ISA Validated Application Methodology

A BI solution from Cognos and ISA Consulting

Pharmaceutical organizations are under intense pressure to bring new compounds to market rapidly and cost-effectively, improve operational performance, drive revenue and market share, and comply with regulatory requirements. Pharmaceutical companies need the information to make critical R&D decisions earlier, reduce spending on failed compounds, and focus their companies' resources on the best candidates for success.

This situation has led to an industry-wide demand for business intelligence tools and technologies to improve decision making and business performance. However, regulatory compliance concerns have often slowed the adoption of these technologies. In particular, the cost and complexity of **software validation** as required by the Federal Drug Administration (FDA) have caused reluctance among life sciences companies to upgrade software or adopt new technologies to improve business and clinical processes.

Software validation should not be seen as an added cost or burden. To the contrary, validation provides long-term savings in time, cost, and resources—because validation provides assurance that the software implementation will function as expected. Validation also brings the advantage of documentation that can reduce the cost and effort required to implement changes or remedy problems over time.

What is validation?

According to the FDA, software validation means confirmation, by examination and provision of objective evidence, that software specifications conform to user needs and intended uses, and that the particular requirements implemented through the software can be consistently fulfilled. While some software can be validated at the design level before it is delivered to end users, business intelligence software cannot be pre-validated; it must be validated in its use environment.

Why does the FDA require validation? The intent is to improve the quality and safety of pharmaceuticals and decrease risks to patients—by reducing defects in software applications that can lead to inferior products. The FDA also facilitates the use of electronic records and e-signatures for compliance documentation, which reduces the cost of compliance.

Validation provides a high degree of assurance that a specific system, process or operation will consistently produce a high-quality result meeting predetermined specifications. Validation is also a legal requirement. The FDA has the authority to shut down the operations of any life sciences company that is not compliant, and fines of $500,000 or more are not unheard of.

With the help of expert partners, the software validation process can be transformed from a "necessary evil" into a competitive advantage. Tapping the experience of those who have successfully completed the validation process can reduce costs, save time, avert surprises, and minimize risk, while delivering the highest quality software implementation.

A strong partnership for proven results

Cognos, an IBM company, is the world leader in business intelligence (BI) and corporate performance management software for the enterprise. By partnering with ISA Consulting, a leading professional services firm specializing in business intelligence and data warehousing, we have created a focused methodology to ensure a successful software validation process for business intelligence applications. Both companies offer a depth of experience with FDA validation requirements, including Title 21 Code of Federal Regulations (21 CFR) Part 11, which requires computer-generated audit trails to document actions that create, modify, maintain, or delete electronic records.

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ISA has developed a proven approach to validating business intelligence applications, specifically Cognos applications. ISA's FDA-compliant Validated Application Methodology leverages ISA's and Cognos' deep experience in the life sciences industry to ensure the complete validation of your Cognos BI solutions. Dozens of leading organizations are using validated Cognos solutions. You can rest assured knowing that your implementation of Cognos BI software will be of the highest quality while providing documented evidence of meeting FDA validation requirements.

How the ISA validated application methodology helps you

Software validation directly affects people in a variety of roles, from software developers to end users. For software project managers, developers, and quality assurance teams, the ISA Validated Application Methodology requires that people in these roles:

- Create clearly defined system requirements
- Use a System Development Life Cycle (SDLC) methodology to develop, maintain, and replace information systems; ISA recommends the Cognos Solutions Implementation Methodology (SIM)
- Create clearly defined test plans and User Acceptance Testing (UAT) sign-offs
- Create and maintain all documentation.

For business intelligence trainers and end users, the ISA Methodology requires that people in these roles create clearly define test plans, which leads to high-quality training manuals and better training for users. As a result, the ISA Methodology ensures that decision makers will be able to produce and use reports with accurate business intelligence, and that the Cognos BI solution will deliver expected results.

Background and scope

The ISA Validated Application Methodology is an ongoing validation approach. It produces Cognos BI implementations that are fully compliant with FDA software validation requirements and allows customers to reduce the risks and costs of compliance. It includes process templates, reports, tests, and other deliverables through every phase of implementation, from analysis and deign through deployment.

There are three major areas of application validation: installation qualification, operational qualification, and product performance qualification.

IQ – Installation Qualification: By FDA definition, IQ requires "establishing confidence that process equipment and ancillary systems are compliant with appropriate codes and approved design intentions, and that manufacturer's recommendations are suitably considered." The ISA Methodology ensures that the Cognos BI environment installation and configuration is performed correctly.

FDA Definitions

- Software validation is the "confirmation by examination and provision of objective evidence that software specifications conform to user needs and intended uses, and that the particular requirements implemented through software can be consistently fulfilled."
- Validation includes "establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specifications and quality attributes."
- Validation protocol is "a written plan stating how validation will be conducted, including test parameters, product characteristics, production equipment, and decision points on what constitutes acceptable test results."

OQ – Operational Qualification. By FDA definition, OQ requires "establishing confidence that process equipment and sub-systems are capable of consistently operating within established limits and tolerances." The ISA Methodology encompasses proper BI tool selection and service-level agreements (SLAs).

PQ – (Product) Performance Qualification. The FDA defines PQ as "establishing confidence through appropriate testing that the finished product produced by a specified process meets all release requirements for functionality and safety." The ISA Methodology meets this requirement through its emphasis on the use of Cognos SIM, formalized system requirements definitions, testing throughout the development lifecycle, and documenting that all test results meet the system requirements

How the partnership works for you

Software validation is an ongoing process. Success can be achieved through the use of a well-defined SDLC methodology such as the Cognos SIM, and proactive customer engagement in BI application development and deployment. The ISA Validated Application Methodology is built upon this foundation and allows life sciences organizations to comply with FDA software validation requirements at a lower cost of compliance.

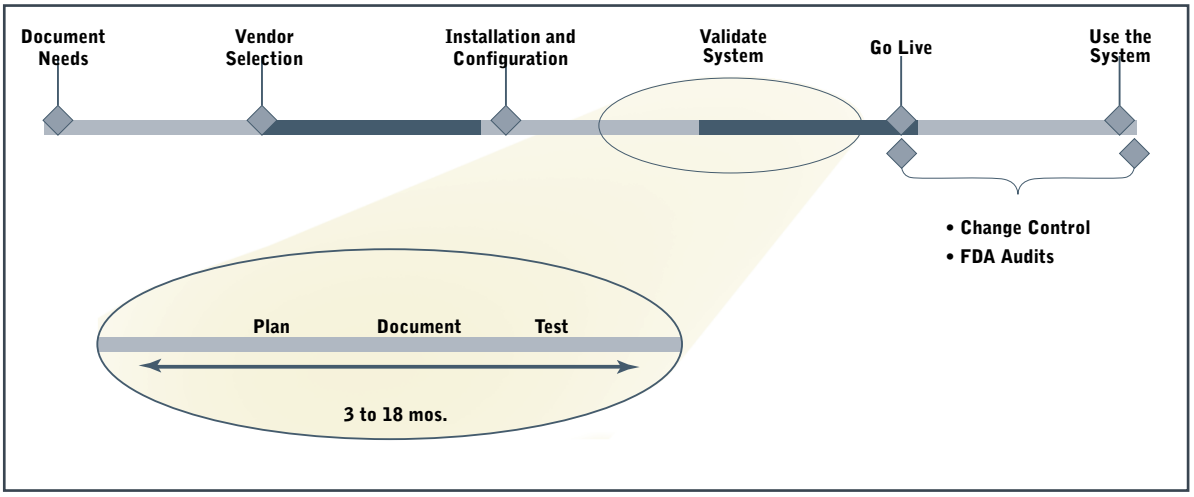
Organizations that have implemented the ISA Validated Application Methodology with Cognos BI solutions have benefited in many ways:

- FDA-compliant documentation that the BI application will meet its specifications
- Assurance that end users will have access to reports with accurate business intelligence
- A high-quality Cognos BI application that will deliver value and results
- Lower business risk
- Lower cost of compliance.

Cognos is the first choice for pharmaceuticals

Pharmaceutical organizations worldwide choose Cognos for our unsurpassed expertise in delivering the information and insight they need to reduce costs, streamline processes, and increase profitability. Cognos has delivered solutions to 25 of the top 30 pharmaceutical firms, along with many leading life sciences and biotech companies.

Project timeline: What a regulated end-user does to use a computer-related system



About ISA Consulting

ISA Consulting specializes in helping companies turn data into information for competitive advantage – utilizing corporate data to increase efficiency, improve performance, and maximize profitability. ISA's mission is to help our customers adopt information-driven solutions to achieve their business objectives. Founded in 1995, ISA serves over 150 customers worldwide with offices in New York, NY, Blue Bell, PA, and Washington, DC.

About Cognos, an IBM Company

Cognos, an IBM company, is the world leader in business intelligence and performance management solutions. It provides world-class enterprise planning and BI software and services to help companies plan, understand and manage financial and operational performance. Cognos was acquired by IBM in February 2008. For more information, visit **http://www.cognos.com**.

For more information

Visit the Cognos Web site at www.cognos.com

Request a call

To request a call or ask a question, go to www.cognos.com/contactme A Cognos representative will respond to your enquiry within two business days.

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