

## Providing Peace of Mind

Since 2000, major Life Sciences companies throughout North America, have chosen CSols to be their preferred CSV Services Vendor for the following reasons:

### I. People

Our Team is comprised of Scientists and Engineers, Regulatory Experts and Information Technologists. Team members average over 10 years of collective real-world experience.

As **Regulatory Experts**, we understand the Compliance (GLP/GMP, 21 CFR Part 11) implications for all Informatics Computer Systems; and we keep abreast of when these regulations change and the potential impact on your validation efforts.

As **Scientists, Chemists and Engineers**, we have the subject matter expertise necessary to understand what work processes / workflow your systems automate and manage. Therefore we understand whether your systems achieve what they were deployed to do.

As **Information Technologists**, we are familiar with the top commercial software products and applications currently being utilized. As importantly, we are true Experts in the software development lifecycle process.



### 2. Our Process

CSols follows a Risk-based approach to Computer Systems Validation. We have a proven and tested methodology for validating Computer Systems in both a prospective and retrospective manner.

Our CSV Project Approach has covered every aspect of Computer Systems Validation from the Strategic Validation Master Plan, to developing and executing Test Scripts and everything in between.

### 3. Our Track Record of Success

CSols has participated in the successful validation of the following types of **systems**:

- ERP (SAP)
- LIMS (Various vendors)
- CDS (Various vendors)
- Laboratory instrument Software (Various)

#### Client list includes:

- BMS
- Schering-Plough
- Synthes
- Regeneron
- Novartis
- Amgen
- Shire

### CSols offers the following services and deliverables:

- |                                   |                             |                                      |
|-----------------------------------|-----------------------------|--------------------------------------|
| ▶ Risk Assessment                 | ▶ Traceability Matrix       | ▶ Validation Test Protocol           |
| ▶ Validation Master Plan          | ▶ Validation Summary Report | ▶ Configuration/Design Specification |
| ▶ Validation Project Plan         | ▶ SOP Review                | ▶ Test Script Development            |
| ▶ Requirements Specification (RS) | ▶ Test Protocol Execution   |                                      |