



## Auditing Solutions Practice Data Sheet

# ASG: Focused on Your Auditing Needs, Delivering Unmatched Value. “It really is that simple.”

One of the most compelling problems facing pharmaceutical, biotech and medical device companies today is the rapid growth of regulatory compliance needs. The global emergence of clinical trials in new countries is escalating already growing concerns over clinical compliance. ASG is proactively helping clients address this concern with our new Independent Auditing Solutions practice. Our industry trained experts have the experience to ease your clinical compliance concerns and provide simple solutions to your complex problems.

### Cost Effective

We built our Independent Auditing practice to offer a cost effective alternative to the more traditional CRO and small compliance group outsourcing model. Our goal is simple: to build an independent auditing practice around the highest quality auditing professionals in the market, to meet your compliance needs.

### Custom Solutions – Flexible Delivery

Utilizing a risk based assessment approach and a tiered pricing strategy to match client specific needs, ASG provides cost effective, personalized GCP, GLP, GMP and computer systems validation Part 11 auditing solutions for any size company. Our auditing professionals can design an entire QA Department, deliver a custom solution to meet your most time sensitive critical needs, or develop a long term Compliance Plan to keep your company in accord with GCP/ICH guidelines as your clinical programs develop.

### Talent Talks

The ASG Independent Auditing Solutions practice incorporates world class talent with one goal – to deliver value you can rely on. We provide:

- Regional auditing teams to control travel time / costs and speed project delivery.
- Tiered pricing programs that match talent levels with the complexity of your specific project.
- Evaluation of your compliance structure to determine current and future needs.
- QA / clinical compliance training.

### ASG Differentiators

- We use client SOPs or ASG SOPs.
- Audits are done by industry compliance veterans, not just senior CRAs.
- All auditors are monitored by senior auditors to ensure Quality Control.
- Client maintains control with a dedicated Project Lead Auditor for larger projects.

### Independent Auditing Services

We provide domestic and international GCP, GLP and GMP auditing of:

- Investigator sites, vendors, CROs, Final Study Reports, Computer Systems Validation Part 11, Pharmacovigilance and Mock Inspections.
- SOP writing / training.

**Contact Us.** Complex problems often require a simple solution...Talent. Contact Dr. Anthony Howlett at 650-871-5000 or Mike Baker, VP at 919-653-6081 to discuss your compliance needs, or visit us at [www.asg-inc.com](http://www.asg-inc.com).