



# Engaging with FDA: An Industry Perspective

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# 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