

Biotechnology

Executives Share Strategies for Successful Dealings With FDA on Product Submissions

SAN FRANCISCO—Communication and good strategy are the keys to successful dealings with Food and Drug Administration, executives with experience in biotechnology regulation said April 7.

Companies need to be on the same page as the FDA. And the key to that is communication, from the investigational new drug application throughout the life cycle, said Jason Rock, chief technical officer for GlobalSubmit Inc., a company based in Philadelphia.

“And a lot of times you’re going to have to present your case every step of the way,” Rock told a session at a conference sponsored by the biotechnology trade group BayBio.

Efficiency matters when asking FDA for answers, said Janne Wissel, chief regulatory officer at Jazz Pharmaceuticals.

“We spend a lot of time thinking about what are the most important questions that we need to ask FDA. And when we think about those questions, we try to make sure we ask them in a way that they can actually be answered. So if I ask, ‘Are you going to approve my drug?’ they don’t have any way of answering that question because it depends on the data,” Wissel said.