LAB ICONICS

LAB ICONICS TECHNOLOGIES LLP

Management of Compliance Services

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LAB ICONICS

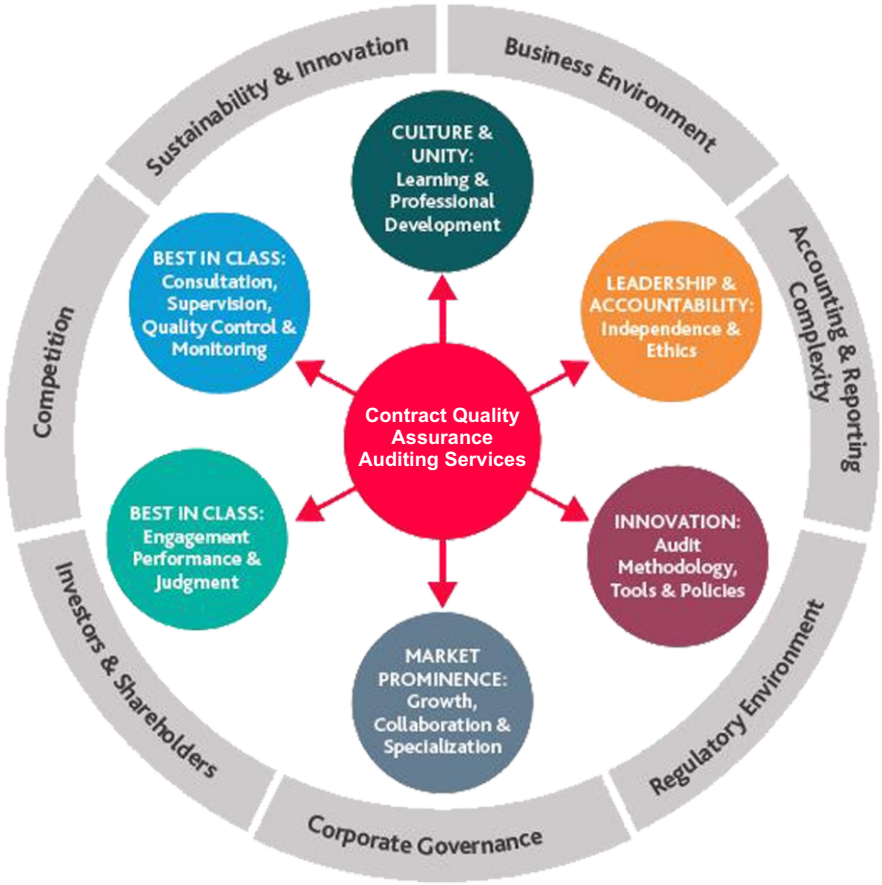
Management of Compliance

Quality and Compliance has become an important element of pharmaceutical development, manufacturing and distribution. In an era of increasing expectation by regulators and becoming more science and fact-based decision-making process, quality assurance professionals play a vital role. The competency and availability of such professionals become vital to the business in order to shape the appropriate business model / operating model for sourcing, manufacturing, storage and distribution of pharmaceutical products. Absence of key element of quality assurance lead to regulatory noncompliance, adverse inspection outcomes, compromised quality, safety and efficacy of the product resulting in field alert or field actions.

Lab Iconics brings an opportunity for our fellow pharmacist to support and strengthen the Quality Assurance professional of your organization in order to achieve an uninterrupted sustainable supply of products to your patients. Our services are designed by the pioneers in pharma quality professionals who will be supported by team of extremely trained professionals to bring your quality system favorable to the intended business.

Contract Quality Assurance

- GMP Trainings
- QMS implementations
- Risk Management
- Inspection Management
- Site Remediation
- Qualification / periodic qualification
    - Facility/ processing area
    - Manufacturing equipment.
    - Analytical Instruments
- Validations
    - Manufacturing process
    - Cleaning process
    - Analytical Methods
    - Computerized System



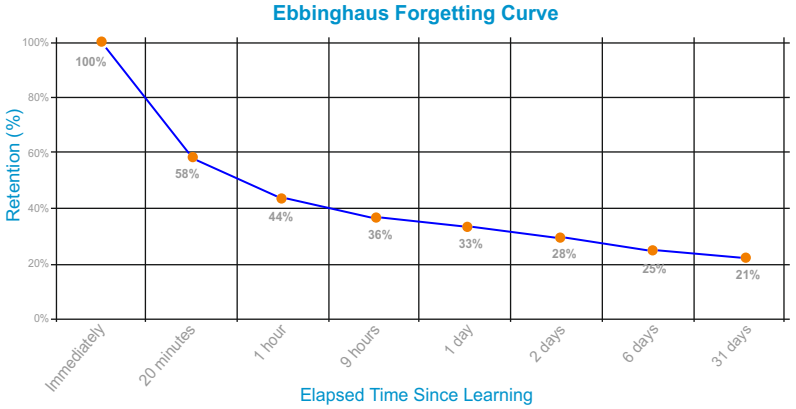
Contract Auditing Services

- End to End Vendor Management
- End to End Auditing Services

GMP Trainings:

Historically, the FDA 483's statistics demonstrates about 20-30% of observation related to failure of training thereby leading to lack of regulatory knowledge and current quality management system.

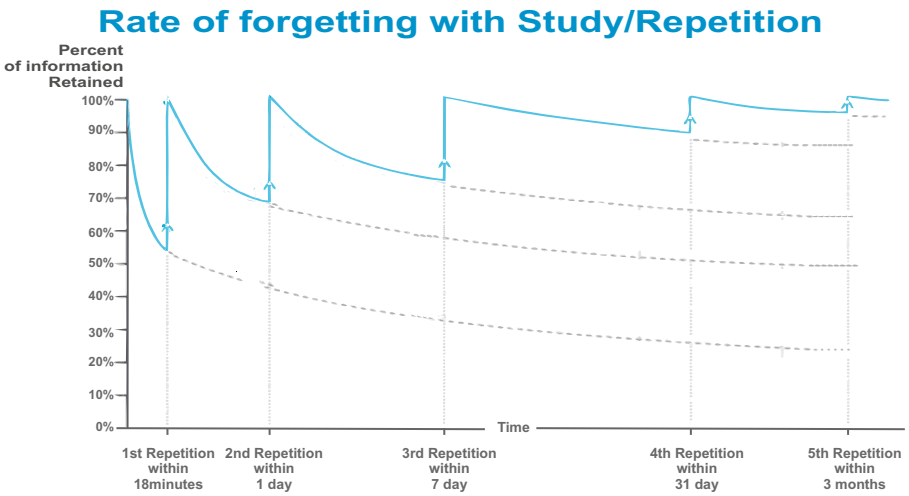
The below graph represents a typical retention time span of human.



Inference;

- After 1 hour, over 50% is forgotten.
- After just 2 days, almost 75% is forgotten
- Within a month 80 % is gone.

Therefore, training becomes vital for your organization to protect the regulatory noncompliance and patient safety. 21 CFR part 211 subpart 211.25 requires training in current Good manufacturing practices.



Training shall be conducted by qualified individuals on a continuing basis and with sufficient frequency to assure that employee remain familiar with cGMP requirements applicable to them.

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Lab Iconics brings an opportunity to our fellow partners to support and strengthen the cGMP training with following comprehensive GMP modules.

- Good Warehousing practice.
- Good Manufacturing practice.
- Good Labeling and packaging practice.
- Good Laboratory practice.
- Good Documentation practice.
- Good Storage and Distribution practice.
- Good Inspection management.
- Concepts of change management
- Deviation management
- Laboratory Investigations.
- Corrective action and preventive action management
- Complaint handling
- Regulatory notification management (Field Alert/ Field Actions)
- Pharmaceutical development – a QbD approach
- Qualifications and Validations
- Continuous Process Verification
- Cleaning validation
- Data Integrity and Governance.
- Analytical Method Validation.

QMS Implementations

There are many ways to build QA in pharmaceutical enterprise. If your organization needs a managed center for quality assurance, we can help set one up. If you already have a center but need best practices that will better handle current compliance, we can help there too. Trust us to design quality assurance for sustained and predictable results in compliance to ICH Q10.

QA Process Assessments and Consulting

Our consultants examine the maturity of your organization's QA function and assist you in enhancing the cost efficiency of QA efforts.

As our client, you can expect a partner that will not only be hands-on, but will also work alongside you to provide quality compliance services as well as the strategy and training to help you improve your quality systems, thus mitigating future risk and addressing specific needs to ensure the quality and regulatory operations are in compliance with current industry standards, as well as FDA and international regulations.

Within the Quality System, we can provide the following services but not limited to:

- Establishment and implementation of quality management systems.
- Policies, Standards, SOP Preparation, and/or Optimization.
- Batch Record Review.
- Establishment and implementation of quality management systems.
- Quality Systems Development, Assessment, Remediation.
- Root Cause Investigations and Corrective Action/Preventive Action (CAPA) Remediation.
- Third-party GMP and GLP Compliance Auditing.
- GAP analysis with respect to all international regulatory requirements.
- Due Diligence Compliance Inspections, Audits and Assistance.
- Qualification and validation of facilities, equipment and utilities.
- Training and Development.
- Data Integrity Compliance

Risk Management

Risk management principles have been established for several decades and are utilized by many business and government sectors to control and mitigate harm to the consumer. Risk in the pharmaceutical sector is defined as the combination of the probability of occurrence of harm and the severity of the harm.

ICH Q9 Quality Risk Management emphasizes harmonized approach to risk management and launch of product Quality by Design (QbD).

Lab Iconics has the right capability to be your partner of choice to implement the core concept of ICH Q9; we offer to provide you end-to-end implementation of Quality Risk Management.

- Risk assessment
  - Risk identification
  - Risk analysis
  - Risk evaluation
- Risk control
  - Risk reduction
  - Risk acceptance
- Output/result of the QRM process
- Risk review
  - Review events

Inspection Management

Inspection management is perceived in two distinct ways, the one in which we host as an auditee for external regulators and customers and another where we host the inspection as part of self-inspection process defined in the quality system and most importantly it is one of the key expectation by all regulatory agencies across geography. Both has extremely distinct processes and outcome.

On the other hand, self-inspection is an important element of quality system for management to identity all probable GMP risk before it becomes a significant nonconformance or potential observation in your inspections.

We, at Lab Iconics offer a pioneer partnering opportunity to support establishing the right inspection management process, set up appropriate tools with training and providing experience to the team. Set up appropriate process of self-inspection along with an auditing support with our qualified and experienced auditors and extend back room support during regulatory audits.

Site Remediation

While inspection management is an important element to prevent any possible observations during inspection, it however becomes more important to ensure the observations (if any) are adequately addressed to prevent any further regulatory actions.

We, at Lab Iconics offer you to prepare a wholistic response post-inspection along with necessary remedial actions to be completed.

Qualification/ periodic qualification

Qualification is key fundamental of pharmaceutical manufacturing businesses; this has been embedded in the core of regulation across the health authorities and they expect to see compliance during inspections. Inappropriate depiction of these regulations in your manufacturing practice pose a significant risk to your business; these risks are not only limited to inspection observations but greater impact can be anticipated in order to achieve the required/optimal process capability of manufactured products. Qualification has wider role to pay to achieve a sustained optimal process capability.

Professionals at Lab Iconics has widespread experience to provide our partners a complete service to qualify manufacturing facilities, manufacturing equipment, laboratory instruments and utilities. Our comprehensive services include preparation of protocols (URS/ DQ/FAT/SAT/IQ/OQ/PQ), onsite execution of these approved protocols and compilation of qualification report for customer to approve. Lab Iconics professionals are extensively experienced to support any inspections.

Validation

Industry and regulators both are moving forward with a new approach of Validation, most recent guideline of FDA provides an overarching guidance of process validation which defines the aspect of design, development, validation and continuous verification. It is becoming extremely important for us to adapt the increasing expectation and design the product development to achieve a consistent continuous manufacturing.

Professionals at Lab Iconics have good exposure to provide our partners a complete service to design, develop and validate to meet sustainable manufacturing with a framework of continuous verification. Our comprehensive services include process, cleaning and analytical method development, validation and continuous verification. Lab Iconics professionals can assist your validation program virtually and support inspections.

Contract Auditing Services

Audit and compliance have become imperative in pharmaceutical manufacturing such as; self-inspection, corporate quality audits, vendor/ supplier audits etc. These audits are becoming integral part of our quality system to meet the expectation of health authorities. Audits at any platform is merely an opportunity to review the effective implementation of quality system through a small sampling event. Therefore, it would be appropriate to state that audits are the only opportunity to visualize the risk as tips of iceberg where the huge portion of it may be unseen or unidentified. And, thus it becomes important to adopt SMART audit tools, intelligent red flag indicators and a competency to mitigate the risk holistically through an effective Corrective and Preventive action management.

We at lab Iconics have abundance experience to provide you a comprehensive audit management program including self-inspection, corporate audits, vendor and supplier audits.

We at lab Iconics very well understand the importance of intellectual properties of our partners and realize that all confidentiality matter is paramount and sacrosanct. We shall adhere to our non-disclosure agreement in letter and spirit.

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