U.S. Food and Drug Administration
Office of Regulatory Affairs

Program Alignment & Product Quality Oversight

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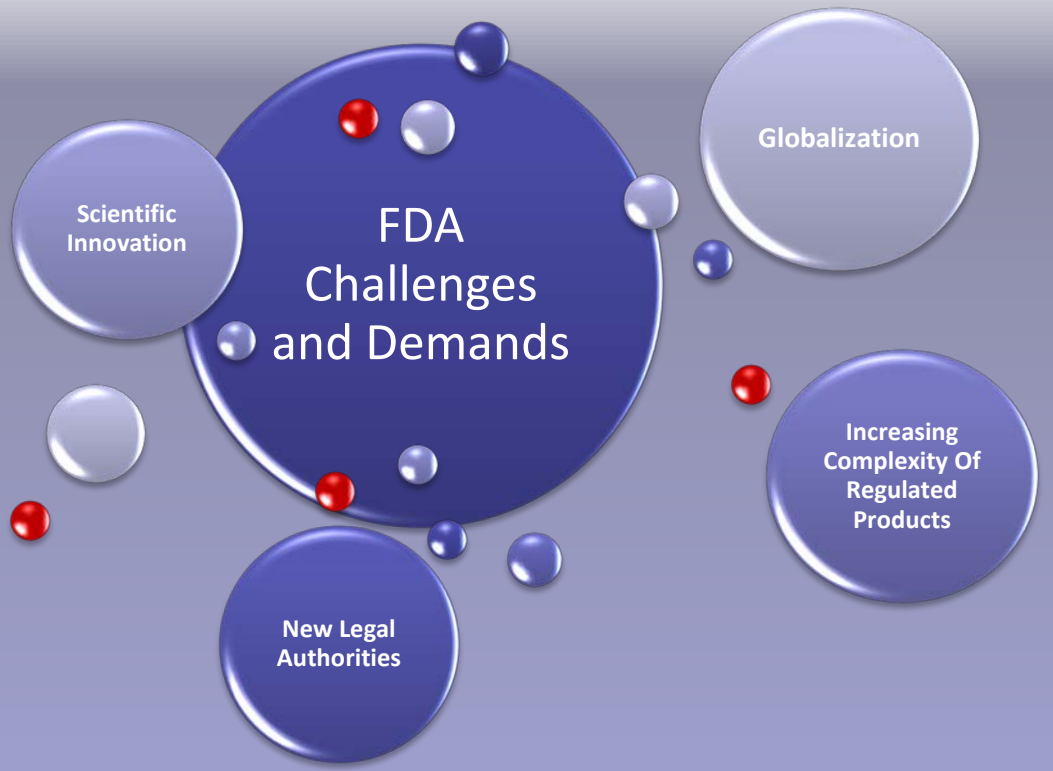
About Program Alignment

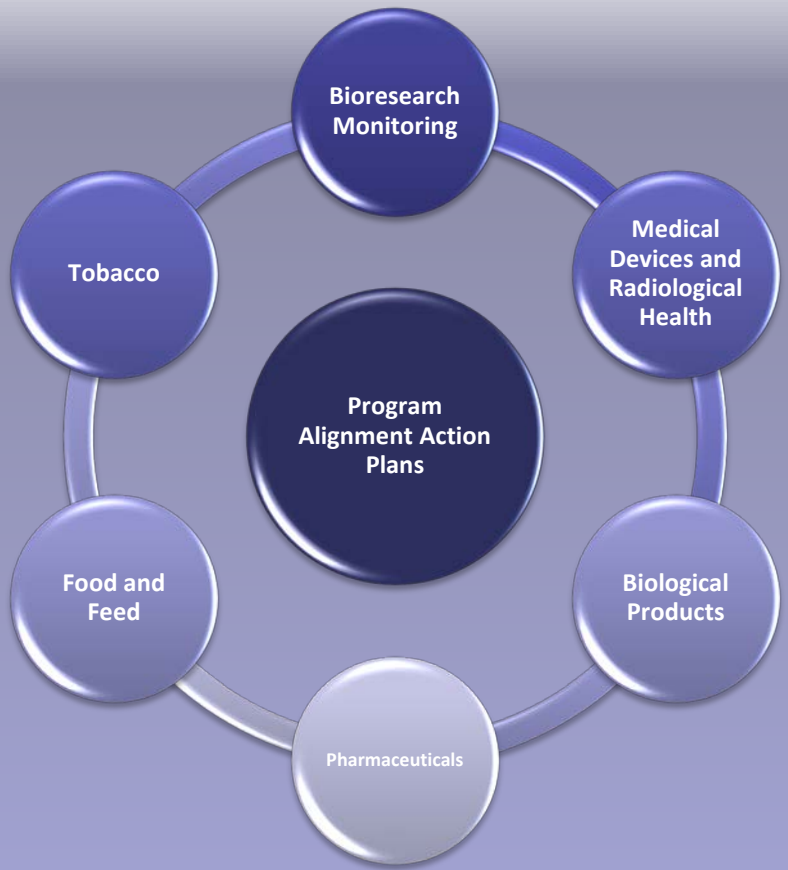
On September 6, 2013, U.S. Food and Drug Administration (FDA) Commissioner Margaret Hamburg, M.D. charged a group of senior leaders with identifying and developing plans to modify functions, processes and structures to meet greater agency demands by facilitating increased operational and program alignment.



Program Alignment Action Plans

- FDA's Directorates, Centers and the Office of Regulatory Affairs collaborated on a set of six fiscal year 2015 Program Alignment Action Plans to define ways to transition the agency to distinct commodity-based and vertically-integrated regulatory programs.

- Key areas in this multi-year effort include specialization, training, work planning, compliance policy and enforcement strategy, imports, laboratory optimization and information technology.



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Pharma Action Plan & other Activities:

- Developed a set of underlying sub-specialization categories in the pharma program.
- Establishment of one risk-based site selection model for surveillance inspections (foreign & domestic).
- FDA, working towards a more team based approach across all components within the pharmaceutical program. Including application review ,inspections, compliance & enforcement. A couple of pilots currently underway…

Strategic Priorities for Pharma

- Immediate For-Cause Public Health Emergency
- Pre-Approval Inspections (Human & Animal drugs)
- Compounding Surveillance Inspections
- Quality Surveillance (GMP) Inspections
- Firms with no inspectional history
- F/U to serious adverse events
- Firms with OAI inspectional classification

Next Steps

On-going & beyond…

Implementing the action plans, & improving our collaboration will take time, commitment, and continued investment and the organization will continuously monitor and evaluate its efforts.

Questions?