

CDRH TPLC Transformation



TPLC Reorganization Goals

- Create an agile infrastructure that can adapt to future organizational, regulatory, and scientific needs.
- Facilitate information-sharing to help make better informed decisions.
- Facilitate professional development for all employees by increasing opportunities for cross-skills development and creating multifunctional positions.



TPLC Reorganization Goals

- Ensure process and policy consistency.
- Minimize organizational layers of review and facilitate employee professional development, to achieve more efficient work processes and allow employees to leverage their knowledge of pre- and post-market information to optimize decision-making.
- Allow the increases in efficiency and organizational flexibility to translate into reasonable employee workloads, so that managers and staff can have healthy work-life balances.



Value Added for You

- Improving our internal processes, coordination and communication → more straightforward & streamlined interactions with CDRH
- Consolidating our structure → provides you with “one stop shopping” in many cases
- Creating a more agile organization → better response to changing regulatory needs and new technologies



Value Added for You

- Ensuring more consistent policy application across the Super Office → easier for you to know what to expect
- Streamlining decision making → more informed interactions with CDRH staff
- Creating a better work-life balance for our employees → increased longevity of your points of contact within the organization due to reduced staff turn-over



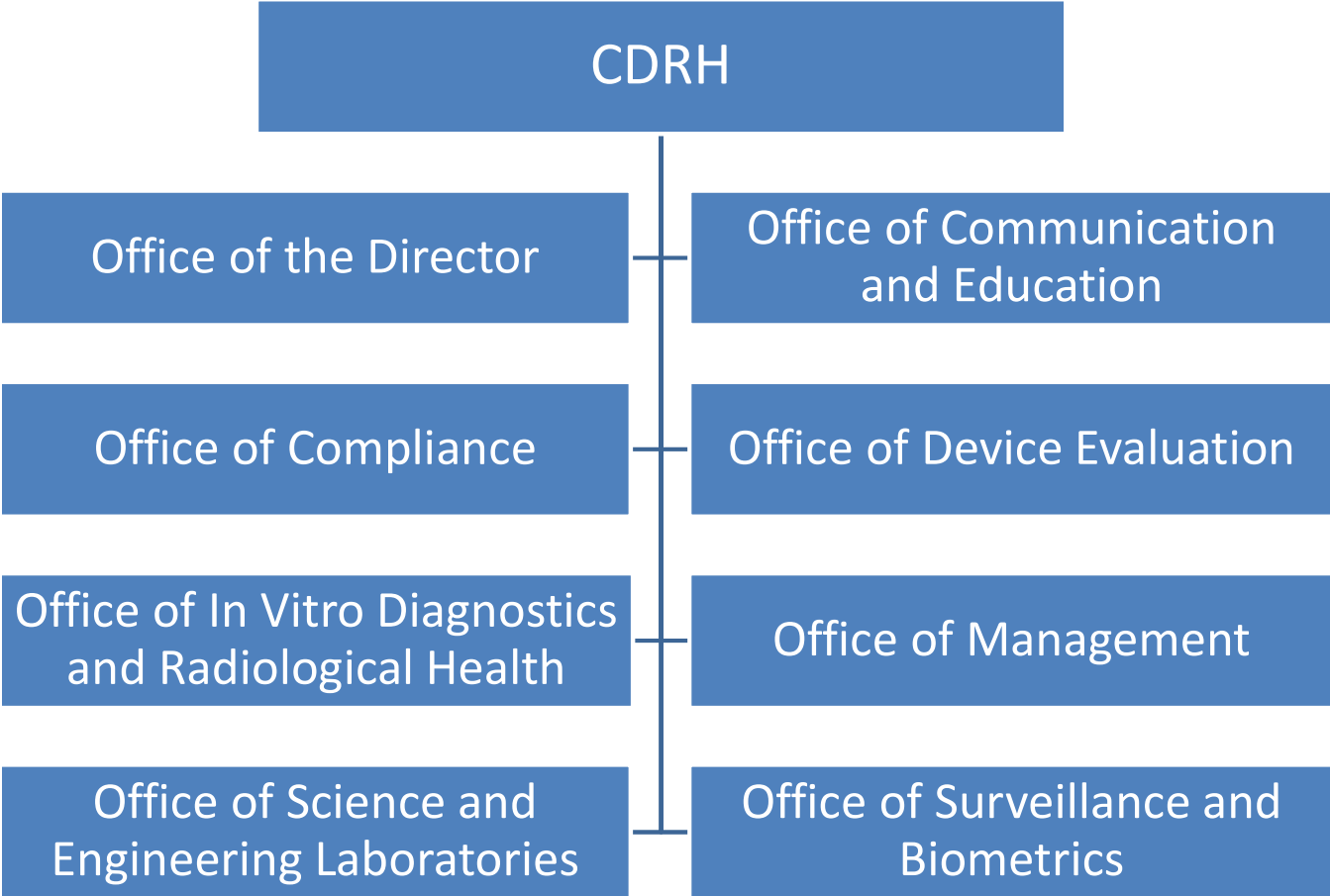
HOW WE ARE CHANGING



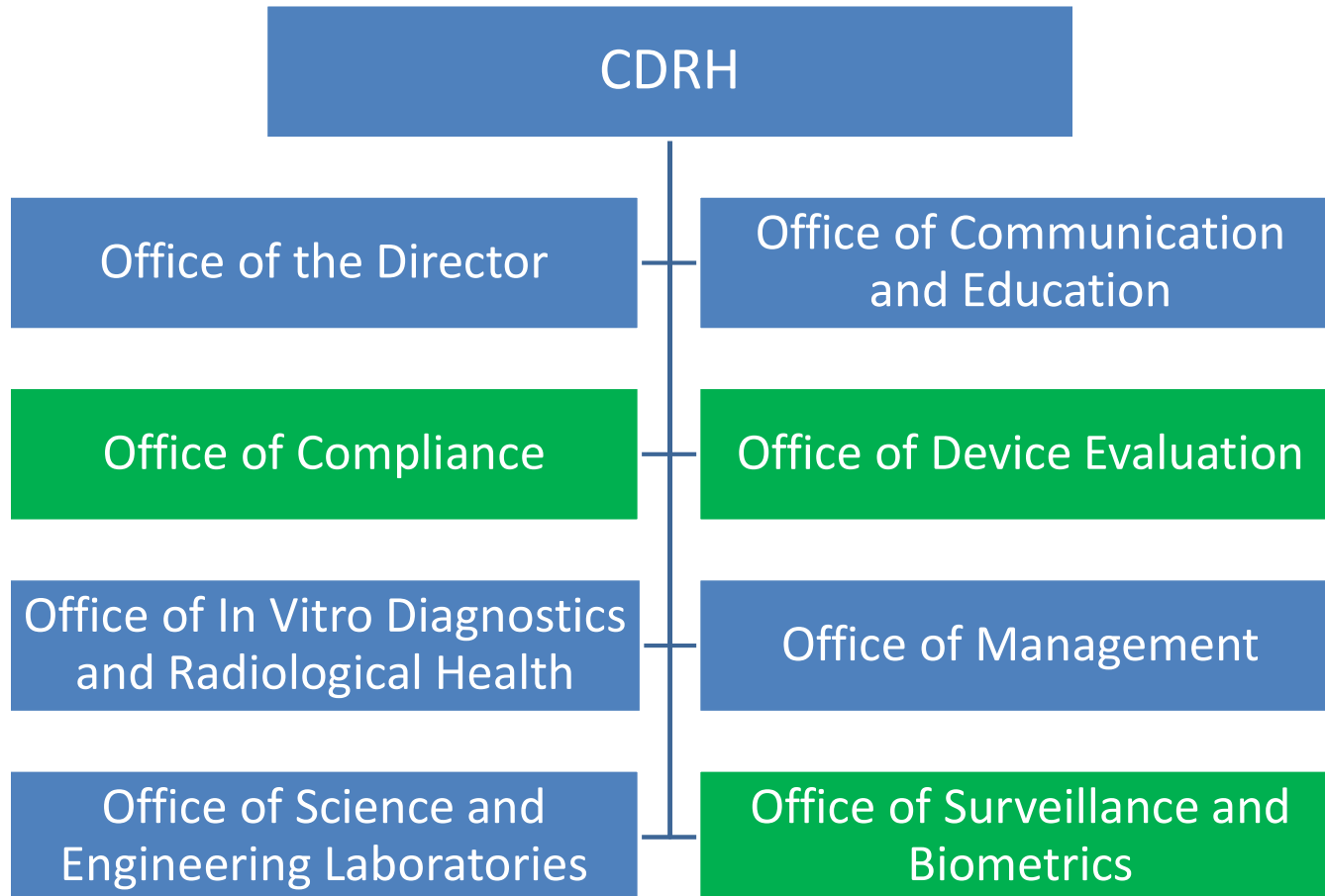
New Design Features

- Working in teams
 - Team management approach
 - Teams within and across divisions
- Common management chain for compliance, premarket and surveillance programs
- Division is the lowest organizational structure
- Empowering staff by driving decision making to lowest appropriate level
- Emphasis on professional development & work-life balance

Current Structure



What Will Change

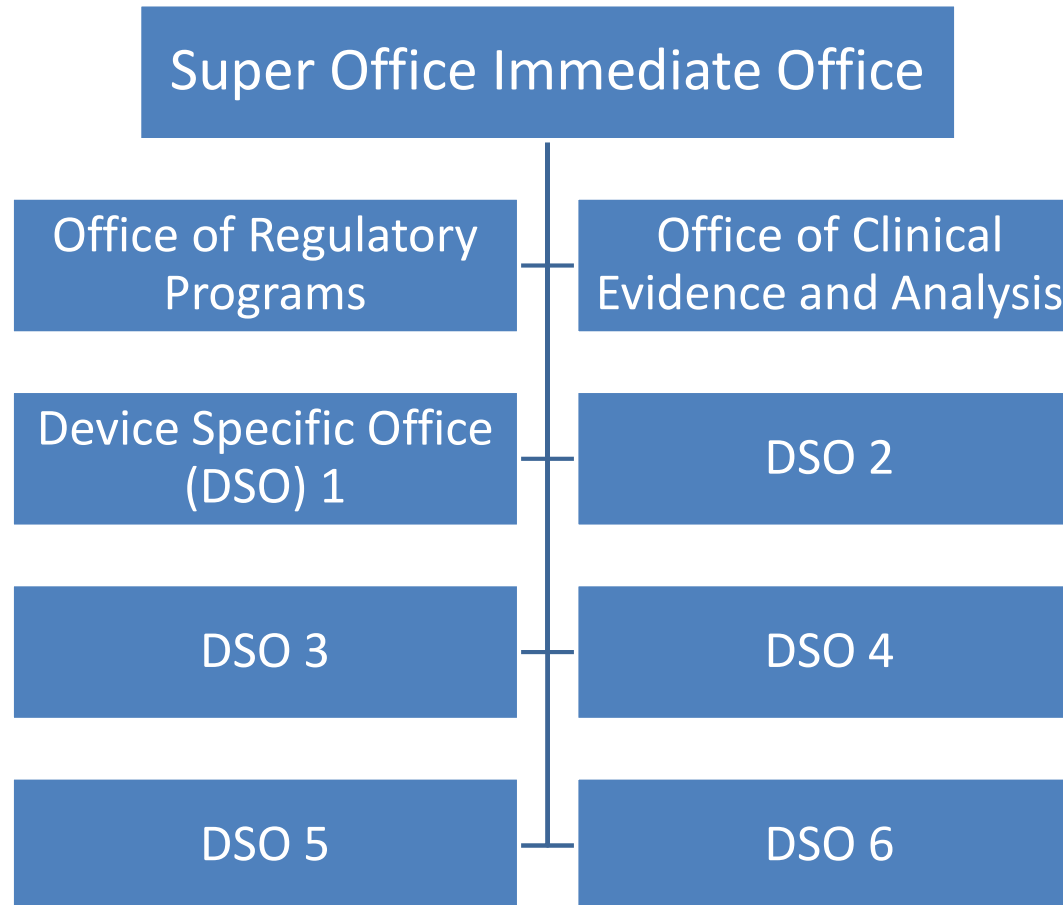




How Will These Offices Change

- We plan to merge these three CDRH offices into one TPLC super office structure:
 - Office of Compliance
 - Office of Device Evaluation
 - Office of Surveillance and Biometrics

Proposed Structure

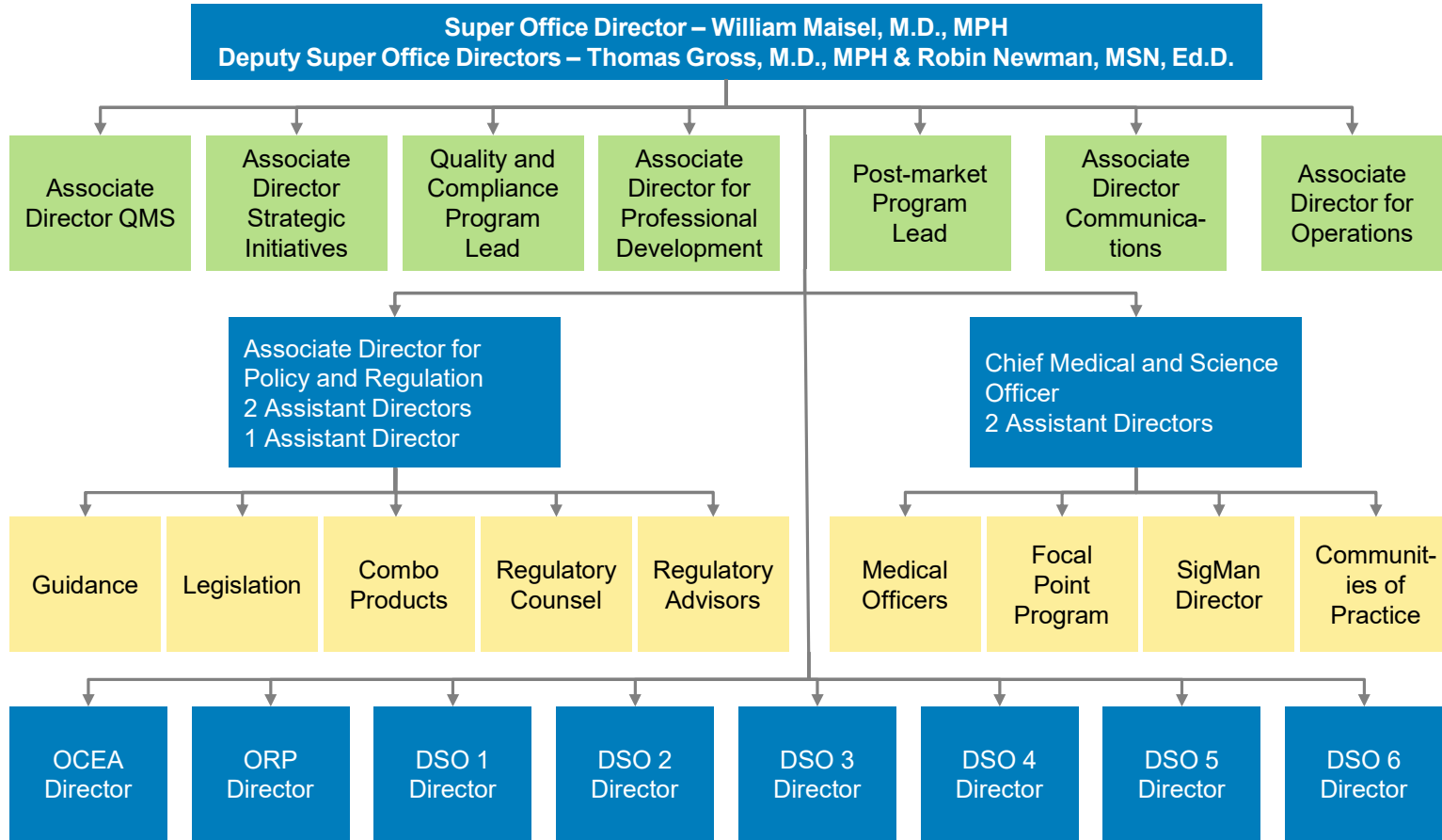




Immediate Office



Future Design: Super Office Immediate Office

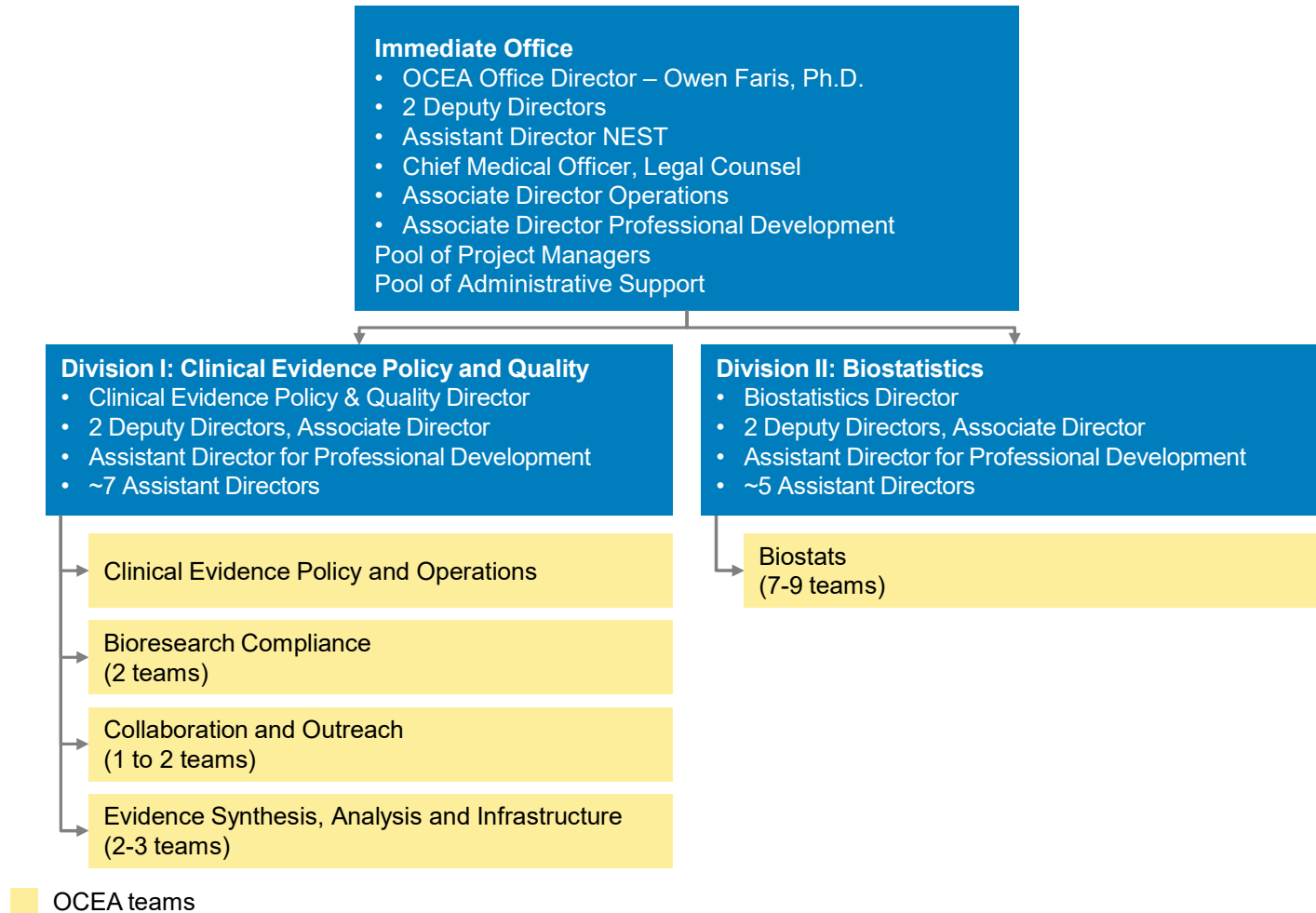




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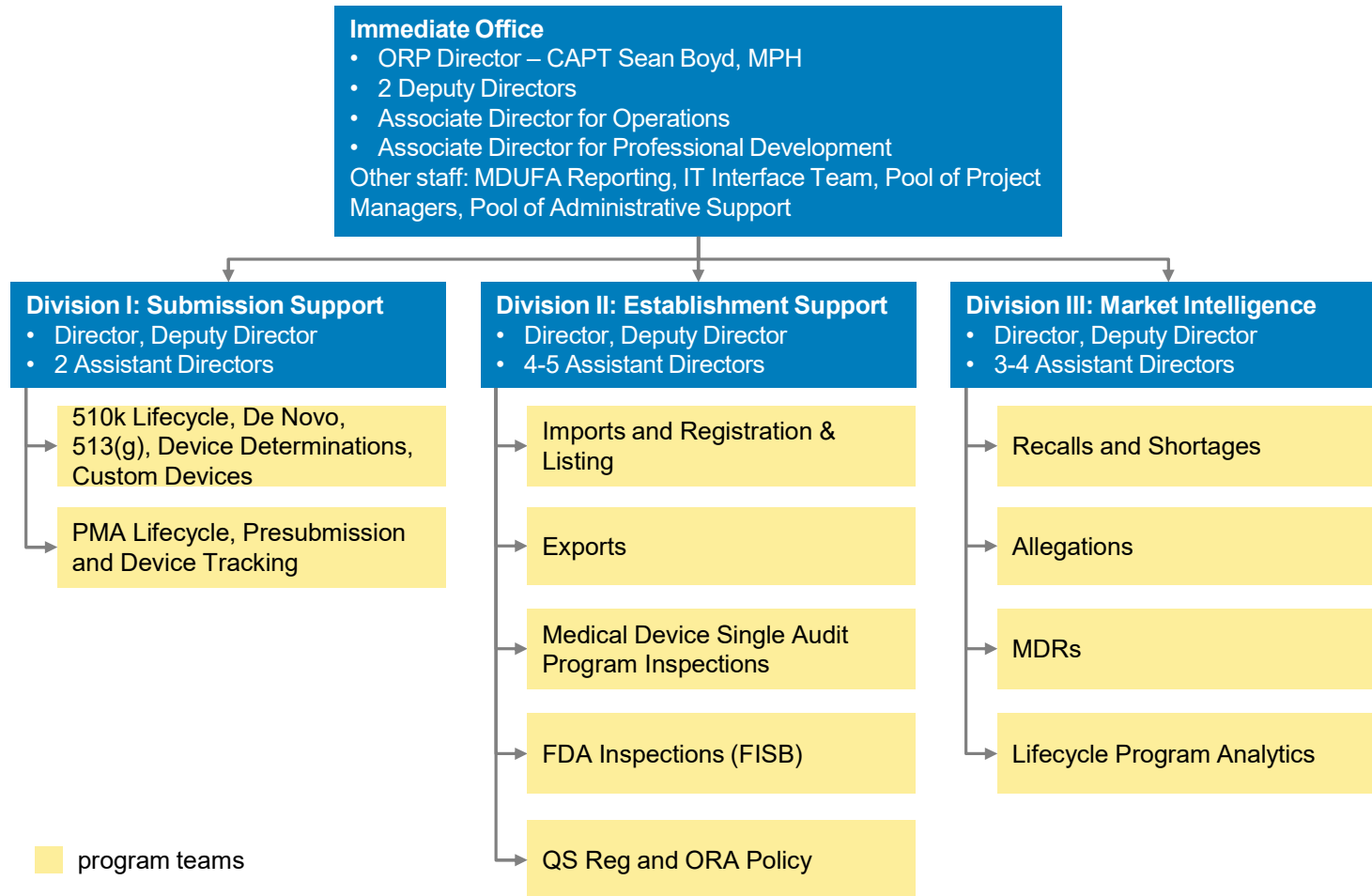
Future Design: Office of Clinical Evidence & Analysis





ORP

Future Design: Office of Regulatory Programs





WHEN THIS WILL HAPPEN



Timing

- We plan to submit the reorganization package to FDA by year's end
- The package is then reviewed by HHS and Congress
- We expect clearance to take at least 6 months



NEXT STEPS



Next Steps

- Remaining TPLC pilots will launch
- Reorganization package submitted to FDA
 - Package then reviewed by HHS and Congress
- Pre-implementation activities
 - Continue pilots
 - Processes reworked to fit our new structure
- Implementation of reorganization
 - Upon FDA, HHS, and Congressional approval
 - Will include communication with our customers to facilitate interactions with the redesigned CDRH