

The Practical Solutions Group: No-nonsense people with sensible answers

Emma Barsky and Leonard Grunbaum of The Practical Solutions Group, LLC, pride themselves on being “go to” people, providing realistic solutions for the pharmaceutical and biotechnology industries’ regulatory problems.

“Our name is our philosophy: the work we do is practical,” said Barsky, who has 20 years of broad pharmaceutical experience in the areas of analytical chemistry, CMC-related operations, QA/QC, outsourcing and project management. “There are consultants, and then there’s The Practical Solutions Group. We treat regulatory issues faced by pharmaceutical and biotech companies as if they were business issues. This allows us to provide realistic regulatory guidance.”

The Practical Solutions Group’s expertise has already been known not only by numerous companies, but also by the Biotechnology Council of New Jersey and the New Jersey Economic Development Authority. “Clients appreciate high-quality, hands-on practical advice. Management of these companies does not benefit from purely academic, textbook consulting,” explained Grunbaum.

According to Grunbaum, whose expertise extends to the areas of validation, quality assurance and compliance enforcement, including 21 CFR part 11, the electronic records/electronic signatures final rule, The Practical Solutions Group is unique in that both principles have been integral parts of their respective companies, so they know the impact their solutions will have on a business. “We are hands-on. We’re not providing ‘theoretical’ advice,” he said.

Positing themselves to assist the bustling Einstein’s Alley demonstrates their business acumen. “Often the pharmaceutical and biotech companies have been the victims of impractical regulatory advice, which introduces inefficiencies into business,” Barsky stated. “We bring a simple value proposition: we help you solve regulatory issues without putting you out of business.”

Savvy high-tech companies turn to The Practical Solutions Group when they need problem-solvers. “Sometimes, it’s crisis management. Or, there’s a regulatory problem, and a company needs our expertise to solve it. What resonates with companies is that we can provide practical answers to regulatory problems without disrupting business goals and objectives,” added Grunbaum.

One pharmaceutical company’s story tells the tale. The Practical Solutions Group was contracted to perform an extensive validation documentation review of multiple computerized laboratory systems, supporting policies and procedures for the validation process and the overall IT infrastructure. The management of the company sensed that something was not in synch but could not put its figurative finger on the problem. “We discovered that the ‘devil was in the details,’” said Barsky.

“We found there was no logical flow to the validation process; certain activities were duplicated; a phased approach was used that effectively precluded the ability to trace testing back to requirements; there were no criteria for the review/approval process; and the Quality Assurance Unit’s input was not timely nor did it address regulatory compliance,” added Grunbaum. “Then, we

provided pragmatic recommendations for improvement in three areas: validation process, change control process and Quality Assurance oversight. These hands-on, compliance-related solutions will help the company work smarter.”

Smart high-tech companies along Einstein’s Alley are turning to The Practical Solutions Group to do the same.

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