



For more information contact:
info@i-solutionsco.com

Are you experiencing...

- **an unplanned regulatory compliance event?**
- **incomplete corrective actions based on internal and external audit findings?**
- **a merger or acquisition with large Quality System variations?**
- **a need for a PROACTIVE compliance improvement approach?**

If the answer to one or more is yes, then i-Solutions should be your business partner! For more than a decade i-Solutions (formerly IMS – Impact Management Services) has designed and delivered solutions on an accelerated basis and at a lower cost to Pharmaceutical, Life Sciences and other industries.

Regulatory Compliance is one of the Pharmaceutical industry's greatest challenges. The receipt of a Warning Letter or a Consent Decree can throw a company into a unbelievable series of events that wreak havoc with normal production schedules, resources, budgets, stock values and the company's public image. No matter how prepared an entity is for such an event, the fact that it is unplanned creates tremendous stress.

Based on years of experience, i-Solutions has created an innovative, proactive approach to the challenging regulatory compliance aspect of pharmaceutical manufacturing.



COMPAS® (Compliance: Proactive Advocacy Support) utilizes the Consent Decree model with proven tools and without onerous terms and conditions, and allows your company to plan for remediation of any aspects of operations that need attention. It allows your company to

budget for the remediation effort as opposed to providing an open check book during the aforementioned events. It minimizes the interruption to normal production schedules and ensures continued product delivery to patients. It allows your company to effectively communicate the proactive efforts it is taking to maintain the highest level of quality achievable to the FDA. It minimizes your risks.

Included below is information that provides a brief overview of the i-Expert Modules and i-Products associated with Regulatory and Compliance.

Regulatory and Compliance

Observation Index

The Observation Index, developed by i-Solutions, has been integral in organizing, structuring and executing compliance projects and programs. The tool captures existing and new audit observations from multiple sources (agencies, customers, vendors, or internal organizations) via electronic data transfer or manual entry. The captured data provides seamless traceability to source documents. The Observation Index is configurable and customizable to facilitate classification and grouping of observations into well-defined categories. It also has the capability to identify duplicate and similar observations. The Observation Index is designed to integrate with CATS® as corrective actions are assigned to observations. Providing one source of truth for tracking the life cycle of an observation (identification, remediation, verification, and certification) is a key element of the Observation Index.

Over a decade
of providing
clients with
solutions that
increase
productivity
and reduce
cost.



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Regulatory and Compliance (Continued)

Regulatory Database

i-Solutions' Regulatory Database captures the critical items needed to manage Product Transfers through the transitional regulatory stages. It incorporates:

- the schedule structure based on dose form, strength, pack type and markets;
- regulatory milestones from 'Regulatory Submission Requirements Defined' through 'Receipt of Regulatory Approval';
- milestone durations; and
- assigned resources.

The application provides progress reports including 'Planned and Actual Percentage Complete', overall 'Project S-Curve' and 'Missed Milestone Analysis' against the baseline schedule. The Regulatory Database provides pertinent information needed by Management to foresee and rectify schedule challenges.



Corrective Action Tracking System (CATS®) is a systematic, user-friendly, database-driven project management tool used to support compliance improvement projects. It consolidates corrective actions derived from audit observations, tracking back to the original observations. The application assures consistency of data by importing directly from source documents and is highly configurable to incorporate client-specific needs.

CATS® provides seamless reporting solutions for internal tracking or reporting to authorities and clients. It correlates activities and resources required to complete corrective actions, enabling early identification of obstacles to critical path commitments. It employs multiple levels of security to ensure controlled access and has proven to be an effective tool for over ten (10) years.



Linked Activity Management Planning System (LAMPS®) is a proprietary program / project management tool designed as the hub of i-Expert modules. The system integrates with CATS® and various Microsoft Applications. The innovative LAMPS® approach provides the capability to manage a vast number of individual projects that comprise overall business-level strategies and programs.

The unique LAMPS® design facilitates a controlled and efficient implementation utilizing a standard set of processes and templates. The system is configurable to allow incorporation of client and program requirements. Turning project data into actionable information, the LAMPS® reporting module keeps executive management informed regarding overall progress and project dependencies while compiling the tactical information (schedule, resource and cost) needed by frontline project managers. The LAMPS® application security design provides strict controlled access to update/modify data. Access via LAMPS® to "time now" data and information is provided by read only access to team members and business users.

"Based on experience and exceptional project execution, i-Solutions has built an invaluable set of world class tools that no one else can offer."

CEO of a Major International Pharmaceutical Company



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Visit Our Website

For additional information on i-Solutions, visit our website at www.i-solutionsco.com. You will find information on:

- i-Products
 - IPIT® – Investigational Product Inventory Tracking
- i-Expert Modules
 - Design Database
 - Product Transfer
 - Lab Analysis
 - NPI Module
 - Merger/Acquisition/Integration
 - R&D and Manufacturing Capacity Planning
 - Performance Improvements and Financial Modeling
- i-Start-Up and Support
- i-Consulting Services
- Operations Improvement
- New Product Introduction

i-Solutions Advantage

Faster
Start-up

Lower
Project
Cost

Accelerated
Delivery

**“i-Solutions
did exactly
what they
said, exactly
on time, and
exactly at the
quoted price.
We could
never have
accomplished
what this
program has
achieved
without them
and their
expertise.”**

***President of a Global
Pharmaceutical
Company***