

# Regulatory Compliance Assistance Offered by Practical Solutions Group

Regulatory compliance basically means ensuring that companies adhere to government regulations. But within that overall framework, there are many layers of complexity. Having experts on hand to help make sense of the sometimes tangled web is beneficial on many levels.

That is where Emma Barsky and Len Grunbaum come in. Partners in their Princeton-based consulting firm, The Practical Solutions Group, they offer assistance to pharmaceutical and biotech companies, emphasizing common sense business principles.

"The goal is for the companies to meet compliance and get approval as quickly and cost-effectively as possible, and we help our clients achieve this," explain Ms. Barsky and Mr. Grunbaum.

"It can be very complex," adds Mr. Grunbaum. "American companies may be doing business abroad and have to comply with foreign government regulations, as well as dealing with the FDA. Companies call us when there is a problem, and they may not have the expertise in a particular area. It can take eight to 12 years to put a product on the market from the initial development. They want to do it as quickly as possible."

## **Broad Experience**

Both Mr. Grunbaum and Ms. Barsky are experts. Ms. Barsky has almost 20 years of broad pharmaceutical experience in the areas of analytical chemistry, quality assurance, quality control,

CMC (chemistry, manufacturing, control)-related operations, outsourcing, and project management.

She has worked for such companies as Bristol-Myers Squibb, Sankyo Pharma, Inc., and Jacobus Pharmaceutical.

Mr. Grunbaum's areas of expertise include computer system validation, quality assurance, and compliance with 21 CFR part 11 (the electronic records/electronic signatures final rule). He has also provided validation and compliance enforcement training to the FDA, and developed quality plans and validation strategies for software companies planning to begin operations in the pharmaceutical industry.

Prior to forming Practical Solutions in May 2005, He was President of META Solutions, Inc.

Ms. Barsky and Mr. Grunbaum worked together in 2001, when, as Mr. Grunbaum explains, "I was the consultant and Emma the client. It was for a year on a high-intensity project. We had a synergy — values, a work ethic, and complementary skills. I'm a problem-identifier, and Emma's a problem-solver, excellent in the detail area.

"To open a consulting business," he continues, "you have to build on something, especially on the contacts you have. The biggest challenge is contacts, contacts, contacts! How do you make someone see that regulatory compliance is part and parcel of the business? We have

been fortunate with our contacts. We have worked with a lot of people and continue to network. We are members of the Biotech Council in New Jersey, among other organizations. We are very encouraged, and we have been in high gear from Day One."

## **Valuable Service**

Clients have included large and small pharmaceutical companies, software companies, clinical research organizations, biotech companies, and laboratories. There is no one overall strategy for every client, points out Ms. Barsky. Each company is different, requiring different techniques and methods.

"One of our most valuable services is performance of due diligence activities. We investigate both the operations and the regulatory compliance side of the business, because for us, they are very, very integrated. We meet with key management people; and evaluate the processes of the company. We need to see complete and accurate information.

"Does the company have the proper resources, proper management, stability, does it keep good records? Can it support the timeline? Is it complying with regulations? Regulatory compliance issues can be symptoms of larger operational problems.

"We also look at the computer system to see if it has been tested. That is Len's specialty," continues Ms. Barsky. "You have to see if you can rely on the data that



15 • TOWN TOPICS, PRINCETON, N.J., WEDNESDAY, JUNE 28, 2006

**SOLVING PROBLEMS:** "We're problem-solvers. We are often called on in times of crisis." Len Grunbaum (left) and Emma Barsky are partners in their consulting firm, The Practical Solutions Group, which provides regulatory compliance assistance to pharmaceutical and biotech companies.

is being produced."

**Business-Oriented**

Mr. Grunbaum adds that Practical Solutions bring more to their clients than just professional expertise, as important as that is. "Every project is different. You have to take your collective experience, intuition, background, and contacts and try to come up with a practical business solution for that company. And you always have to expect the unexpected. There are always different challenges."

"We really go into the details," observes Ms. Barsky. "We are very creative in giving people suggestions and solutions in achieving compliance and maintaining compliance. In the process, we save the company money with our advice. That is the

difference between us and other consultants. Our advice will end up being very business-oriented. We will do our best to help the company achieve compliance, and we will find creative ways that complement the company's culture, budget, and timeline.

"It is so challenging and stimulating," she adds. "It is so rewarding at the end of the day to feel you have found solutions for the client. Professionally and intellectually, it is the most rewarding experience in the world."

Looking at the overall picture and developing "practical solutions" is key, agree Ms. Barsky and Mr. Grunbaum. "First and primarily, our advice is that without a business context, it's like serving coffee without a cup. It can't be done. Our clients are businesses, and we emphasize the business end of all our work. It's a very down-to-earth, practical approach."

Practical Solutions can be reached at 609-683-0756, Website: [www.practicalsolutionsnj.com](http://www.practicalsolutionsnj.com).

—Jean Stratton