



Case Study

Supporting a Global Audit Program - How the *convergence* Business Model Provides Consistent High Quality EHS Audits and Business Value

Client: Fortune 500 US Multinational

Sector: Pharmaceuticals

Services: Environmental, health and safety (EHS) auditing for compliance to laws, regulations, company policies, and best practices; EHS Management Systems

Additional Specialty Focus Areas: Process Safety; Radiation Safety; Registration, Evaluation, Authorization and Restriction of Chemicals (REACH); Toxic Substance Control Act (TSCA); Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); Leak Detection and Repair Program (LDAR)

Countries Involved: USA & Puerto Rico, Canada, United Kingdom, Argentina, Austria, Belgium, France, Germany, India, Ireland, Italy, Netherlands, Spain, Turkey, Venezuela, Egypt, Russia, Mexico, Brazil, China, Korea, Taiwan, Australia, Singapore and Japan.

Value to Client:

- The Client executed consistent high quality EHS audits by involving experienced professional in-country *convergence* auditors across its worldwide operations.
- *convergence* provided country auditors with a special technical expertise to augment the Client's internal audit team, enabling a rigorous review of operations the Client deemed a risk or potential liability.
- The Client was able to reduce the size of audit teams by about one-third, reducing costs and the logistical burden on the auditees.
- The *convergence* resources helped the Client consider audit findings from a more systematic perspective, focusing recommendations and subsequent activities on company-wide improvements.
- *convergence* country auditors reduced communication gaps with the auditee with their bilingual skills, and ensured the audit team understood and appreciated regional and country practices or culture.
- With the growth and maturation of the Client's engagement with *convergence*, there is now a global network of EHS professionals that understand the Client's culture, systems and audit program. *convergence* resources can work as a seamless part of the Client's EHS audit teams without the Client's expense or burden of adding additional in-house resources.

The Client said: "***convergence*** consistently brought the right person with the right expertise and experience to complement the audit team".



The *convergence* business model builds upon an alliance of experienced EHS country auditors to match the Client with the right auditor with:

- The required technical expertise;
- Experience in the industry's sector and operations;
- Detailed knowledge of local laws, language and customs; and
- Bilingual skills – speaking and writing

The Client is in a heavily-regulated industry, with EHS and other regulations overlapping to create a complex, challenging situation. Furthermore, regulations and enforcement practices can vary significantly from one country to another. Compliance must be documented and assured on an ongoing basis to avoid costly product recalls, significant liabilities, and damage to company reputation.

Client Needs

The Client was looking to reduce audit expenses, make audits less burdensome for the audited facilities and bring a fresh perspective to the internal audit teams.

How It Started

Intrigued by *convergence's* use of in-country resources and deep pharmaceutical sector experience, the Client invited *convergence* to join the internal audit team and audit EHS compliance at one manufacturing facility in Europe. The key stakeholders – audit team, facility management, and line staff – appreciated the difference in the audit result.

As an outcome of the early successful audits in which *convergence* joined the Client audit team, the Client decided on a different approach to their internal audit program. Looking back the Director HSE Compliance Assurance explains,

“Our Global HSE Audit Services group wants to ensure that we critically evaluate all of our auditable units. We made a conscious decision almost ten years ago that at least one external auditor should participate in our Global HSE audits to make certain that our internal evaluations received the utmost scrutiny.”

It Takes Off

convergence has worked with the Client for over a decade as its audit program matured to include audits on management systems, internal standards, and focused issues including: process safety (PSM); radiation safety, REACH, TSCA, FIFRA and LDAR.

The *convergence* model proved ideal for the focused audits as well because it brought top-notch professionals in the technical area of focus to the audit team. These experienced professionals provided benchmarking information, and helped the Client assess the impact of new or emerging issues.

Over the years the Client's EHS audit program has typically involved 20 audits each year in approximately 25 different countries. The



operations are diverse, and include manufacturing, research & development, laboratories, distribution centers, and marketing and sales offices.

The Relationship Expands Beyond Audit

The Client invites *convergence* to:

- Deliver Environmental Management System training to their EHS Corporate Team, and present EMS topics to their EHS Global group; and the only external consultant invited to do so.
- Provide consulting support for 2+ years to develop their Genetically Modified Organisms safety systems and compliance programs for their R&D facilities in the United Kingdom.
- Undertake Due Diligence assessments for an acquisition of a large pharmaceutical facility in Germany and subsequently provided consulting to develop complete H&S Risk Assessment programs.
- Undertake external validation of their revised Asbestos Management program at a large facility in the United Kingdom.
- Provide specialist consultant in Epidemiology to solve an Industrial Hygiene problem encountered at their manufacturing facility in Brazil.
- Provide input and comment during their redevelopment of internal EHS Standards and Procedures.
- Undertake review of their Corporate Global EHS Management System, involving interviewing senior executives and realigning Corporate procedures.
- Propose changes to their Pharmaceutical Supply Chain Initiative (PSCI) program to realize efficiencies and robust management reporting and metrics.
- Prepare 49 country health and safety legal compliance registers (in English and the native language) that apply to their marketing, sales and administrative office operations, and keep the registers current.

“...This audit model has driven numerous HSE improvements throughout the corporation and these enhancements continue to drive our efforts toward world class HSE performance.”

The Client's Director of HSE Compliance Assurance describes their satisfaction with their relationship with *convergence*:

“Our alliance with convergence consulting LLC allows us to acquire the specific and local HSE expertise needed for our varied types of audits, which are performed throughout the world. This audit model has driven numerous HSE improvements throughout the corporation and these enhancements continue to drive our efforts toward world class HSE performance.”

For more details on *convergence*'s worldwide EHS audit program experience or our extensive experience with the pharmaceutical sector please contact us at infomail@cc-global.com.