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# US Public Policy & Regulatory Affairs

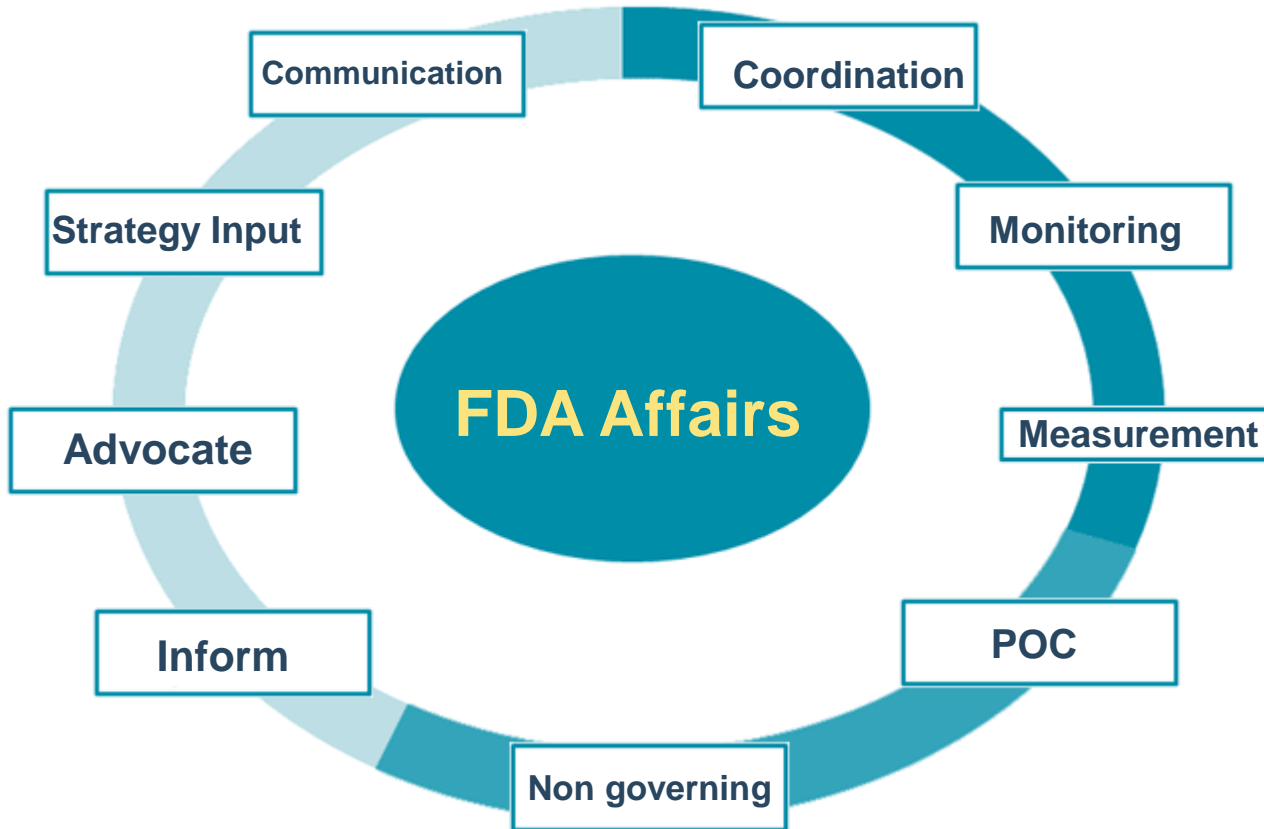
Elizabeth Miller, Pharm.D.

- ▶ 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.



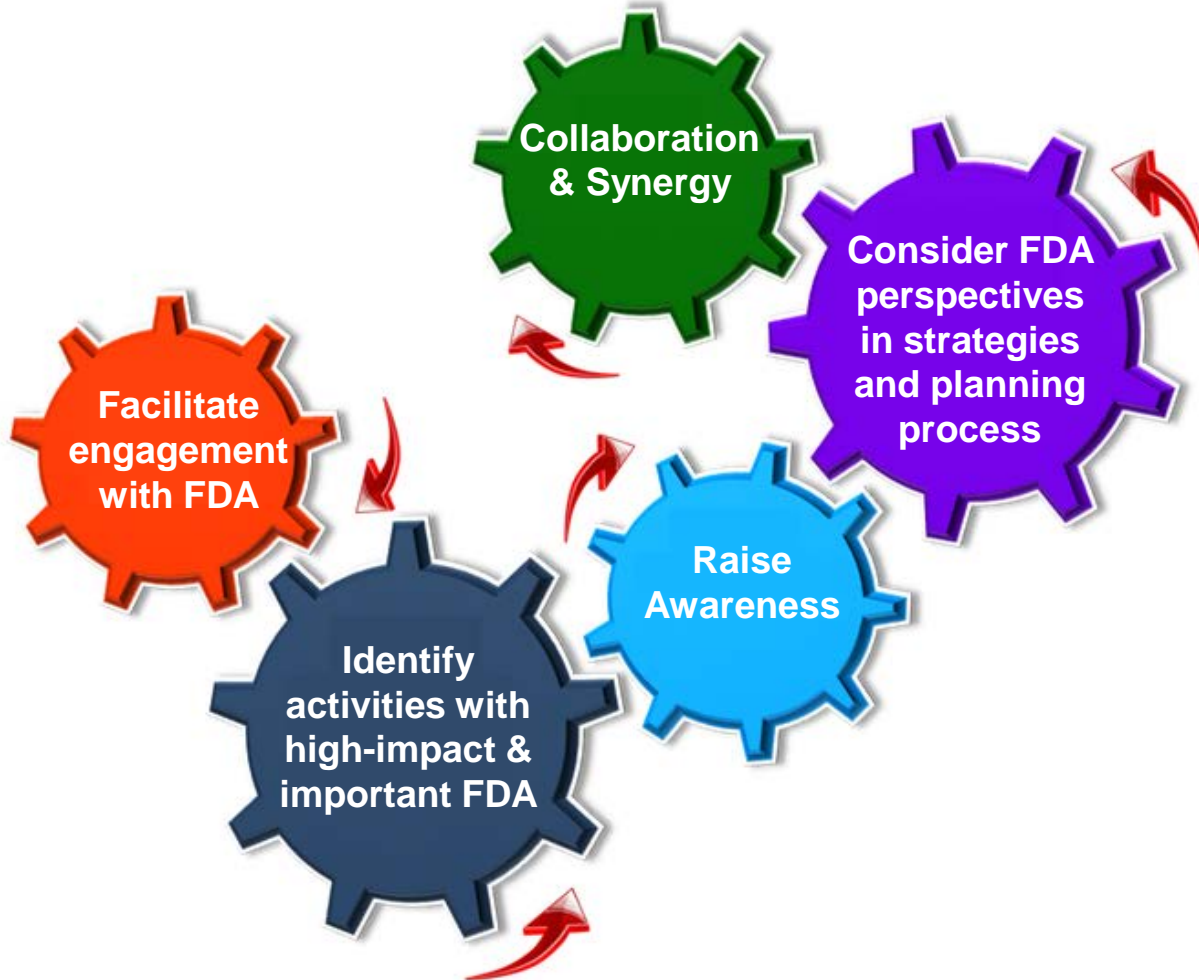
**U.S. FOOD & DRUG  
ADMINISTRATION**

# “FDA Affairs” Function



- ▶ 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.





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# Questions





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# Thank You