



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.

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 Operations Improvement.

Operations Improvement

Merger / Acquisition / Integration

The Merger / Acquisition / Integration process focuses on the creation of customized plans to facilitate fast mobilization and start-up. The tools that this process utilizes are proven for integrations ranging from stand-alone sites to international multi-site organizations. Workshop formats, network design options, presentation and schedule templates, standardized reports, process documentation, and financial workbooks are just a few of the many tools that are a tried and proven part of this process. These tools enable management to make course corrections and align dependencies throughout the transition before delays occur. i-Solutions' proprietary tools aid organizations in achieving or exceeding post merger and integration goals in all business areas.

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.

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



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Operations Improvement (Continued)

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.

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.

“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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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.

Lab Analysis

The QC and Planning software application was created to assess the critical elements associated with Lab Analysis functionality. Those elements include analysis of raw materials to finished product samples, associated volumes, actual times to conduct analyses and investigations as well as estimated number of FTEs to meet the demands within the required time frames. The application can import data from related systems (i.e.; TrackWise, LIMS, Stability Database, Spreadsheets) and can calculate required and available resources for specific work volumes and types of laboratory analyses. With this unique tool i-Solutions can provide Management with insight to areas that need attention.

i-Solutions' LAMPS® software application is the link that ties the aforementioned i-Expert modules together.



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.

"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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Visit Our Website

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

- i-Products
 - CATS® – Corrective Action Tracking System
 - IPIT® – Investigational Product Inventory Tracking
- i-Expert Modules
 - New Product Introduction
 - Observation Index
- i-Start-Up and Support
- i-Consulting Services
- Regulatory and Compliance

i-Solutions Advantage

Faster
Start-up

Lower
Project
Cost

Accelerated
Delivery

"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*