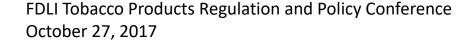
Engaging with FDA: An Industry Perspective

Valerie Briggs Solomon Managing Counsel, R&D and Regulatory RAI SERVICES COMPANY





Key Principles of Engagement

- Commitment to FDA compliance
- Advocacy for company products and submissions
- Comprehensive harm-reduction strategy
- Science-based regulatory decisions
- Uniform regulatory enforcement
- Industry engagement and timely guidance





A Work in Progress

- Early uncertainty and skepticism—on both sides
 - Approach to engagement and compliance has evolved over time
- Continuing direct engagement with CTP
 - Regulatory filings, correspondence, site tours, public workshops, meetings
- Continuing industry engagement
 - GMP Draft, ENDS TPMPs, TPSAC, scientific forums and meetings

