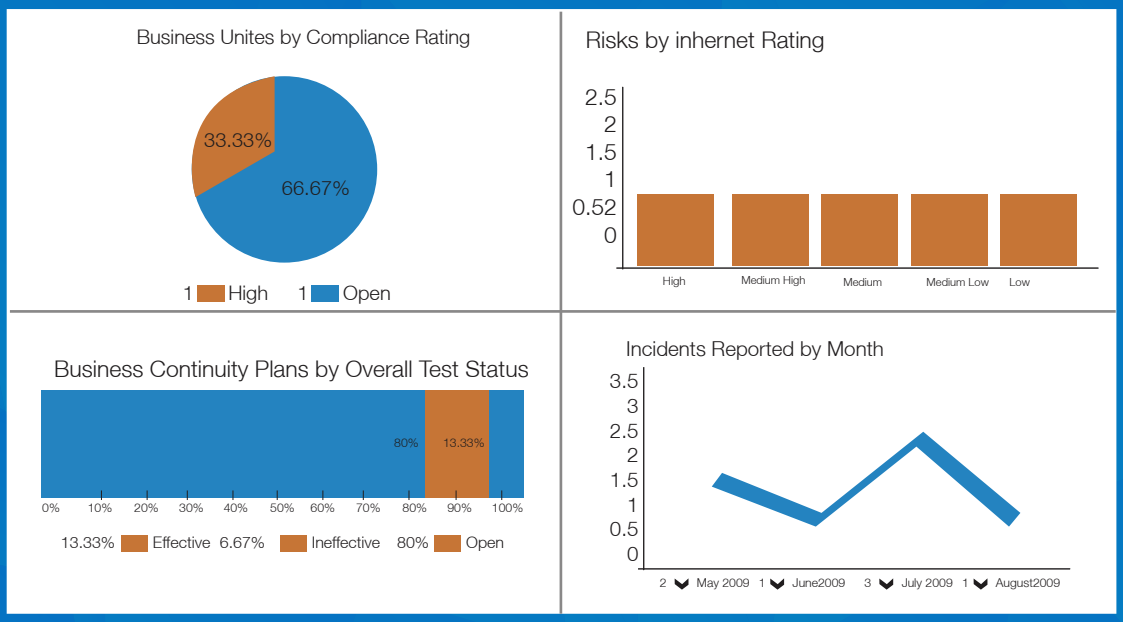


Figure 2,Governance Risk and compliance platform

# GRC SOLUTION VALUE PROPOSITION & KEY BENEFITS

- Comprehensive & flexible methodology leveraging industry best practices and subject matter expertise from life sciences & healthcare domain, providing quick time-to value and ensuring full compliance to FDA 21 CFR requirements
- Implementation consulting expertise featuring expert implementation Design emphasis on compliance sustainability through automated monitoring and risk management of controls for CFR requirements & other applicable regulations
- Integration of compliance data from all operational application cutting the effort, cost and pain of control data collection and managing multiple databases and spreadsheets
- Enable business process re-engineering and IT portfolio optimization. Ensure compliance to the GxP requirements in the Pharmaceutical industry
- Significant reduction in compliance cost and time by utilizing built-in process control repositories and risk registers
- Complete platform based service offering for compliance oversight to deal with routine inspections & regulatory audits
- Complete "Advisory" to "Implement" services for your enterprise GRC program

# HCL CREDENTIALS IN LIFE SCIENCES INDUSTRY

- Strong domain and technical expertise in the life science (Pharmaceutical, Medical devices) business functions —Drug Discovery, Pre-Clinical, Clinical, Manufacturing, Regulatory, Supply chain, Sales & Marketing
- Experience in industries regulated and monitored by multiple regulatory agencies including USFDA, MHRA, EMEA, TGA.
- Consultants experienced in facing multiple regulatory audits successfully
- Good understanding of GxP regulations (GMP, GLP, and GCP).
- Expertise in information systems audit and control consulting
- Consultants experienced in Computer System Validation

# KEY SUCCESS STORIES

Case study 1
Client: Leading medical device manufacturer
Engagement: Equipment qualification and process validation & compliance

Business Problem:
Qualification of the equipment with complete automation and Validation of the medical device manufacturing process

Solution:
- Equipment qualification
- Factory acceptance test
- Equipment Installation
- Site acceptance test
- Performed Installation qualification/ Operational qualification and performance qualification of the equipment

Process Validation:
- Design of Experiments for studying the parameters that are critical to quality (CQC)
- Engineering studies on each of the critical to quality components in the entire production line for process ruggedness

Result:
- Validation exercise was conducted meeting the requirements of the regulatory agencies and to the satisfaction of the customer
- Time to compliance is considerably reduced by implementing SoPs for control implementations

Case study 2
Client: Leader in the design and development of cardiovascular medical products.

Engagement: Audit automation & validation of OTSS applications

Business Problem:
Off-the-shelf software (OTSS) was purchased by the client from an outside supplier which was to be used as part of their quality system. OTSS applications needs to be validated by considering 21 CFR part 82 requirements and client's quality management system and within the stipulated time period specified by the client.

Solution:

- Validation of systems and applications
  12 OTSS applications were validated meeting the client's

- Quality management system for validation of OTSS application by evaluating the risk associated with the application with respect to safety and quality of the product and designing the test cases.

- Deployable audit scripts as per compliance requirements

Result:
Reduced audit cycle time & cost of compliance.

For more information, please visit
http://www.hcltech.com/it-infrastructure-management/governance-risk-and-compliance-consulting
or email us at CFS-GRC-PMG@hcl.com