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The ASHVINS Group presents "Optimizing Outsourced Validation for Clinical or Compliance Applications" at a seminar associated with the Annual Meeting of the International Society of Pharmaceutical Engineers (ISPE), October 2008. The IPSE meeting held in Boca Raton, FL emphasized the changing technologies impacting pharmaceutical manufacturing professionals from around the world.

#### **PRESS RELEASE**

ISPE Associated Seminar; "Optimizing Outsourced Validation for Clinical or Compliance Applications". Presented Oct. 2008 by **The ASHVINS Group, Inc.**; Technology Professionals <http://www.ashvinsgroup.com>

MIAMI FL. USA – October 29, 2008. Lynn Hilt, President and CEO of **The ASHVINS Group, Inc.**, an Information Technology consulting firm focused in medical and life science industries, presented a seminar on "Optimizing Outsourced Validation for Clinical or Compliance Applications"

Validation is the most critical phase in the implementation of clinical data management or compliance systems operating in an FDA regulated environment. The FDA dictates strict guidelines for validation of systems that establish, manage, manipulate and store clinical data. In many organizations the primary focus is on selecting and implementing the application. Unfortunately the testing follows at the end of the implementation lifecycle as an afterthought. Unless an organization has the luxury of having a pool of trained and experienced validation experts available, it may be more cost-effective and efficient to hire a professional validation consulting firm to assist in test execution, documentation and oversight. Outsourcing the validation of the clinical or compliance system offers tangible benefits. These include:

- Independent and objective assessment of the application to increase performance confidence
- Availability of experienced resources trained in validation per FDA guidelines
- Dedicated, focused attention without internal distractions to support rapid implementation strategies
- An experienced professional validation consultant backed by an organization of testing expertise has access to the skills necessary to support the core validation disciplines in addition to having the software tools to automatically document testing that overall ensures project and organizational success

Once the decision to outsource the validation has been made by an organization, steps can be taken to CONTROL and OPTIMIZE the process to insure success.

#### **ABOUT ASHVINS GROUP**

**The ASHVINS Group** is a full application lifecycle development organization (in business since 2000) that provides technology services to global healthcare organizations including companies such as Baxter, Abbott Laboratories, Smiths Medical, Beckman Coulter, Insulet, Thermo-Fisher, Allergan and Siemens Medical. A variety of IT skills are available from The Ashvins Group to round out an application development or Project Team. Skill sets include Project Management, System/Process Engineers, Software Developers, Software Quality Assurance Specialists and Documentation Specialists. The blend of clinical experience combined with IT related processes/systems expertise makes The Ashvins Group a valuable partner who can deliver results and assist in identifying enabling technology that will enhance business capabilities and value. The company has an approved GSA IT 70 schedule # GS-35F-0561T for supporting government programs.

#### **CONTACT OPTIONS**

For additional information contact **The ASHVINS Group** as summarized below.

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