

Life Science Management & Contract Development Organisation of the Year

NDA Partners LLC

USA



By utilising the very best talent available anywhere in the world, NDA Partners delivers extraordinary value to its clients.



NDA Partners® is a life sciences management consulting and contract development organisation (CDO) specialising in expert product development and regulatory advice to the pharmaceutical, biotechnology, and medical device industries worldwide. The company distinguishes itself from other consultancies through its ability to assign top-tier expert consultants to lead all engagements, its ability to provide the full spectrum of functional expertise needed to conduct complete product development programs from bench to marketing authorisation, and its leadership in working with early-stage product development companies.

The highly experienced principals and expert consultants of NDA Partners include three former FDA Center Directors, the former Chief Executive Officer and Chief Science Officer at the United States Pharmacopeial Convention, more than 25 former senior level regulatory agency executives, five with senior level experience in EU regulatory agencies, and dozens of former industry product development executives, academic practitioners, and opinion leaders.

NDA Partners helps early-stage biopharma and medical device companies identify the most appropriate regulatory pathways, prepare effective preclinical and clinical development plans, design efficient and informative study protocols, assess data, evaluate readiness for regulatory submissions, prepare for meetings with regulatory agencies, and submit regulatory applications. It helps Asian and European pharmaceutical companies navigate US regulatory requirements and assists US companies entering global markets. In addition, the firm assists investment funds with due diligence and in addressing difficult development, regulatory, and scientific issues faced by portfolio companies, and is a major provider of litigation support and expert testimony services for law firms dealing with the complex issues of patent infringement, product liability, and supply chain failures.

For clients with limited internal staff, NDA Partners provides contract development services by forming world-class development teams that design, plan, and manage product their development programs. Corporate LiveWire judge Andrew Walsh commented: "By utilising the very best talent available anywhere in the world, NDA Partners delivers extraordinary value to its clients."



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