



## Global Compliance Capability, Regional Resources

### Europe



**Integrity Solutions Limited**  
Middlesbrough, Cleveland, UK

### Asia



**Yamatate Corporation**  
Tokyo, Japan

### Americas



**VeriScientia, Inc.**  
Cary, North Carolina, USA



## Global Consulting Network

Providing risk based solutions that balance benefits and cost. Global capabilities combined with the use of regional resources to ensure customer focused, sustainable solutions.

### Computerized System Compliance covering

Clinical • Medical Device • Laboratory • Manufacturing

### Cost-effective solutions addressing your specific needs

Validation • Compliance • Quality Systems • Organization • Resources



The Global Consulting Network (GCN) is a strategic partnership between Yamatake Corporation (Japan), VeriScientia (US) and Integrity Solutions Limited (UK).

GCN provides a unique blend of regional knowledge to provide global solutions and cost effective resource.

GCN provides Computerized System Validation and Compliance services to Life Science companies on a local and global basis. Our extensive range of services is geared to ensure that we are able to meet the specific needs of our customers including:

*Organizational Improvement Management*

*Policy and Standards Implementation*

*Quality Systems Implementation*

*Auditing and Gap Analysis*

*Validation Strategy Development*

*Validation Execution*

*Compliance Project Management*

*Competency and Skills Development*

The GCN client base exceeds 30 global companies. GCN's primary assets are its consultants who have been drawn from all areas of the Life Science's industry to bring an essential blend of management, quality assurance, people and technical skills.

The GCN specializes in Process Control System, IT Application and Laboratory System compliance in all areas of GxP (Good Clinical Practice, Good Laboratory Practice, Good Manufacturing Practice, Good Distribution Practice and Good Vigilance Practice).

Our approach is always based on risk and pragmatic sustainable solutions. This ensures that our customers receive an optimal balance between cost and benefit. For GCN, this ensures that we enjoy high percentage of repeat business from our valued customers.

## **STRATEGY PLANNING**

GCN will develop an improvement or project strategy to address the identified root causes. Depending on the nature and complexity of the compliance problem, a range of improvement

activities may be initiated. In order to measure success, it is essential that any improvement initiative be set measurable targets that can be achieved in a reasonable timeframe. This will ensure that commitment and momentum is maintained.

## **SUSTAINABLE SOLUTIONS**

At GCN, we have learned that the secret to sustainable solutions lies predominantly with ownership of the outputs. This is why GCN, where possible, ensures that improvement teams include a blend of customer resource and GCN personnel. This way, the project team is able to address the real issues of the organization and ensure transfer of knowledge from our consultants to the customer team.

## **SKILLS DEVELOPMENT**

Skills development is an essential component of sustainable solutions. The development needs of organizations and individuals however differ greatly and as such GCN offers a range of development approaches from off-the-shelf training to mentor support. The specific needs of the organization or individual are determined and the most appropriate development approach provided. Off-the-shelf and customized training programs include:

*Computerized System Validation*

*Maintaining the Validated State*

*Electronic Records and Electronic Signatures Compliance*

*IT Infrastructure Compliance*

*Computerized System Lifecycle Risk Assessment and Management*

## **COMPLIANCE GAP ANALYSIS**

Gap analysis is used to determine shortfalls against new regulation or internal standards. As gap analysis techniques are typically applied to existing systems that may have been in place for many years, it is essential that the gap analysis process evaluates the risk of identified shortfalls. Remediation actions should be aimed at improving compliance to an acceptable level of risk rather than providing costly solutions that bring little improvement to business performance.

## **AUDIT SERVICES**

A range of audit services including Supplier Auditing, Health checks, Surveillance Audits, Project Audits are offered. Auditing is a valuable and effective approach to identifying systematic and specific shortfalls within and organization. GCN also undertakes “open audits” where traditional auditing techniques are combined with interview techniques in order to identify more quickly critical issues and concerns.

## **VALIDATION INFRASTRUCTURE**

GCN offers validation processes, procedures and systems based on industry standard lifecycles. Customer personnel are actively engaged in the development of such processes, procedures and systems in order to ensure appropriate ownership following implementation.

## **VALIDATION PLANNING**

Site and Project Validation Plans are developed to provide a prioritized approach to facility, equipment and computer systems validation. Validation strategies adopt a scaleable approach to validation based on business risk.

## **VALIDATION EXECUTION**

The GCN is able to support all validation and operational lifecycle activities including:

- Validation Planning
- Requirements Specification
- Vendor Assessment
- Functional Design and Design Qualification
- Implementation Management (including software code review)
- Testing / Qualification
- Data Migration
- Validation Reporting
- Change Control
- Security Management
- Quality Auditing
- Disaster Recovery and Continuity Planning
- Periodic Review
- Training

Our resource provides a number of roles from validation leadership to protocol development and execution. The GCN has extensive experience in Laboratory System, Process Control System and Business Applications.

## **ELECTRONIC RECORDS AND SIGNATURES COMPLIANCE**

Electronic Records and Electronic Signatures (ERES) regulation and regulatory guidance continues to be a prominent issue for Life Science companies. Although 21 CFR Part 11 is continues to be the most prominent regulation, European and Japanese guidance is raising the global perspective of ERES compliance.

## **PROJECT MANAGEMENT**

GCN provides Computerized System implementation and validation Project Management services. Our unique blend of technical computing skills, quality and compliance knowledge and project management experience ensure that delivered solutions meet all customer needs.

The success of our Project Management services is derived from our ability to integrate implementation and validation activities and to leverage the effort of implementation consultants and system vendors.

Many of our customers maintain their own in house project management capability, however, still recognize that a robust project definition is fundamental to the success of the project. GCN provide consultancy support to assist in the development of project definition:

*Definition of a robust business case*

*Definition, re-engineering of business processes*

*Definition of clear, concise and complete User Requirements*

*Development of risk based project strategy, project plan and financial plan*

*Project Risk Assessment and Management*

**VeriScientia, Inc.**   
<http://www.veriscientia.com/index.html>

**Integrity Solutions Limited**   
<http://www.integrity-solutions.co.uk/>

- BPP and Best Practice for Pharmaceuticals are trademarks of Yamatake Corporation in Japan.
- Other product names, model nos., and company names may be trademarks of the respective company.

*Specifications are subject to change without notice.*

---

## **Yamatake Corporation Advanced Automation Company**

Knowledgeware Business Department

Shinagawa Seaside South Tower  
4-12-1, Higashi-Shinagawa,  
Shinagawa-ku, Tokyo 140-0002, Japan  
TEL: +81-3-6810-1203  
FAX: +81-3-5796-0648

URL: <http://www.azbil.com>

Printed in Japan (SZ)  
1st Edition: issued in Aug. 2007

*Printed on recycled paper.*