COMPLIANCE SOLUTIONS FOR LIFE SCIENCE INDUSTRY

REGULOGIX

The Unified Solution for Compliance

REGULATORY COMPLIANCE AND VALIDATION SERVICES

We assist you in dealing with the increasing demands of national and complexity international regulations.

Regulatory Compliance Services in the Life Sciences Industries

Compliance to the regulations is becoming a global and complex scenario putting increasing demands on a company's time and resources. Pharmaceutical, biotechnology and medical device manufacturing must observe national and international legislation to increase product safety and ensure the health of consumers.

The obstacles to compliance

- ✓ How to balance the on-going changes in the industry and the implementation of new technologies with the need for compliance.
- ✓ How to find time and resources to stay up-to-date with regulatory developments and to be constantly prepared for an inspection.
- ✓ How to meet consumer demand for high quality standards at good prices in tougher economies.

We save your time and costs

At Regulogix, we provide regulatory compliance solutions to the life science sector to enhance and maximize the operational performance of its customers by helping clients to achieve their business objectives in a professional, timely and cost effective manner.

Practical and dependable solutions

Regulogix specializes in IT Regulatory Compliance with focus on implementing Risk Based Validation solutions based on GAMP 5 principles for Computerized System Validation.

Your partner in success

Focus on regulatory developments and validation activities consumes time and resources that you need to speed your products to market.

Our team want to partner with you to take care of

- Validation Strategic Planning
- Validation Project Management
- Risk Assessments
- Compliance Audits and Validation
- Specialized Validation Training
- Regulatory Services and Submissions
- Intellectual Property Services

OUR SERVICES

COMPUTERIZED SYSTEMS VALIDATION

Computer systems facilitate the daily work of Life Sciences manufacturers. Computers are found more and more in research and development departments, in manufacturing sites, and in storage and distribution and quality control areas. They create, modify, maintain, archive, retrieve or transmit data. Computer systems are a central factor determining work sequences; they are faster and less expensive than manual interventions.
Where a computer replaces a manual operation, there should be no resultant decrease in product quality or quality assurance.

Key challenges

Any computerized system that could influence the safety and quality of pharmaceutical products must be validated.

A validation program must verify whether

- ✓ The computer and its applications work as intended and according to specifications and regulatory requirements
- ✓ The computer data is protected from unauthorized access and changes, as well as unintended loses
- ✓ The quality management system works in sync with the computerized systems with regard to the good practices.

Comprehensive validation assistance

We focus on implementing internationally accepted GAMP 5 guidelines and its current interpretations for validation of computerized systems applying Risk Based Approach and Life Cycle Management Philosophy. Our validation program covers:

- Validation Master Plan
- Risk Assessment Plan and Report
- User Requirement Specifications
- Functional Specifications
- Design Specifications
- Infrastructure Qualification Protocol and Report
- Installation Qualification Protocol and Report
- Operation Qualification Protocol and Report
- Performance Qualification Protocol and Report
- Validation Summary Report
- Traceability Matrix
- Assessment for compliance with regulations pertaining to electronic records and signatures (e.g., 21 CFR Part 11)
- Supplier Assessment Report
- Periodic Review Report

ERP Systems

Business systems and applications are increasing in complexity and integration, so that companies can deliver real- time manufacturing, engineering, sales and accounting information across the entire enterprise.

Roles of Enterprise Resource and Planning

ERP systems are widely used by enterprises internally and externally to integrate activities like SCM, inventory management, manufacturing, accounts finance, HRM, quality management, sales, distribution etc. The configuration of an ERP depends on the operational requirements of the business and the software validation requirements are governed by the concerned regulations. Hence validating the ERP system becomes complex and challenging for the enterprises bound by the regulatory pressure.

Key challenges

The most troubling issues while validating the ERP systems are:

- ✓ The screening of the key processes for validation of the ERP which are important from the regulatory point of view.
- ✓ The extent of validation to be carried out while considering a particular business process

Informed business decisions

Regulogix Solutions adheres to a risk management and process analysis strategy which allows enterprises to identify key opportunities to manage and mitigate risks related to long term software validation costs working in accordance with the current GAMP guidelines. We make you understand the risks so that you can make intelligent business decisions while meeting your compliance requirements.

Professionals at Regulogix have sound experience of validating wide range of ERP systems. Based on GxP and risk assessment of the processes of ERP systems with respect to the specifications, we deliver to you, the stepwise captured qualification results traceable, point to point, to the specifications.

Laboratory Computerized Systems

The regulatory requirement

The validation of computerized systems is required by the OECD (Organisation for Economic Co-operation and Development) principles of Good Laboratory Practice. (Consensus document no. 10). " All computerized systems used for the generation, measurement or assessment of data intended for regulatory submission should be developed, validated, operated and maintained in ways which are compliant with the GLP principles".

The objective of any chemical analytical measurement is to get consistent, reliable and accurate data. Proper functioning and performance of analytical instruments and computer systems plays a major role in achieving this goal. Therefore, laboratory computerized system validation (CSV) should be part of any good analytical practice and this is equally important for those working in a regulated and in accredited

Regulogix provides outright solutions for building a quality environment for your quality assistants i.e., Laboratory Computerized Systems like HPLC, LC, Mass Spectrophotometer, GC, FTIR, KF Titrator, TOC, Stability Chamber etc. We recognize the profound impact of the FDA's 21 CFR Part 11 regulations on the operations of our clients using the laboratory computerized systems. Regulogix helps ensure that your instruments meet performance standards at the point of installation through proven performance testing and documentation.

We ensure the quality of your quality assistants

Process Control Systems

Process control systems are used for the automation of manufacturing processes (data collection, data supply, monitoring and controlling of the manufacturing process [PLC], and linking superimposed systems for manufacturing control [MES]. Process control systems encompass a wide range of systems: from small controls, e.g. built into manufacturing devices or equipment, to large, distributed control systems, like those for the operation of plants for manufacturing bulk materials or APIs.

Key challenges

- ✓ Determining the critical quality parameters and attributes and having specified instruments for verification of the same
- ✓ For large and complex systems, determining the key attributes that affect the quality of product directly/ indirectly

Standardization through GAMP

One of the key benefits of GAMP are the life cycle documents, which have proven their effectiveness as communication tools along the entire validation and life cycle of drug products.

Regulogix works with the customer to create a functional specification for the control system, a documented risk assessment to analyze potential hazards and existing mitigations, a design specification for the entire machine, and installation and operational qualification protocols.

We provide validation services for following types of Process Control Systems : -

- ✓ **PLC + SCADA**
- ✓ **PLC + HMI**
- ✓ **PLC + HMI + Camera System**
- ✓ **Building Management Systems**
- ✓ **Data Logger Systems**

Our strength in validating process engineering and control systems can help you achieve the right level of validation. Regulogix works closely with you to bring early success and payback from your automation investment.

Infrastructure Qualification

Whether you develop, test, manufacture or deliver active pharmaceutical ingredients, vaccines, or pharmaceutical products, your software applications are based on an infrastructure, including:

- ✓ Servers, that host data, databases or files, applications or special services
- ✓ Client workstations
- ✓ Network components and protocols

The computer infrastructure coordinates and allocates resources to users and applications to enable data sharing, and also provide communication services. Before the computer system can be validated, the infrastructure must be qualified to prove its security, availability, reliability and usability, and to ensure that data is transferred accurately.

Once the validation qualification is available, it can be referenced in all validation programs, and doesn't need to be repeated for each application supported by the infrastructure.

Our experts understands both the technical aspects and the regulatory requirements and help you qualify your computer infrastructure or conduct the complete validation, including:

- ✓ Segment GxP and Non - GxP components of the network
- ✓ Assist in establishing procedures for: *establishing and managing support services, performance monitoring, incident management, corrective and preventive action, operational change and configuration management, repair activity, periodic review, backup and resort, business continuity management, security management, system administration*.
- ✓ Establish the configuration and specifications of the network and its components
- ✓ Qualify the network and its components
- ✓ Qualify the data backup, recovery and disaster recovery mechanisms
- ✓ Support the ongoing maintenance of the network and its configuration
- ✓ Implement recovery plans

Clinical Applications and Statistical Software

Dependence of the industry on Clinical and Statistical softwares

Software applications are used for various clinical, statistical and pharmacokinetic studies in the clinical pharmacology field. To list a few: CTMS, SAS, ClinPlus, WinNonlin and many more.

Computerized Systems form a part of Good Clinical Practices regulations as well, to be validated.

As per the FDA, four key drivers against which the systems must be evaluated are authenticity, data and system integrity, confidentiality and non repudiation. This goes equally well for software applications used for clinical purposes as well.

At Regulogix, we -

- ✓ Help you streamline the validation process for the key functionality of your Clinical Trial Applications/ Statistical Softwares/ Pharmacokinetic Applications as per the current best practices advocated by the regulations.
- ✓ Assist you in the validation sequence right from drafting the comprehensive user requirements and associated test cases to verify that electronic records are generated, maintained, and archived in an accurate, reliable, and secure manner.

Our success in validation services is driven by our knowledge of regulatory issues related to the software and the associated IT systems.

21 CFR Part 11 Assessment and GAP Analysis

US FDA 21 CFR Part 11

The US Food and Drug Administration rule 21 CFR Part 11 applies to electronic records and signatures. Key areas of regulation which require attention are:

- ✓ The definition of an electronic record
- ✓ Access control, security and data consistency
- ✓ Audit Trails
- ✓ Electronic copies for inspection
- ✓ Retention and maintenance of records
- ✓ Application of electronic signatures

Part 11 makes you put into place both procedural controls (i.e., notification, training, SOPs) and administrative controls, in addition

Solutions for compliance issues

Regulogix offers services to assist you, acting as your 21 CFR Part 11 compliance team, we:

- ✓ Establish a consistent company-wide Part 11 interpretation
- ✓ Integrate Part 11 with corporate policies and guidelines
- ✓ Take inventory. Identify and prioritize the systems that are subject to Part 11 for inspection
- ✓ Introduce and execute assessment and gap analysis
- ✓ Identify non-compliant systems and the tools and solutions for bringing them into compliance

Validation Lifecycle

All validation projects are carried out gradually in defined phases. The planning phases result in specification documents. A detailed report is produced after each qualification phase. In the case of failed qualification, retests will be performed until the qualification test has been passed successfully. The validation process ends with the final system acceptance and the validation report.

Validation Planning

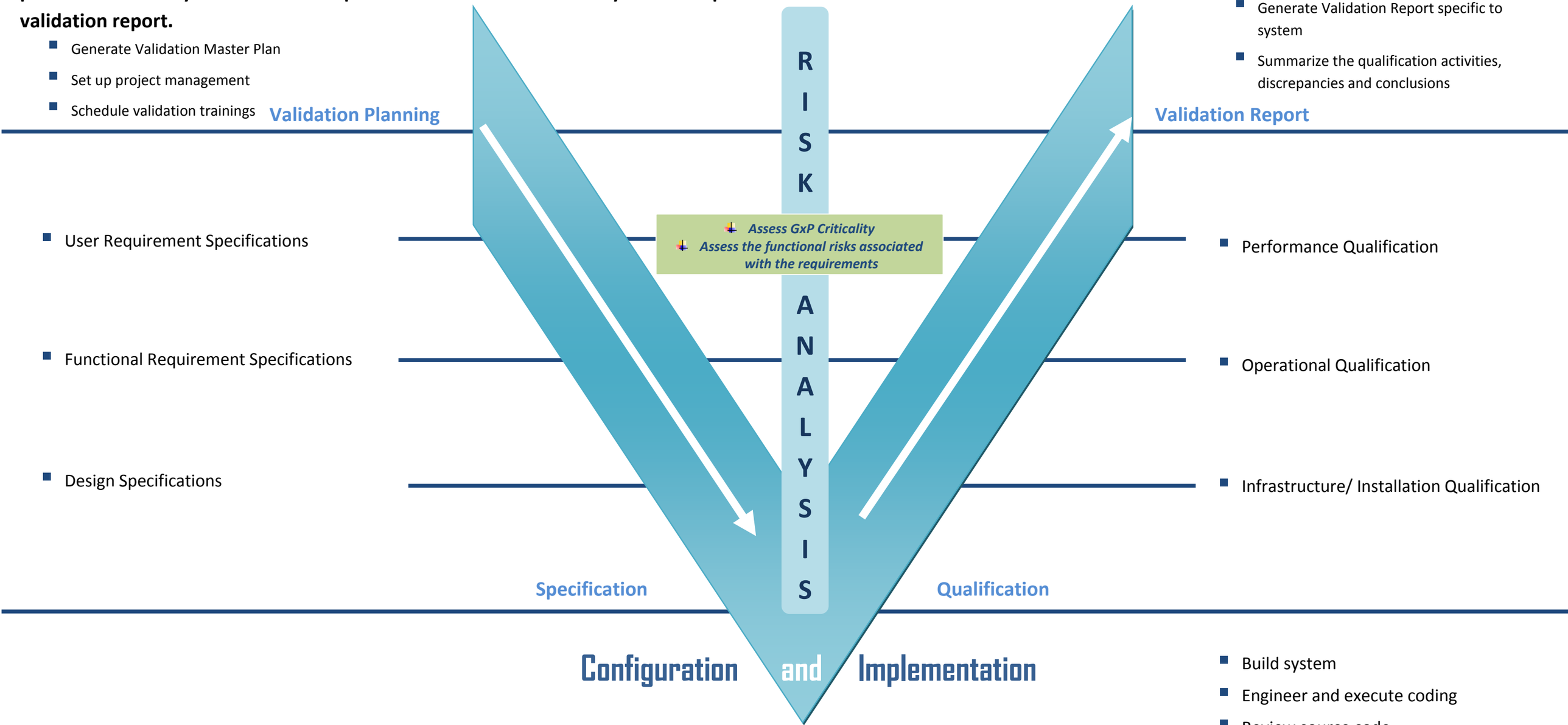
- Generate Validation Master Plan
- Set up project management
- Schedule validation trainings

Periodic Validation Review Change Management

- ✓ **Maintain the validated state**
- ✓ **Manage Change Control procedures**
- ✓ **Use revalidation measures**

Validation Report

- Generate Validation Report specific to system
- Summarize the qualification activities, discrepancies and conclusions



Specification

- User Requirement Specifications
- Functional Requirement Specifications
- Design Specifications

Qualification

- Performance Qualification
- Operational Qualification
- Infrastructure/ Installation Qualification

Configuration and Implementation

- Build system
- Engineer and execute coding
- Review source code
- Software integration testing

SPREADSHEET DEVELOPMENT AND VALIDATION

Spreadsheets in regulated industries

Using spreadsheets in a regulated environment for GxP purposes whether as an operator interface, as a data manipulation tool or for data storage, it comes with a lot of responsibility though how so ever simple it may appear to use.

Log-on security for the application and spreadsheets, independent audit trail, electronic signatures, data security, authorizations are the key implications of the rule 21 CFR Part 11.

Warning letters are being sent that cite, for example, a company's "failure to use fully validated computer spreadsheets to calculate analytical results for in-process and finished product testing." Responding to such situations can impact your time-to-market

We customize and simplify

The validation effort poses a significant challenges primarily because of the capabilities of the modern electronic spreadsheets; for example: excel spreadsheets with automated reporting and data manipulation and presentation through the use of forms, macros, modules driven by high-level programming language such as VBA

Regulogix provides spreadsheet development and validation services to help build authentic spreadsheets which can be used in the regulated environment and generated reliable and authentic data. We provide also you with the documented evidence of their correct functionality.

The process is designed to maximize efficiency and focuses on repeatability of the usage of the spreadsheets and helps its customers build confidence in the spreadsheets outputs both for regulatory compliance (21 CFR Part 11) and operational accuracy.

Our validation experts develop your spreadsheets and deliver fully validated applications so you can continue to use the flexibility, familiarity and interconnectivity of Excel.

REGULATORY SERVICES

Regulogix provides highest standards for regulatory submissions which are the most critical milestones in the business process of the lifescience sector. Our experienced regulatory team understands that you get one chance at a submission and ensures that all deliverables meet regulatory guidance standards. Our area of expertise are :

a. Dossier Preparation and Submission :

For different segments Pharmaceuticals, Nutraceuticals, Veterinary, Biotech Products, Vaccine, and Medical devices

- Preparation of the quality dossier (planning, preparing, compiling)
- Preparation of Quality expert reports, Non clinical expert reports, environmental compatibility testing, etc.
- Communication with regulatory authorities
- Monitoring of deadlines
- Variations
- Reformatting ATCTD to CTD and CTD to eCTD
- Company specific dossiers provided in ACTD and CTD as well as regional format for Asia, Africa, CIS, Central America, South America, North America, Middle East countries.
- Dossier conversion (from one country to another)

b. DMF compilation in CTD format

c. Drafts data for

- Process Validation,
- Stability Study reports,
- Dissolution profile,
- Certificate of analysis and related reports

d. Reports on

- Bioavailability / Bioequivalence Studies,
- Justification for fixed dose combination
- Prepare Periodic Safety Update report (PSUR).
- Preclinical studies like Toxicity, Carcinogenicity, Teratology & Reproduction toxicity.

e. Prepare Summary of Product (SPC), Pack Insert, Product rationale

TEMPERATURE MAPPING

What is Temperature Mapping?

Temperature mapping is the process of mapping the differences and changes in temperature which occur within a single temperature controlled system due to influences like opening doors, proximity to cooling fans, personnel movement, the quantity of products being stored at any given time.

Regulatory implications

As regulators increase their emphasis on GMP requirements for controlled thermal storage requirements, the definitive method to demonstrate that all controlled storage equipment, or storage areas, stay within the specified limits is through a thorough Temperature Mapping Study.

Why do Temperature Mapping?

Clause 3.19 of the PIC/S GMP guide states:

"*Storage areas should be designed or adapted to ensure good storage conditions. In particular, they should be clean and dry and maintained within acceptable temperature limits.* ***Where special storage conditions are required (e.g. temperature, humidity) these should be provided, checked and monitored.***"

A temperature mapping exercise is expected to collect the following information:

- ✓ The impact of interventions (door openings / power failures, etc.)
- ✓ Identification of hot and cold spots
- ✓ Variation of temperature at a single point
- ✓ Temperature variation across the area
- ✓ Length of time of any temperature excursions

What we offer?

Temperature Mapping Study comprises four broad activities:

- ✓ Protocol development
- ✓ Trial execution
- ✓ Data analysis
- ✓ Reporting

Our Temperature Mapping Services include:

- ✓ Freezers, Ultra Low Freezers, and Control Rate Freezers
- ✓ Refrigerators
- ✓ Incubators
- ✓ Cold Rooms
- ✓ Autoclaves
- ✓ Ovens
- ✓ Stability Rooms
- ✓ Stability Chambers
- ✓ Warehouse Storage Facilities and more

TRAINING FOR STUDENTS AND INDUSTRY PROFESSIONALS

Well trained employees are essential for business planning. Regulogix is proud to offer a range of regulatory compliance training programs covering the current regulatory requirements in aspects of Computerized Systems Validation in Lifescience Sector, Regulatory Affairs and Submissions; and Intellectual Property Rights which proves beneficial to the industry professionals, academicians as well as students aspiring for careers in regulated industries in lifescience sector. All courses can be customized to the need of the students and industry professionals. Fundamental and in depth training seminars are delivered onsite.

For Students

Participants will learn about

Computerized System Validation in Life Sciences Sector

Giving *students an insight into the practicalities of the pharmaceutical industry where computerized systems are the key work force for the life science industry. We shall provide the students with the basics of the quality management system in the Pharmaceutical industries working in parallel to the business processes.*

Regulatory Affairs and Submissions

Country wise *Regulations and requirements; Types of key regulatory submissions; Regulations in India; Regulatory Submissions to DCGI; Schedule M and its implications in India*

Intellectual Property Rights

Introduction *to IPR; the regulations and treaties governing IPR all over the world; Indian Patent Act 1970 and its amendments; IPR in Pharmaceuticals; patent search; drafting of patent claims and specifications; Indian Patent scenario; Case Studies*

For Industry Professionals

Participants will learn about

Regulations and guidance governing Computerized System Validation

Covering *various regulations and guidance that lay down specific requirements for the Computerized Systems being used in the regulated environment. The training will gives a detailed insight into the regulations like US FDA 21 CFR Part 11, 210, 211, 820; Therapeutic Goods Associations; EU – Eudralex Volume 4 for Good Manufacturing Practices; ANIVSA; PIC/s guidelines, GAMP guidelines*

GAMP 5 and Good Practices Guides

Covering *detailed insight into the GAMP 5 guide and its supporting good practice guides*

Types of Computerized Systems and their validation

Covering *the types of computerized systems being used in the life sciences sector which need to be validated as per the regulations. We also give you an insight on the Good Validation Practices for these Computerized Systems.*

Compliance Solutions for Life Sciences Industry

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