Regulatory Education for Industry (REdI):
GENERIC DRUGS FORUM

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Overview of Office of Pharmaceutical Quality (OPQ)

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OPQ Mission & Vision

Mission

The Office of Pharmaceutical Quality assures that quality medicines are available to the American public

Vision

The Office of Pharmaceutical Quality will be a global benchmark for regulation of pharmaceutical quality

Motto

One Quality Voice

Why OPQ?

- **Single unit in CDER dedicated to product quality**
  - Across all drug products (new, generic, OTC)
  - Across all sites of manufacture (domestic and foreign)
- **"One quality voice" oversight throughout the lifecycle of a drug product**
  - Integrates review, inspection, surveillance, policy and research
  - Spans pre- and post-approval for new and generic drugs
  - Strengthens pharmaceutical quality on a global scale

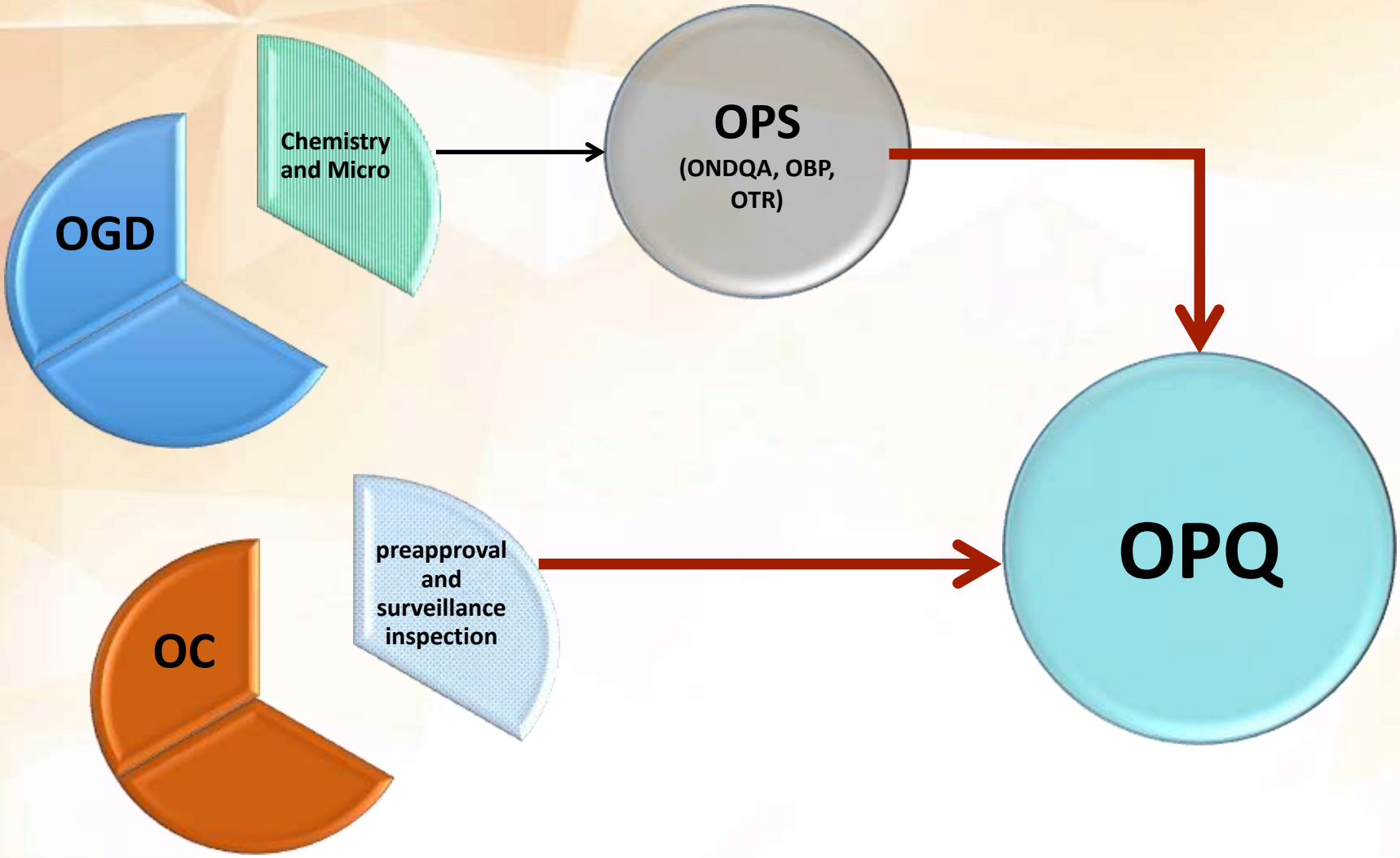
OPQ Value Statements

- **Put patients first by balancing risk and availability**
- **Have one quality voice by integrating review and inspection across product lifecycle**
- **Safeguard clinical performance by establishing scientifically-sound quality standards**
- **Maximize focus and efficiency by applying risk-based approaches**
- **Strengthen the effectiveness of lifecycle quality evaluations by using team-based processes**

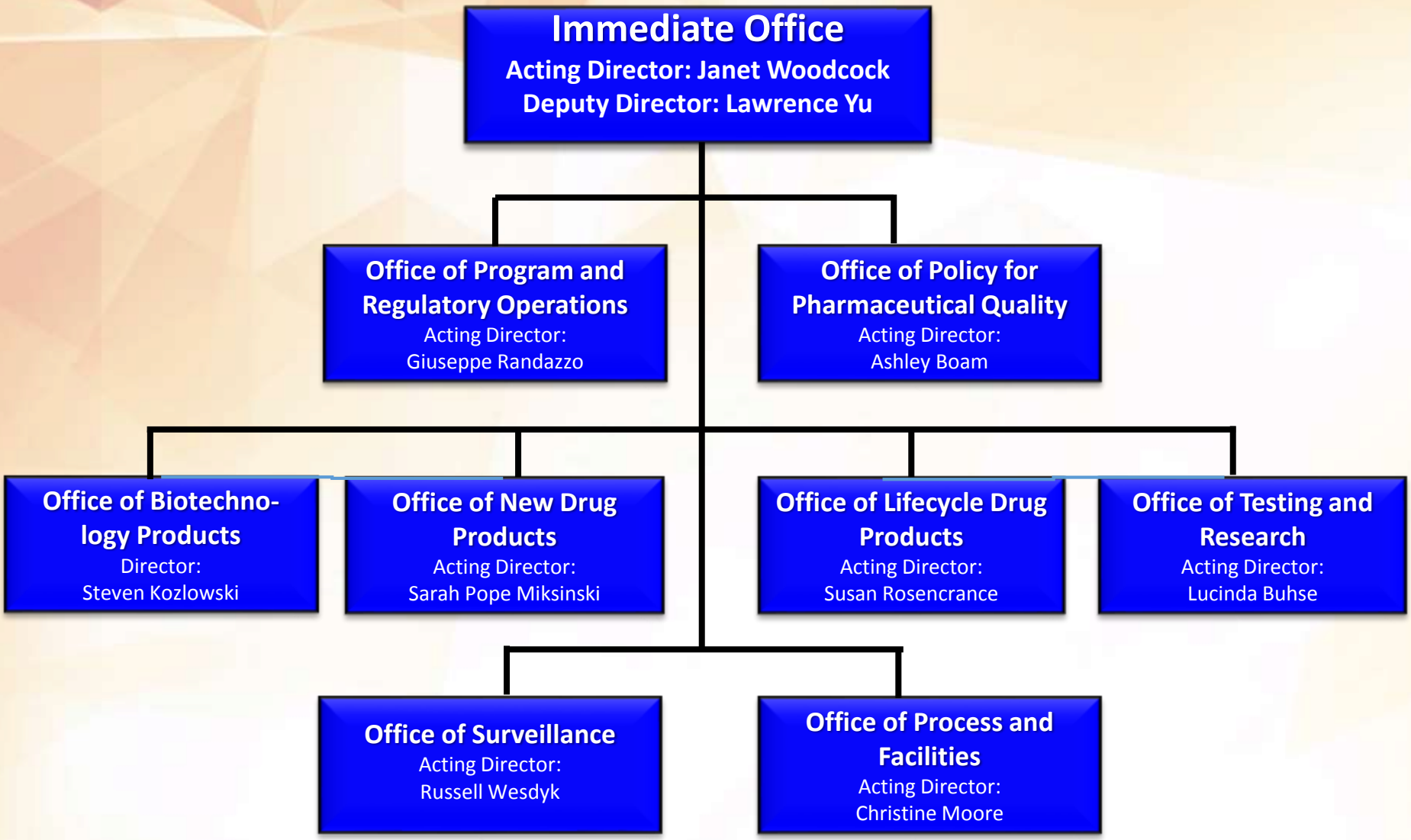
OPQ Value Statements (cont.)

- Enhance quality regulation by developing and utilizing staff expertise
- Encourage innovation by advancing new technology and manufacturing science
- Provide effective leadership by emphasizing cross-disciplinary interaction, shared accountability, and joint problem solving
- Build collaborative relationships by communicating openly, honestly, and directly

How OPQ was formed?



OPQ Organization



OPQ Objectives

1. Assure that all human drugs meet the same quality standards to safeguard clinical performance

2. Enhance science- and risk-based regulatory approaches

3. Transform product quality oversight from a qualitative to a quantitative and expertise-based assessment

4. Provide seamless integration of review, inspection, surveillance, and research across the product lifecycle

5. Encourage development and adoption of emerging pharmaceutical technology

1. Assuring that All Human Drugs Meet the Same Quality Standards to Safeguard Clinical Performance

- **Same quality standards for new and generic drugs**
  - Impurities
  - Dissolution
- **Clinically relevant specification**
  - Connect quality to safety and efficacy
  - Maintain quality by establishing acceptance criteria based on clinical relevance, instead of process capability or manufacturing process control

2. Enhancing Science- and Risk-based Regulatory Approaches

- **Put patients first by balancing risk and availability**
- **Implement risk-based approaches**
  - Review
  - Inspection
- **Advance regulatory science**
  - OBP and OTR laboratory research
  - FDA sponsored research
  - Additional regulatory science effort

3. Transforming Product Quality Oversight from a Qualitative to a Quantitative and Expertise-based Assessment

- Comprehensive QOS and question-based review
- Product quality informatics
- Quality metrics
- Question-based inspection and evaluation (NIPP)
- Integrated quality assessment (IQA)

Product Quality Informatics

- Enables an efficient science-driven assessment that requires significant transformation in how OPQ collects, evaluates, and learns from the product quality data submitted to FDA

- Core areas of Product Quality Informatics:
  - ➢Structured data submission and collection
  - ➢Knowledge management and communication
    - ✓Established standards for approval
    - ✓Risk mitigation
  - ➢Post-market surveillance and quality monitoring
  - ➢Intelligent data analysis

Quality Metrics

- Objective measures of:
  - Quality of a drug product
  - Quality of a facility
  - Effectiveness of systems associated with the manufacture of pharmaceutical products
- Induce the right behavior and responsibility for industry → better FDA surveillance of the firms' quality state
- Reduce product-related shortages and quality related recalls → promote improved product and process capability
- Achieve product quality without extensive regulatory oversight

New Inspection Protocol Project (NIPP)

- New paradigm for inspections and reports that will advance pharmaceutical quality
  - Standardized approach to inspection
  - Data gathering to inform “quality intelligence” of sites and products
  - Risk based and rule based process using expert questions
  - Semi-quantitative scoring to allow for comparisons within and between sites
  - More common inspection report structure
  - Positive behaviors recognized and rewarded when facilities exceed basic compliance

4. Providing Seamless Integration of Review, Inspection, Surveillance, and Research

- Team-based integrated quality assessment (IQA)
- Lifecycle management
- New inspection protocol project (NIPP)
- Quality metrics
- FDA lab-based surveillance
- Program alignment across FDA

Team Based Integrated Quality Assessment (IQA)

- Maximizes each team member's expertise
- Provides aligned patient-focused and risk-based drug product quality recommendations, inclusive of drug substance, drug product, manufacturing, and facilities
- OPQ teams
  - ➢Are highly collaborative
  - ➢Work effectively within timelines
  - ➢Discuss/Communicate with key stakeholders

  **Discussions on quality risk and link to the patient are critical.

Team Based Integrated Quality Assessment (IQA) (cont.)

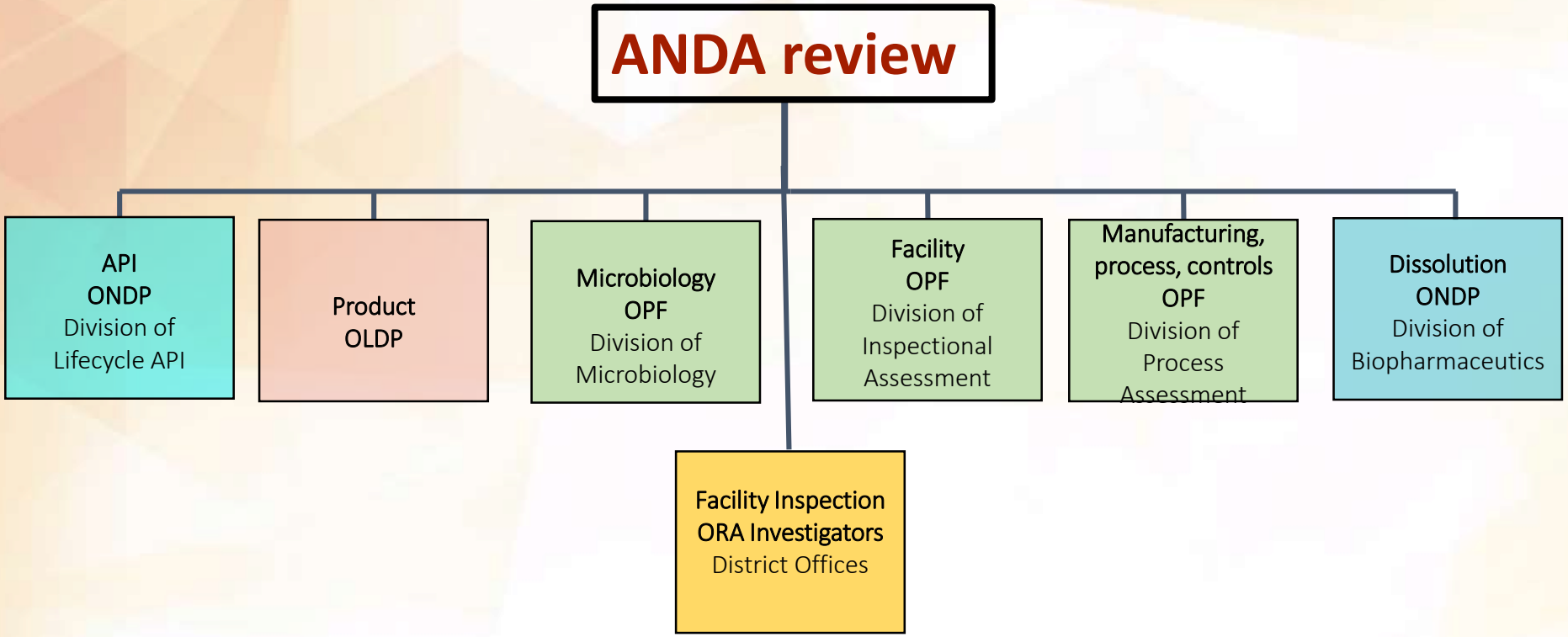
Quality Review Functions for ANDAs and Lifecycle Management

- Matrixed across OPQ, with the regulatory lead located in the Office of Lifecycle Drug Products (OLDP)
  - Drug substance and Biopharmaceutics review in ONDP
  - Process and facility review and microbiology in OPF
  - Post-marketing functions in OLDP – responsible for monitoring the lifecycle of NDA (post year 3 for NMEs and post year 1 for non-NMEs) and ANDA drug products

ANDA Integrated Quality Assessment (IQA) Team

- Application technical lead (ATL/OLDP)
  - Responsible for overseeing the scientific content of the assessment
- Regulatory business process manager (RBPM)
  - Responsible for process and timeline
- Discipline reviewers
  - Drug substance, drug product, process, facility, microbiology, biopharmaceutics, and Office of Regulatory Affairs (ORA) investigators
- Other members (as needed)
  - FDA laboratories (e.g., Office of Testing and Research), policy, surveillance, and other offices

ANDA Integrated Quality Assessment (IQA) Team within OPQ



Advantages of ANDA Integrated Quality Assessment (IQA)

- Knowledge management across offices
- Uniform quality standards and parity of oversight to both brand and generic drug products
- Lifecycle management
- Enhanced staff communication and collaboration

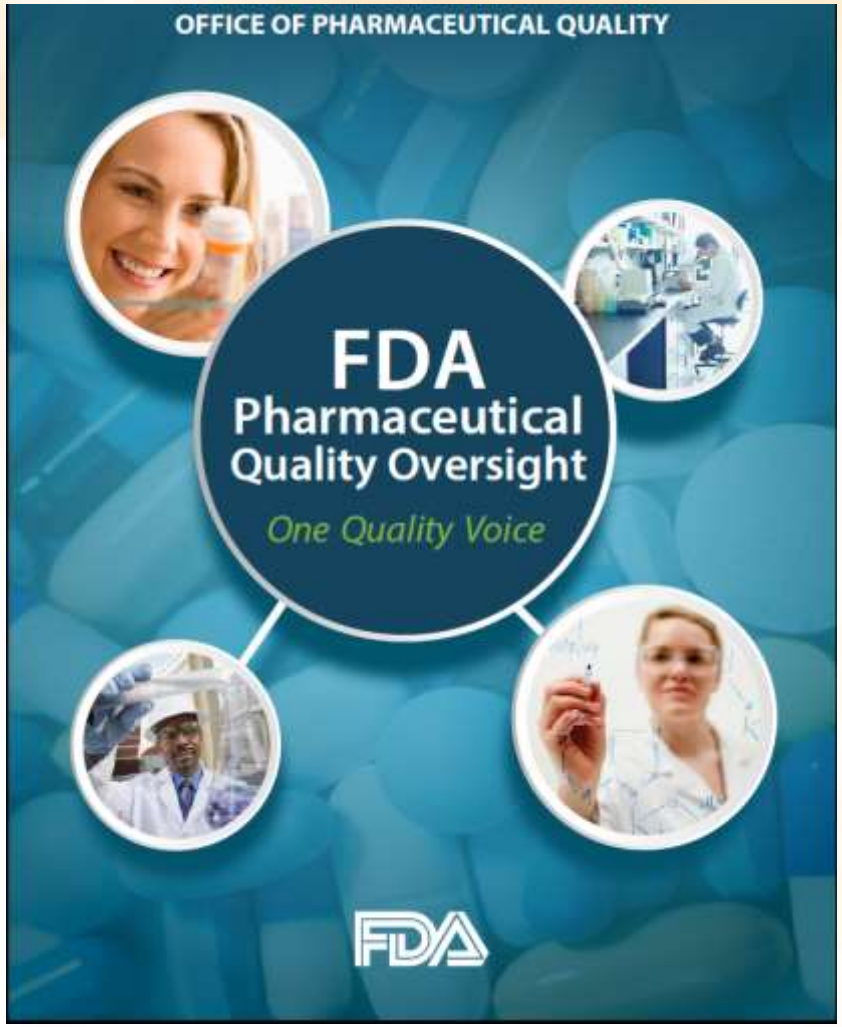
5. Encouraging Development and Adoption of Emerging Technology

- Emerging pharmaceutical technology team
- Emerging pharmaceutical technology guidance
- Continuous manufacturing
  - Sponsored research
  - Published scientific review
  - Planned FDA Science Board presentation
  - Policy

Acknowledgements

- Lawrence Yu
- Christine Moore
- Susan Rosencrance
- Sarah Pope Miksinski

White paper recently published on FDA website:



FDA Pharmaceutical Quality Oversight: One Quality Voice

Questions?

Evaluation: surveymonkey.com/s/GDF-D1S3