

Case Study: Regulatory Process & Policy

Helping invent & navigate personalized medicine

Challenge

Regulatory compliance is non-negotiable, but it can also be a potent, forward-looking source of competitive advantage. Having the right guidance and a voice among policy makers is key.

Solution

YourEncore experts have advised and helped educate large, mid-sized, and emerging life sciences clients through focused and targeted briefing programs, created patient and policy-level coalitions, and acted as key regulatory and policy advisors.

RESULTS

YourEncore experts have helped the FDA and industry parties as they come together and forge Critical Path programs and advance the agenda of the Reagan/Udall Center.

Our experts' advice and counsel was also crucial in the development of the Patient-Focused Drug Development initiative – as well as the next steps that will result in a rebalancing of how the FDA views risk/benefit of new, more targeted therapies.

“If you’re not at the table, you could be on the menu. YourEncore helps inform clients and gives them a voice to act with confidence.”

- Peter J. Pitts, Former FDA Associate Commissioner