Innovative Regulatory Science Group

Tuesday, June 30, 2026

Subject: Comment on SEC Draft Strategic Plan FY 2026–2030, File Number DSP-3

Dear Securities and Exchange Commission:

I am writing to provide comments on the SEC's Draft Strategic Plan for Fiscal Years 2026–2030. I appreciate the Commission's focus on capital formation, innovation, regulatory modernization, market integrity, and investor protection.

As a regulatory affairs professional and life sciences entrepreneur with 25+ years, 50+ regulatory submissions across drugs, biologics, and medical device programs, spanning clinical-trial applications through marketing approval. Including BLA-stage advisory work, and 19 years teaching regulatory science at several Universities. I believe it is important for the SEC to recognize that life science companies face financing challenges that differ significantly from many other startups. Biotechnology, diagnostics, medical devices, and biomanufacturing companies often require substantial capital years before commercial revenue is possible. These companies must navigate scientific uncertainty, FDA-regulated development pathways, clinical evidence requirements, manufacturing readiness, quality systems, and long commercialization timelines.

For that reason, regulatory certainty is critical. Investors are more willing to fund early-stage life science innovation when companies can clearly explain their development pathway, regulatory expectations, manufacturing plan, and key risk milestones. Uncertainty in either the securities framework or the product development framework can delay investment, increase cost of capital, and slow the advancement of promising technologies.

I encourage the SEC to consider ways to modernize capital-raising pathways for highly regulated innovation sectors while maintaining strong investor protections. In particular, exemptions such as Regulation Crowdfunding could be more useful for life science companies if annual raise limits were increased, for example from $5 million to $20 million, provided that appropriate

safeguards remain in place. These safeguards could include clear risk disclosures, milestone-based reporting, use-of-proceeds transparency, and plain-language explanations of regulatory and development risks.

This type of modernization would not eliminate risk, but it could allow more responsible capital formation for companies developing products, platforms, and infrastructure that require longer timelines and larger early investments than many traditional startups. It could also help broaden participation in innovation financing while preserving the SEC's core mission of protecting investors, maintaining fair and orderly markets, and facilitating capital formation.

Thank you for the opportunity to provide comments.

Respectfully,
Dr. Leona Saunders
Innovative Regulatory Science Group, LLC
https://regulatorysciencegroup.com/