

Regulatory Compliance Simplified

BUSINESS WIRE: Regulatory Compliance Simplified. Under this umbrella, **The Practical Solutions Group, LLC (PSG)**, an FDA regulatory compliance consultancy, helps life sciences companies to implement common sense business operations for preclinical, clinical and manufacturing support that reduce business/operational risks (e.g., inefficiencies and costly delays) while maintaining regulatory compliance.

PSG provides interpretation of regulatory compliance requirements to pharmaceutical and biotechnology companies, and software companies that support them. Len Grunbaum, partner of **The Practical Solutions Group**, added “we have introduced some timely and welcome innovations to the regulatory compliance implementation landscape. Through our analysis of each company’s operational risk factors and practical recommendations, our clients realize business efficiencies while maximizing profitability and minimizing regulatory deficiencies.” Those that engage **The Practical Solutions Group** earlier in the process have discovered that it is better business to proactively identify and address operational risks prior to them becoming regulatory issues which, in turn, could have profound implications on company’s profits.

“We advocate a practical way of meeting regulatory compliance requirements.” Adds partner Emma Barsky, “We help companies to overcome the regulatory compliance burden while keeping operations simple, flexible and scalable.” The partners operate under the premise that it is easier, less costly and less time-consuming to comply with **FDA regulations** by:

- Exercising common sense
- Assessing operational and business risks in adopting compliance practices,
- Applying hands-on understanding of the intent of FDA regulations
- Knowing how to minimize documentation without compromising quality

PSG has proven that this thinking allows companies to achieve and maintain regulatory compliance without having to:

- Add staff
- Engage in non-productive activities or
- Increase operating costs.

PSG’s approach results in financial benefits to life sciences companies, as these selected cases illustrate:

- A Contract Research Organization (CRO) can now **save four-six weeks and tens of thousands of dollars each time their EDC system is configured to support a client clinical trial;**
- A specialty sub-investigator has been able to **triple in size without having to re-engineer its processes;**

- By **strategically reducing its documentation suite by 50%**, a CRO is now in regulatory compliance;
- A software developer is now **able to commercialize its product in the life science industry without having to re-vamp its corporate culture or structure.**

Emma Barsky and Len Grunbaum are the partners of The Practical Solutions Group, LLC. Ms. Barsky leverages her proven expertise in the areas of GXP Quality Assurance and Project Management. Since the time the business was launched, Ms. Barsky has performed multiple overall quality and computer validation assessments, conducted multiple field investigations, helped start-up companies to build a quality infrastructure in order to successfully pass client audits and managed multiple projects that required the assistance of subcontractors.

Mr. Grunbaum is a recognized expert in the industry, particularly in the areas of data management computerized systems and processes that support them, Quality Assurance and Compliance with 21 CFR part 11. He has written extensively on these subjects, won best articles awards, and has delivered numerous tutorials and training sessions to clients and industry groups on the subject. He has also provided compliance enforcement training to the FDA and helped to build quality infrastructures for pharmaceutical and biotech companies, and organizations that support them.

About PSG

PSG focuses on creating an environment which helps companies to improve operational efficiency, productivity and profitability while maintaining regulatory compliance. The areas of core expertise include data management and supporting processes (EDC, computer systems validation, project management, 21 CFR part 11-related issues), QA/QC consulting (building a quality infrastructure and processes for GXP activities), GXP audits/assessments/due diligence and selecting and managing outsourcing partners for GXP activities.

Contacts

The Practical Solutions Group, LLC

Emma Barsky, 609-683-0756

ebarsky@practicalsolutionsnj.com

or

Len Grunbaum, 609-683-0756

lgrunbaum@practicalsolutionsnj.com