



For more information contact:  
**[info@i-solutionsco.com](mailto: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 and the i-Product associated with New Product Introduction.

## 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.

### 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.

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





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## New Product Introduction (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.

### 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.



**Investigational Product Inventory Tracking (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.

**"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](http://www.i-solutionsco.com). You will find information on:

- i-Products
  - LAMPS® – Linked Activity Management Planning System
  - CATS® – Corrective Action Tracking System
- i-Expert Modules
  - Merger/Acquisition/Integration
  - R&D and Manufacturing Capacity Planning
  - Performance Improvements and Financial Modeling
  - Product Transfer
  - Observation Index
- i-Start-Up and Support
- i-Consulting Services
- Operations Improvement
- Regulatory and Compliance

## 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***