



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

Are you experiencing . . .

- **new business challenges or change initiatives?**
- **the lack of available in-house resources or required expertise?**
- **the need to know achievable timelines and associated costs?**
- **requirements for proven technology, tools and project management support?**
- **being a project team of one?**

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.

Below are details about a selection of our i-Products, Tools and Methodologies, i-Start-up Support and i-Consulting Services.

i-PRODUCTS



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.



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.

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



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OUR TOOLS AND METHODOLOGIES

i-Solutions focuses on three areas of specialization: Operations Improvement, Regulatory and Compliance, and New Product Introduction. The information below provides a brief overview of the various i-Expert Modules associated with each of the areas of specialization.

Operations Improvement

Design Database

The Design Database is a tool that facilitates the optimization of manufacturing networks. The nucleus of the tool set and process is data collection, data management and data analysis. The analysis results in business decisions based on factual information, not emotion and politics. The i-Solutions approach of utilizing our Design Database process to investigate, explore, analyze and perform “what-if” scenarios guides clients through decision-making processes. This progression leads to developing concepts, selecting options for detailed study, and identifying scenarios to be modeled. This results in data driven recommended solutions ready for board approval. The i-Solutions methodology is unique in so much as client personnel involvement through the process is not only critical, but is required. The database is customizable and configurable to client requirements. Its inherent integration with i-Solutions’ proprietary tools and expert modules allows a project team to hit the ground running.

R&D and Manufacturing Capacity Planning

In both R&D and Manufacturing it is critical for Management to know the current capacity status within their organization. i-Solutions Capacity Management tools identify all aspects of Capacity Planning including human, procedural, machine/equipment and total facility utilization. The most critical identification is that of existing constraints in all of the previously mentioned areas. This enables Management to make informed decisions of how best to increase capacities while minimizing overhead costs. Capacity Planning can be effectively conducted on individual sites or on global networks.

Product Transfer

i-Solutions has been instrumental in the successful implementation of multiple pharmaceutical Product Transfer programs involving hundreds of products, tens of thousands of finish packs, and hundreds of regulatory markets. Product Transfer differs from Technical Transfer in that it is the “transition of product supply responsibility” from the current source to the future source. Product Transfers executed in compliance with current Quality and Regulatory procedures and policies are enormous and complicated tasks. i-Solutions experience and capability to deliver proven methodologies, processes, templates, financial tools and integrated schedules assures a systematic approach to managing, tracking and measuring progress of complex product transfer initiatives. Strategic i-Solutions knowledge includes elements such as sourcing design, discontinuation, divestment, formula and pack rationalization, site readiness, regulatory, logistics, and stock build.

“I don’t know where we would be without the program management expertise, processes and the data management tools offered by i-Solutions. We could never have done the project without them.”

***Executive of a
Specialty Consulting
Company***



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Operations Improvement (Continued)

Performance Improvements and Financial Modeling

i-Solutions has designed and executed many individual and multiple-site performance improvement exercises. The tools used in these exercises provide a framework for the engagement of both Senior Management and Site Leadership to more effectively and efficiently accomplish their mutual goals. The performance improvement exercises include analysis of site Organization Structures, Operational Workshops, Reporting Templates and various Financial Modeling tools. Presentations, board papers, workshop reports, budgets for implementation plans and schedules, and financial metrics are some of the deliverables that are a result of the analyses. The unique aspect of our tools and processes is the full engagement of site staff in the development of the recommended solutions. Because of this aspect, the solutions not only meet the established goals, but are also politically neutral.

New Product Introduction

NPI Module

i-Solutions has developed a practical tool to assist senior management in the acceleration of new product development rather than new product concepts. Our NPI Module provides the ability to effectively manage the multitude of handoffs between various internal and external organizations. It covers major aspects of the activities performed by the R&D organization and identifies coordination points between Manufacturing, Supply and Commercial groups early in development. The result is the timely availability of pertinent information needed to make key management decisions ranging from getting to market quickly to not going to market at all.

Investigational Product Inventory Tracking (IPIT)

IPIT is a cost-effective software system developed by i-Solutions that tracks investigational product inventory during the clinical trial period from production through disposition and product return from clinical site locations. The system captures pertinent information (i.e., Expiration Date, Product ID, Lot Number) via barcodes. It is able to capture disposition and receipt of shipping data from express carrier tracking notifications. IPIT captures Destruction, Lost and Human Trials traceability information. The generation of automated email alerts for critical issues to users and sponsors is part of the system's capabilities. The system is configurable to meet client specific needs, contains full transactional logging and can be operated on a stand-alone, network or web enabled basis.

**Over a decade
of providing
consulting and
project
management
services that
support clients
in reaching
their strategic
goals.**



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Regulatory and Compliance

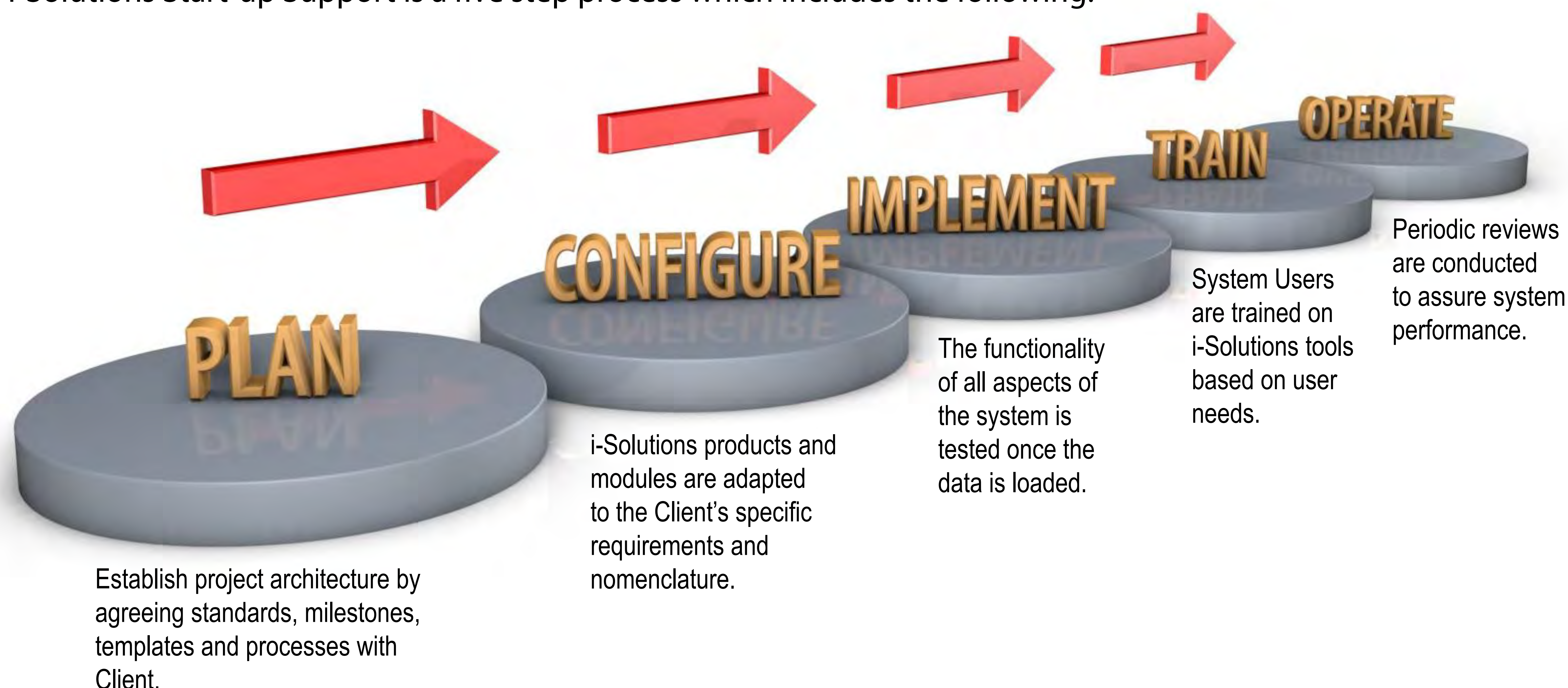
Observation Index

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.

Support Services

i-Start-up and Support

i-Start-up Support is comprised of multiple initiatives including project and tool mobilization. A trademark of i-Solutions Start-up Support is a five step process which includes the following:



Utilizing this methodology clients achieve accelerated mobilization, scope clarity and integrated business tools. Trained client staff, client operated tools and i-Solutions support result in a unique and advantageous business relationship.

**"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***



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i-Consulting Services

In addition to our state-of-the-art i-Solutions products we continue to provide traditional consulting offerings.

i-Solutions integrates with your team to achieve quantifiable results through:

- Program Management for Business Change Programs
- Outsourcing Management
- Acquisition Management and Integration
- Regulatory Compliance Management
- Analytics and Performance Measurement
- Strategic Sourcing and Supplier Development
- Plant/Organizational Performance Improvement
- Due Diligence

We apply proven project management principles to achieve sustainable business change through:

- Project start-up and execution planning
- Rigorous on-site project management
- Strong control of deliverables, scope, schedule, cost and resources
- Use of tools and processes specifically developed for business change programs
- Experienced, effective staff
- Objective, data driven performance management

"i-Solutions is a tremendous value for the cost. Their data management tools, scheduling capabilities, processes, procedures, and services have been extraordinary in delivering solutions for our company."

***VP of a
Pharmaceutical
Company***