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Nancy Chew

Consulting and Expert Testimony

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Primary area of expertise: FDA Regulatory Affairs

Profile:

Internationally recognized FDA regulatory affairs expert, Nancy Chew has provided regulatory services to pharmaceutical, biotechnology, and medical device manufacturers for more than 40 years. She began forensic consulting in the 1980s

Specialty Focus: Pharmaceutical, biotechnology, and medical device regulatory testing and data requirements; product development; FDA regulatory liaison; regulatory submissions; Investigational New Drug (research) applications (INDs); New Drug (marketing) Applications (NDAs); FDA approvals and US Agent for FDA matters.

Nancy has directed, written, or contributed to a wide range of regulatory submissions (dossiers): INDs, NDAs, 505(b)(2) NDAs, 510(K)s, and pre-meeting briefing books. She is widely published and is sought after as a speaker, educator, and expert witness.

Review your selection for the Index of Expertise.

There are three types of Index selections: Enhanced Listings, Basic and Index only.

Category	Area of Expertise	Listing Level
Banking & Bankruptcy	Biomedical	Basic Listing
Business & Finance	FDA Regulatory Affairs	Enhanced Listing
Business & Finance	Securities/Stock Litigation	Basic Listing
Medical & Health	Drug Development	Basic Listing
Medical & Health	FDA New Drug Review/Approval Procedures	Basic Listing
Medical & Health	Pharmaceuticals	Basic Listing