

FDA CDRH TPLC Future Direction & Strategic Priorities

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Office of Compliance

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CDRH Vision

Where do
we want to
be?

Patients in the U.S. have access to high quality, safe, effective medical devices, of public health importance, first in the world.

What does it take?

- Focus on quality
 - Patient centric perspective
 - Value
 - Collaboratively seek solutions
 - Speed
- Accelerate Innovation
 - Enhanced data and capability
 - Proactive/Predictive
- Adaptive regulatory framework

It is all about the patients!



CDRH Total Product Life Cycle (TPLC) Transformation

Office of Product Evaluation and Quality





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

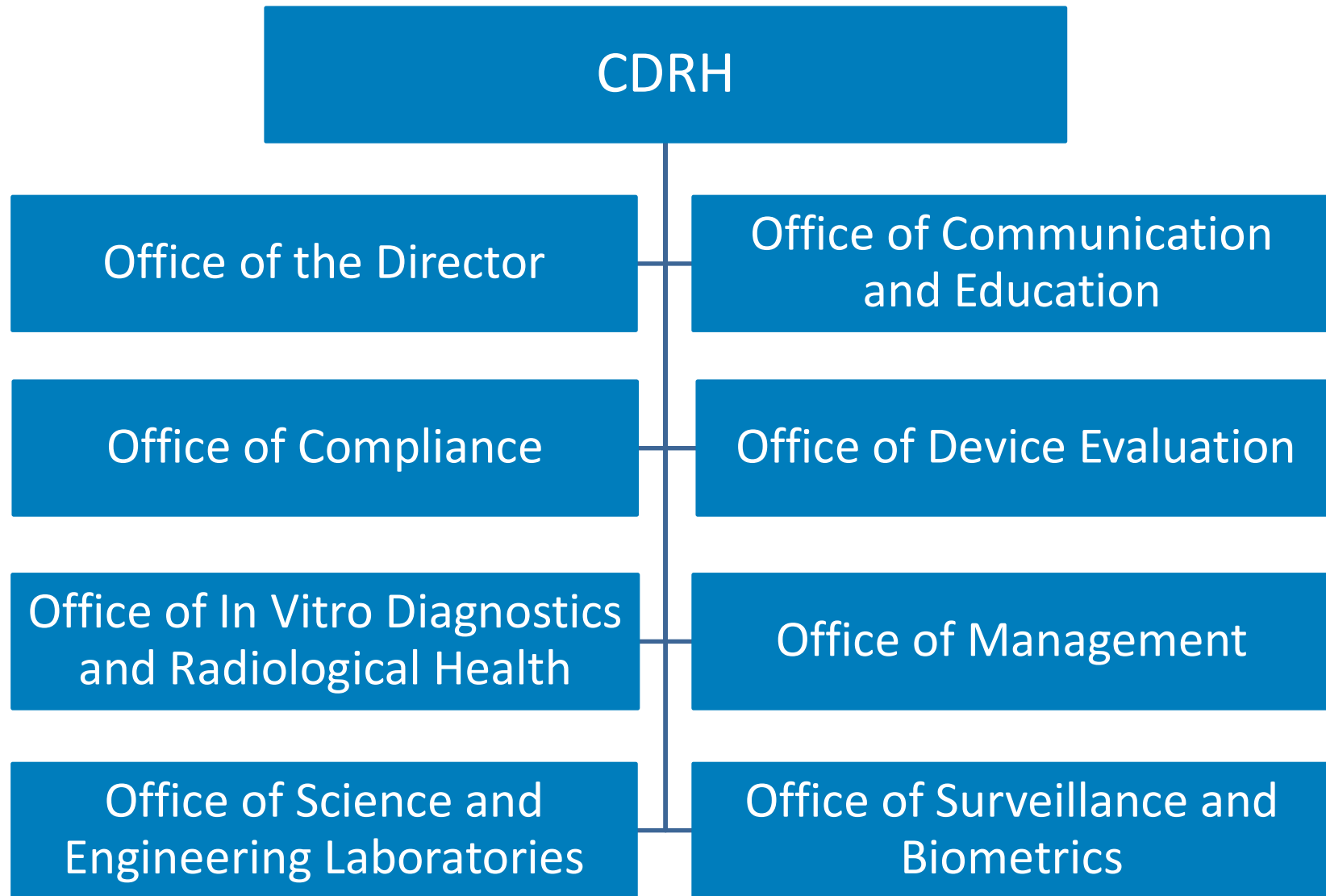
- Ensure process and policy consistency.
- Minimize organizational layers of review and facilitate employee professional development, to achieve more efficient work processes and allow employees to leverage their knowledge of pre- and post-market information to optimize decision-making.
- Allow for an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



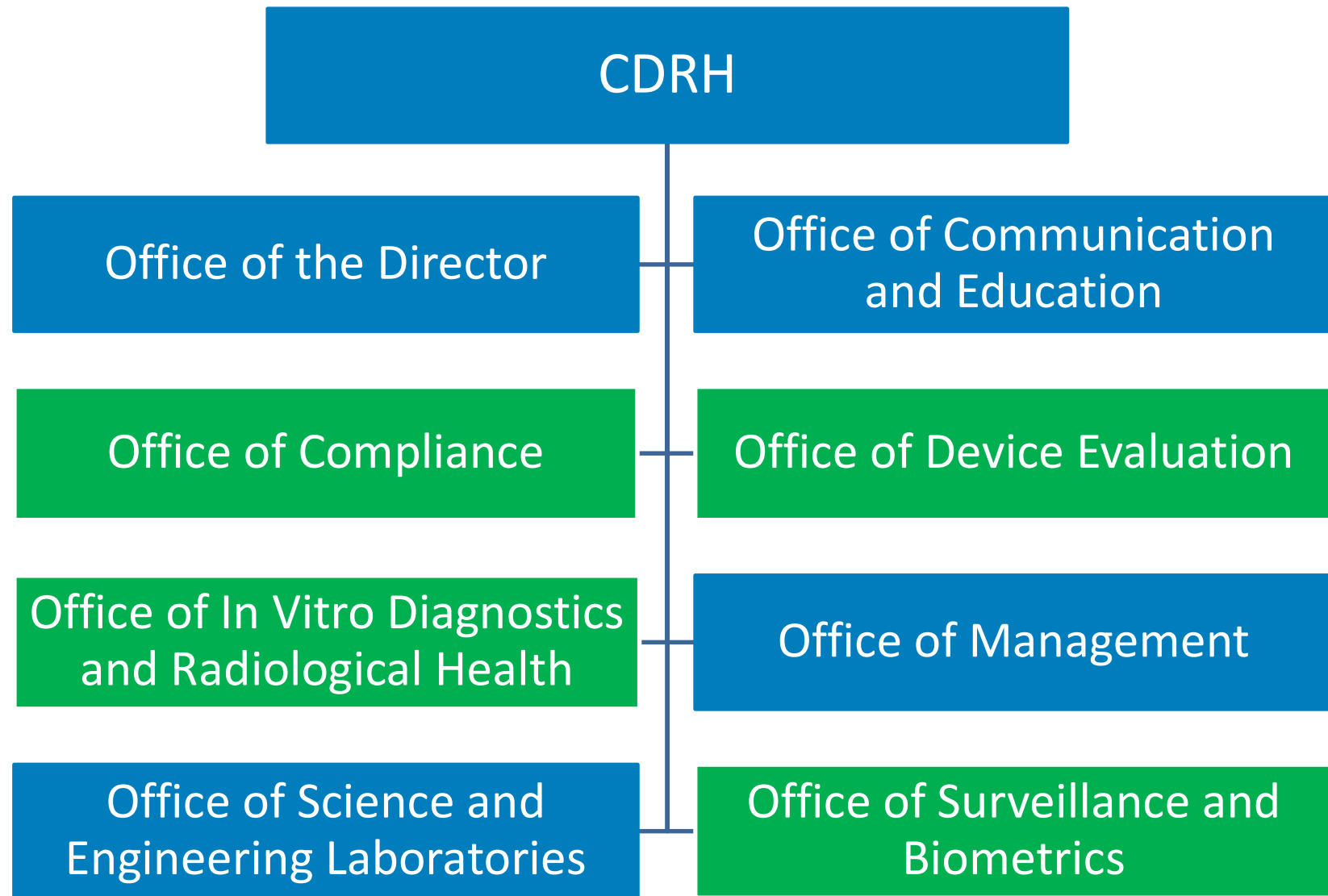
HOW WE ARE CHANGING

Current Structure

FDA



What Will Change



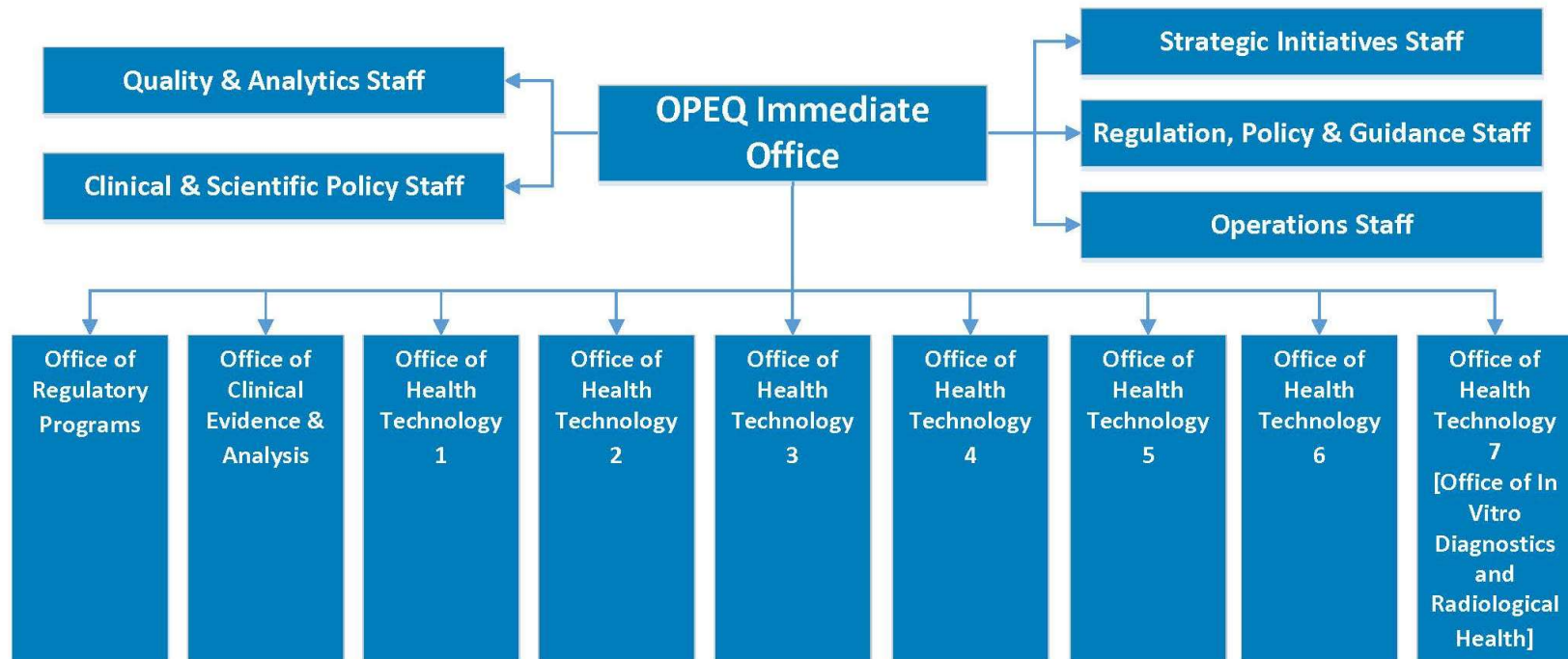
How Will These Offices Change

- Merging 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

Future Design

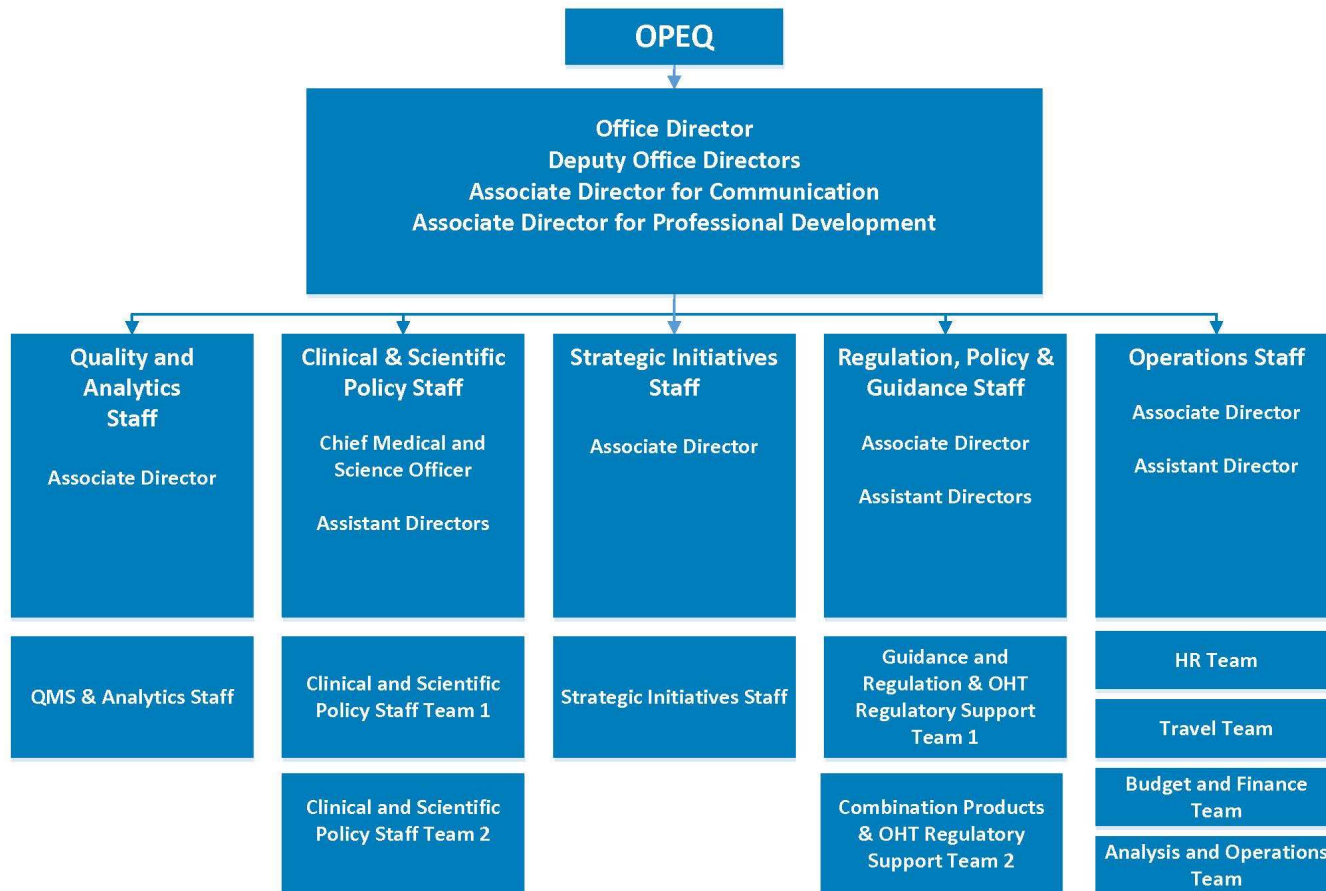
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Office of Product Evaluation and Quality (OPEQ)



Future Design

Office of Product Evaluation and Quality (OPEQ) Immediate Office



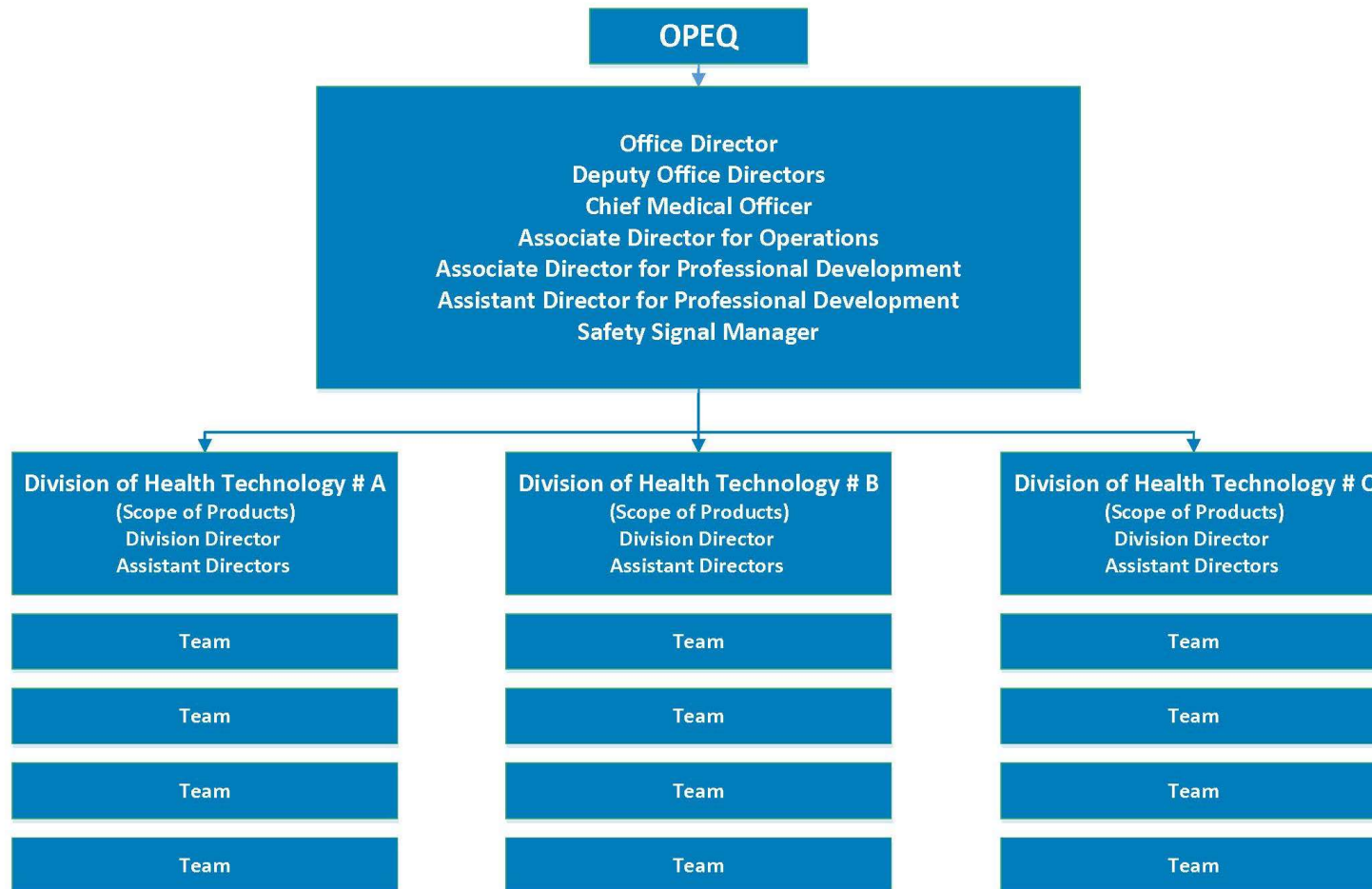


OPEQ Design Features

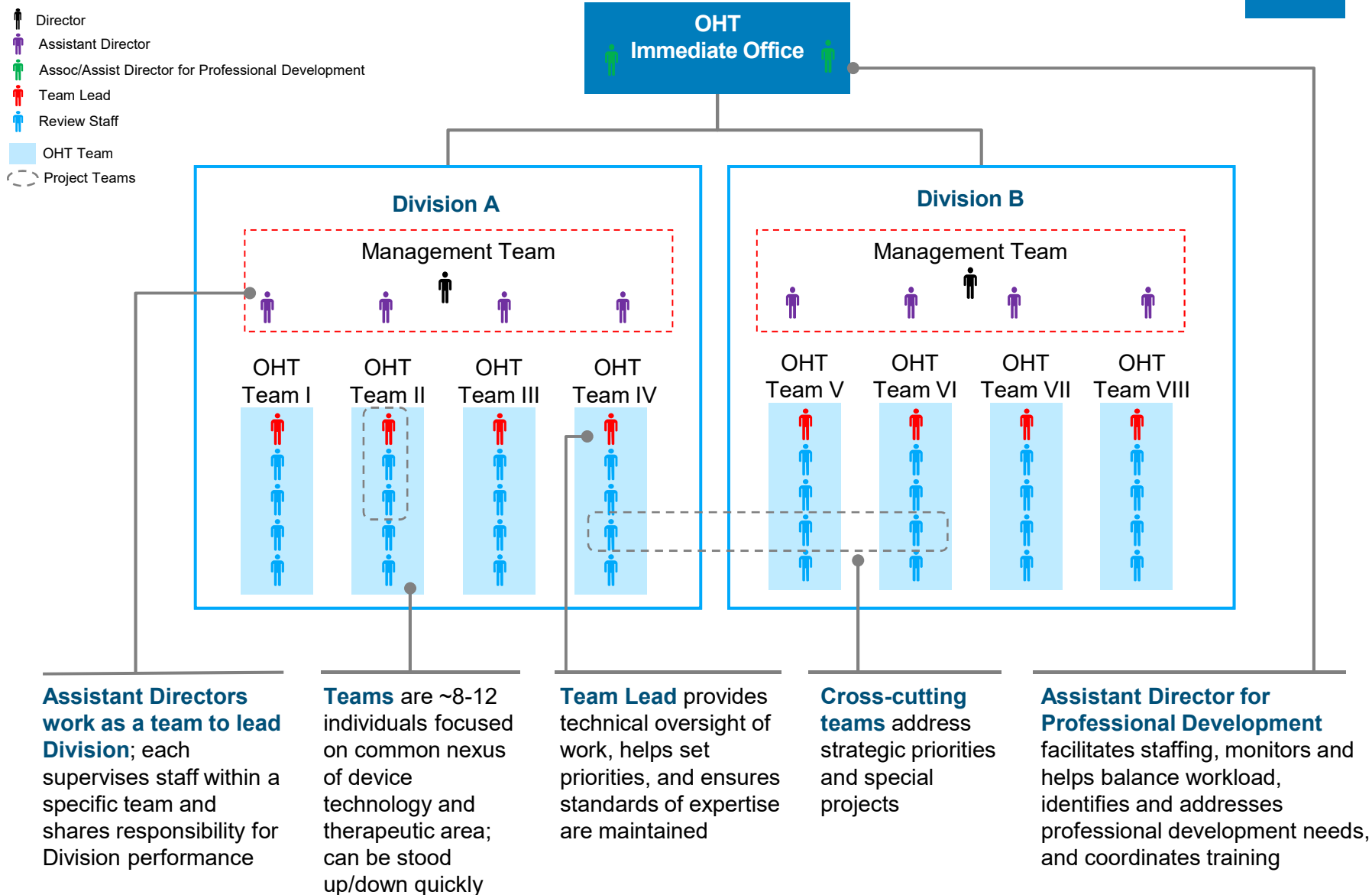
- Working in teams
 - Team management approach
 - Teams within and across divisions
- Common management chain for compliance, premarket and surveillance programs
- Division is the lowest organizational structure
- Empowering staff by driving decision-making to lowest appropriate level
- Emphasis on professional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

Future Design

Office of Health Technology # (OHT #: Scope of Products)



Future Team Design: OHTs



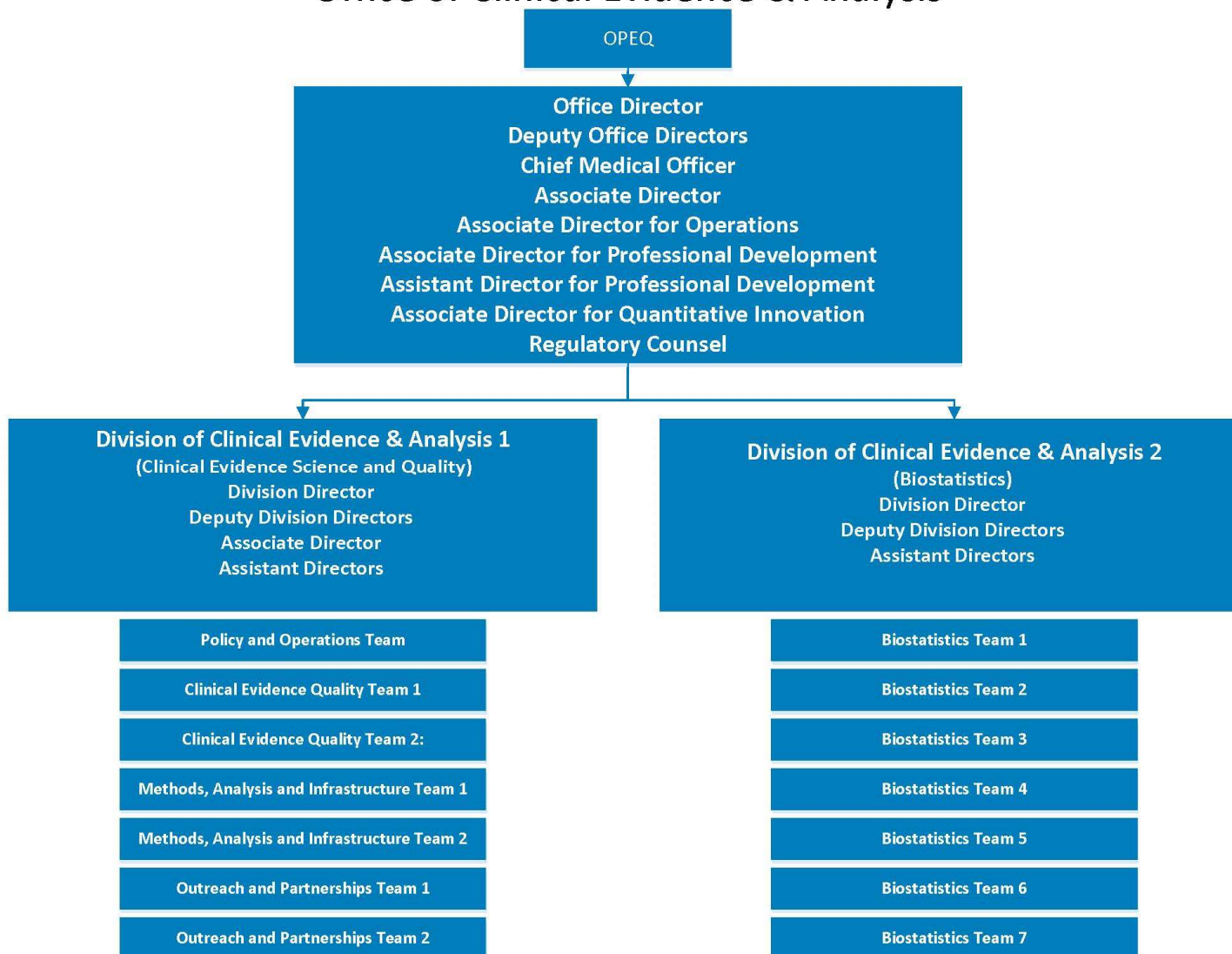
Future Product Specific Offices



OHT	Scope of Products within OHT	Office Director
OHT 1	Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices	Malvina Eydelman, M.D.
OHT 2	Cardiovascular Devices	Bram Zuckerman, M.D.
OHT 3	Reproductive, Gastro-Renal, Urological, General Hospital Device and Human Factors	Ben Fisher, Ph.D.
OHT 4	Surgical and Infection Control Devices	Binita Ashar, M.D.
OHT 5	Neurological and Physical Medicine Devices	Carlos Pena, Ph.D.
OHT6	Orthopedic Devices	Raquel Peat, Ph.D., MPH
OHT 7 /OIR	In Vitro Diagnostics and Radiological Health	Donald St. Pierre (Acting)

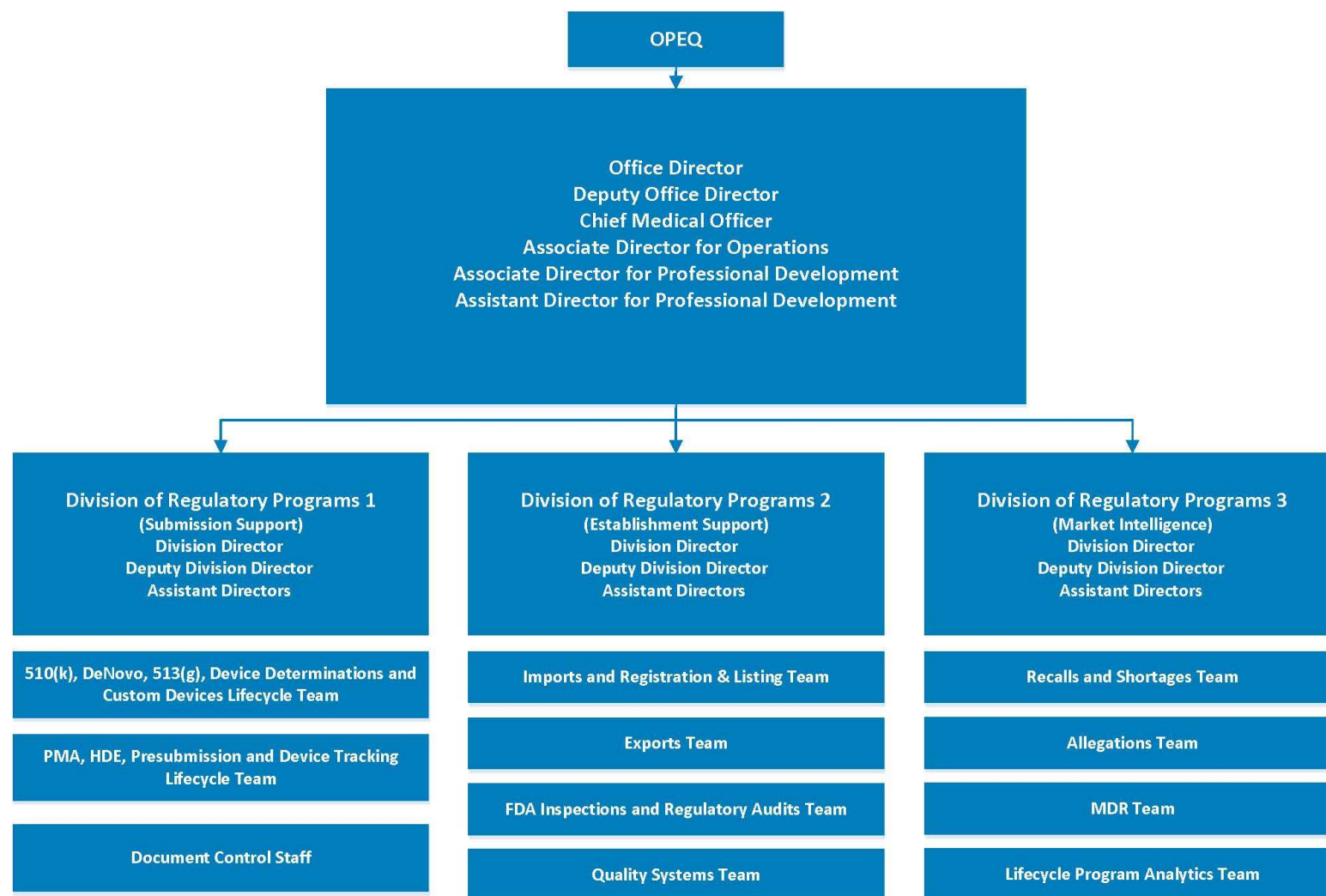
Future Design

Office of Clinical Evidence & Analysis



Future Design

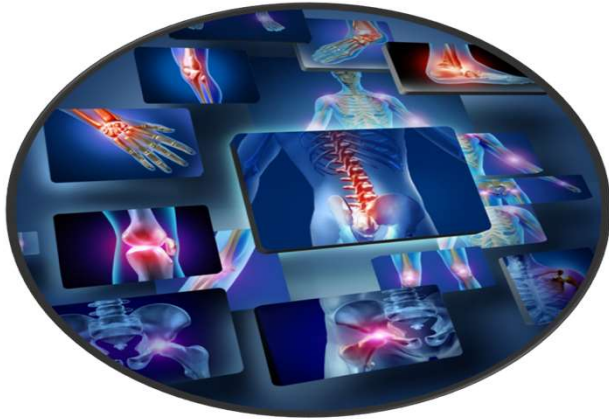
Office of Regulatory Programs



CAPT Raquel Peat, PhD, MPH- OSMA 2018



OFFICE OF HEALTH TECHNOLOGY 6



Future Design

Office of Health Technology 6
(OHT 6: Orthopedic Devices)



OHT 6 A focuses on Joint Arthroplasty Devices

Some examples of our products are shown below:

Knee Arthroplasty Devices

Partial Knee Arthroplasty



Total Knee Arthroplasty



Shoulder Arthroplasty Devices

Total Shoulder Arthroplasty



Reverse Total Shoulder Arthroplasty→



Hip Arthroplasty Devices

Total Hip Arthroplasty



Acetabular Shell Systems→



OHT 6 B focuses on Spinal Devices

Some examples of our products are shown below:

Intracolumnar Spinal Devices



← Intervertebral
Body Fusion Cages

Vertebral Body →
Replacements



← Total Disc Replacements

Extracolumnar Spinal Devices



← Pedicle Screw
Instrumentation

Anterior/Lateral →
Plates



← Spinous Process Plates



OHT 6 C focuses on Restorative, Repair and Trauma Devices

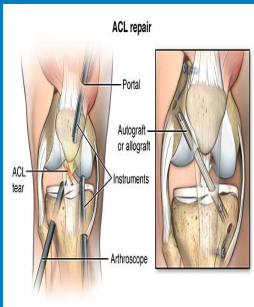
Some examples of our products are shown below:

Restorative, Repair, Trauma and Fracture Fixation Devices



← Bone Void Filler

Bone Cement →



Tendon and
← Ligament
Repair/Replacements

Fracture Fixation Devices →



Stereotaxic, Bone Growth Stimulators and Fracture Fixation Devices



← Stereotaxic
(Mako robot)

Bone Growth →
Stimulator



← Intramedullary rod, also
known as an intramedullary
nail (IM nail) or inter-
locking nail or
Küntscher nail (without
proximal or distal fixation)



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 OPEQ → easier for you to know what to expect
- Streamlining decision making → more informed interactions with CDRH staff
- Focus on professional growth and 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



NEXT STEPS



Next Steps

- Reorganization package
 - Under review; seeking approval in 2018
- People
 - Planning & conducting critical training
 - Hiring with the future in mind
- Processes
 - Develop core processes and procedures for OPEQ
 - Simplicity is our strategic priority



Next Steps

- Structure
 - IT changes to support reorganization
 - Piloting OPEQ structure as appropriate
- Will communicate with our customers to facilitate interactions with the redesigned CDRH

Please tell us what information is important for you to know during this transition.

CDRH Strategic Priorities

CDRH Strategic Priorities 2018-2020

Making Our Vision A Reality



The Strategic Priorities will focus on the enhancement and widespread application of three approaches we've already started.

Employee Engagement,
Opportunity, and Success

Simplicity

Collaborative Communities

Our Measure of Success

By December 31, 2020, more than 50 percent of manufacturers of novel technologies for the U.S. market intend to bring their devices to the U.S. first or in parallel with other major markets.

2018-2020 Strategic Priorities

Employee Engagement, Opportunity, and Success



- **Reduce unnecessary burdens**
- **Foster creativity and teamwork**
- **Facilitate open dialogue**
- **Promote an environment of trust and mutual respect**
- **Create opportunities for professional growth and personal development**
- **Provide a reasonable work life balance**

2018-2020 Strategic Priorities

Simplicity



- Continuous process improvement
- Streamline our policies, processes, programs, and approaches, as appropriate
- Stop doing or streamline what we determine is not sufficiently “value added”
- Remove unnecessary burdens (both on our stakeholders and ourselves)
- Spend more time on what matters most

2018-2020 Strategic Priorities

Collaborative Communities



- Forum where public and private sector members work together to solve both shared problems and problems unique to other members.
- An environment of trust and openness, where participants feel safe and respected to communicate their concerns.
- Members share a *collective responsibility* to help each other obtain what they need to be successful.

THANK YOU!



