US Public Policy & Regulatory Affairs
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Strengthened and optimized communications and collaborations with regulatory authorities.

Improved science and policy alignment with regulatory authorities.

Increase engagement with regulatory authorities on quality and public standards.
Tailoring USP Programs to Stakeholders Needs
“FDA Affairs” Function

- Communication
- Coordination
- Strategy Input
- Monitoring
- Advocate
- Measurement
- Inform
- POC
- Non governing

FDA Affairs

Non governing Very High
Regulatory Intelligence Framework

- Appointees, Personnel, Programs
- Relationships and Interactions
- Trends by Commodity
- Outputs, Actions, and Precedents
- Approvals/Clearances
- Product Specific Data
- Advisory Committees
Activate and evolve centralized FDA Affairs function.

Develop and implement comprehensive regulatory affairs communications program.

Create sustainable mechanism to identify and communicate regulatory trends to USP organization.

Build an engagement plan for USP’s regulatory affairs function.
Engagement, Strategy, & Appropriate Alignment

Collaboration & Synergy
Consider FDA perspectives in strategies and planning process

Facilitate engagement with FDA

Raise Awareness

Identify activities with high-impact & important FDA
Questions
Thank You