SheppardMullin

Events

Compliance Congress for Specialty Products Conference

Pre-Launch Compliance Considerations for Specialty Pharmaceuticals
09.25.2024 | 8:45-9:45 AM

Connect with Your Specialty Pharmaceutical Peers & Drive Compliance Efficiency. Overcome Risks & Challenges Associated with Complex Therapeutics - Benchmark Strategies & Evaluate New Solutions for Rare, Ultra-rare & Orphan Diseases.

Agenda

Pre-Launch Compliance Considerations for Specialty Pharmaceuticals

- Advice from those who have already successfully launched: 3 key things I wish I had known
- Nuances and readiness do's and don'ts for launching a new product and/or launching a new indication for an approved product
- Timelines, best practice and approach: from training employees and preparation for PDUFA date to pre-approval for payer communication
- Updates on preapproval payer formulary interactions
- Dealing with competitors: what are your competitors saying? How do you train your salespeople to respond when they hear incorrect information about your product?
- Best practice for medical and promotional information review: comparative claims and competition
- How to evolve your policy library so it gives the right direction before and after launch
- Status on off label communication: nuances for communications for unapproved use of approved product
- Update on the Pre-approval Information Exchange (PIE) Act, passed by Congress on December 23, 2022, and signed as part of the Consolidated Appropriations Act, 2023

Speaker:

- Dominick Disabatino, Partner, Sheppard Mullin

Click here to register.

Attorneys

Dominick P. DiSabatino

Practice Areas

FDA Regulatory

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