Introductions and Day Two Postmarket Overview

FDA Small Business
Regulatory Education for Industry (REdI)
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Learning Objectives

- Review Today's Agenda and Today's Speakers
- Virtual Attendees Practice the Polling Option
- Learn about the future CDRH Total Product Lifecycle (TPLC) Reorganization
- Discuss Medical Device educational resources
- Enjoy the day, ask questions and learn something new

Agenda – Day 2 Device Track

Time	Topic	Speaker
8:30 – 9:10:	Introduction to the Quality System Regulation and Design Controls	Tonya Wilbon
9:10 – 9:50:	User Needs, Design Input, Design Output and Design Review	Vidya Gopal
9:50 – 10:10:	Break	
10:10 – 10:50:	Design Verification, Validation and Risk Analysis	Joseph Tartal
10:50 – 11:30:	Design Transfer and Design Change Controls	Andrew Durfor
11:30 – 12:45:	Lunch	
12:45 – 1:25:	UDI Update 2018	Loretta Chi
1:25 – 2:05:	Medical Device Reporting	Anike Freeman
2:05 – 2:25:	Break	
2:25 – 3:05:	FDA Medical Device Inspections	Maida Henesian
3:10 – 3:45:	1:1 Q&A Session	In Person Attendees

Poll Question

Do you currently market or distribute a medical device?

A. Yes

B. No

C. Not Sure

Poll Question

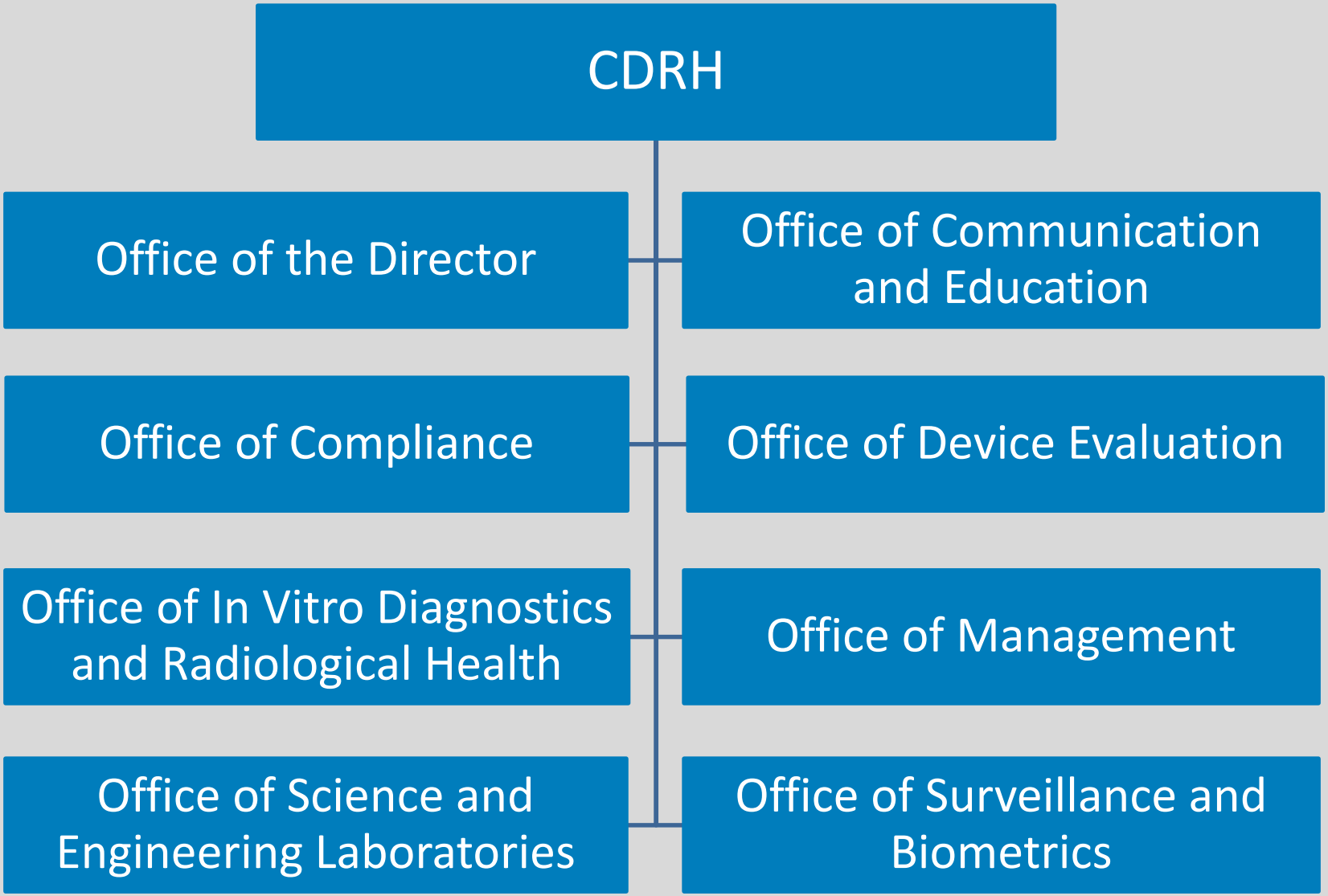
Have you heard about CDRH Total Product Lifecycle (TPLC) Reorganization?

A. Yes

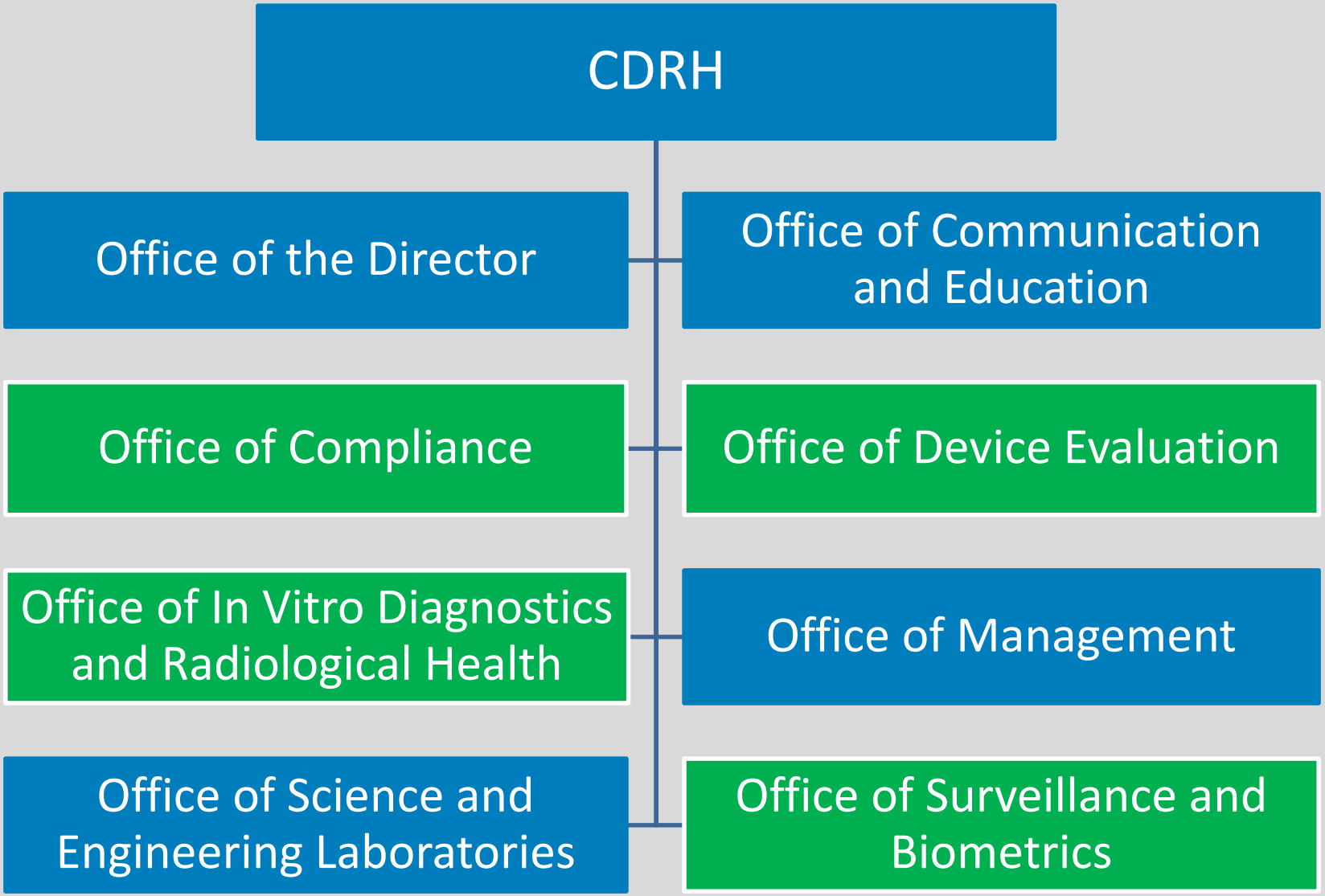
B. No

C. Not Sure

Current Center Structure



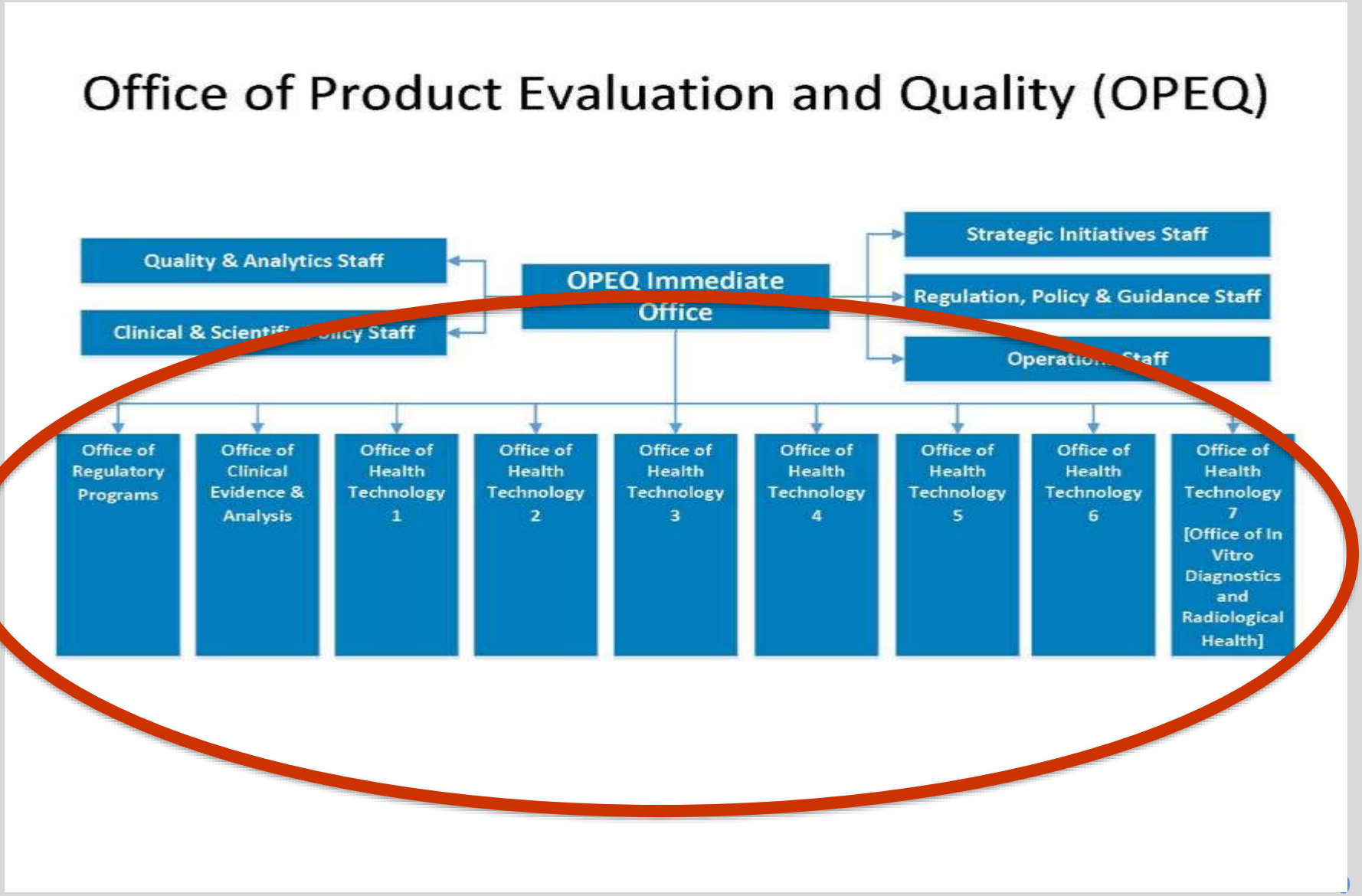
What Will Change



How Will These Offices Change

- Merge these four CDRH offices into the Office of Product Evaluation and Quality (OPEQ)
  - Office of Compliance
  - Office of Device Evaluation
  - Office of Surveillance and Biometrics
  - Office of In Vitro Diagnostics and Radiological Health
- Offices of Health Technology (OHT)

Future Design



OPEQ Features/Goals

- Common management chain for premarket, compliance and surveillance programs
- Share/exchange information to make more informed decisions
- Ensure process and policy consistency
- Work in teams
  - Team management approach
  - Teams within and across office and divisions
- Drive decision-making to lowest appropriate level

Industry Education Resources

Three Resources

1. **CDRH Learn: Multi-Media Industry Education**
   - over 125 modules
   - videos, audio recordings, power point presentations, software-based "how to" modules
   - mobile-friendly: access CDRH Learn on your portable devices

   www.fda.gov/Training/CDRHLearn

2. **Device Advice: Text-Based Education**
   - comprehensive regulatory information on premarket and postmarket topics

   www.fda.gov/MedicalDevices/DeviceAdvice

3. **Division of Industry and Consumer Education (DICE)**
   - Contact DICE if you have a question
   - Email: **DICE@fda.hhs.gov**
   - Phone: 1(800) 638-2041 or (301) 796-7100 (Hours: 9 am-12:30 pm; 1 pm-4:30pm EST)
   - Web: **www.fda.gov/DICE**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