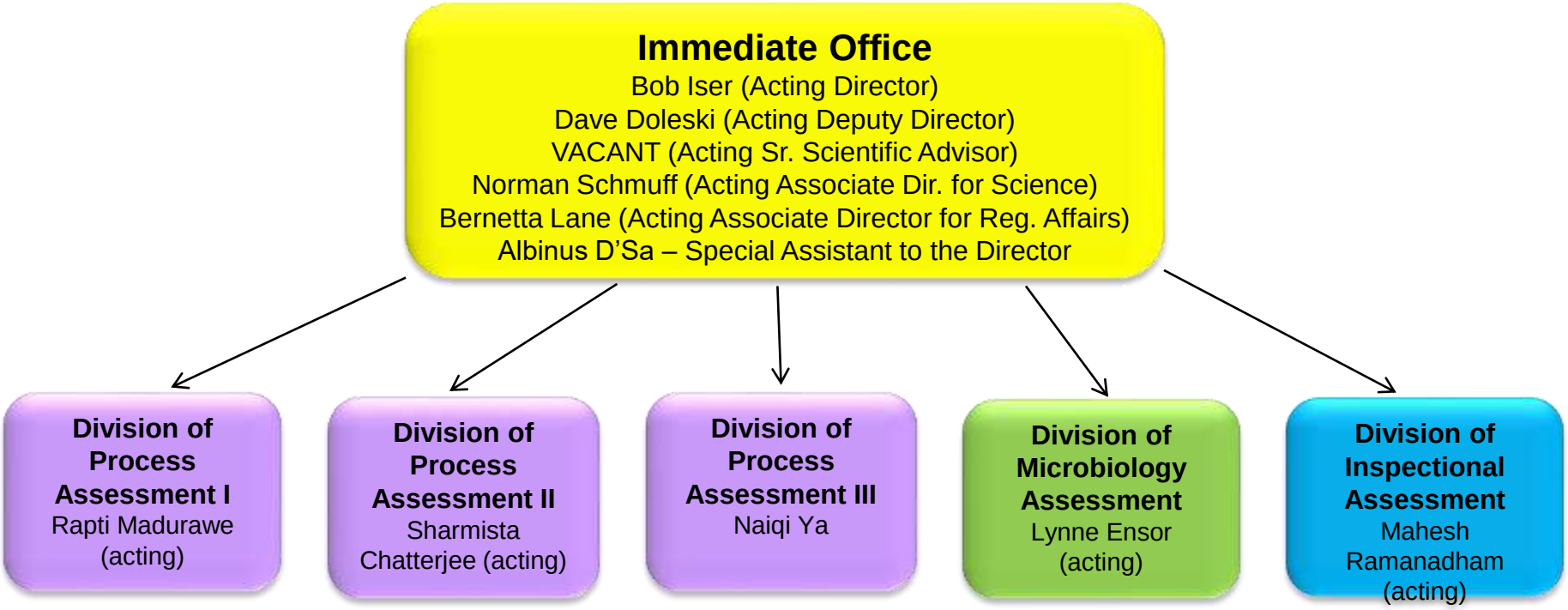
Introduction to the Office of Process and Facilities

Robert Iser, M. S.
Acting Director
Office of Process & Facilities
CDER/OPQ

SBIA Pharmaceutical Quality Symposium
July 20-21, 2016

Office of Process and Facilities (OPF)



Process Assessment Divisions I, II, III:

- 6 branches solid drug products
- 2 branches for liquid drug products
- 1 branch for complex drug substances

Microbiology Division:

- 3 branches for sterile small molecule drug product and substance
- 1 branch for biotech drug substance and product

Inspectional Assessment Division:

- 3 branches
- Mixed product and application types

VISION

To be the premier global regulatory organization for holistic assessment of pharmaceutical manufacturing

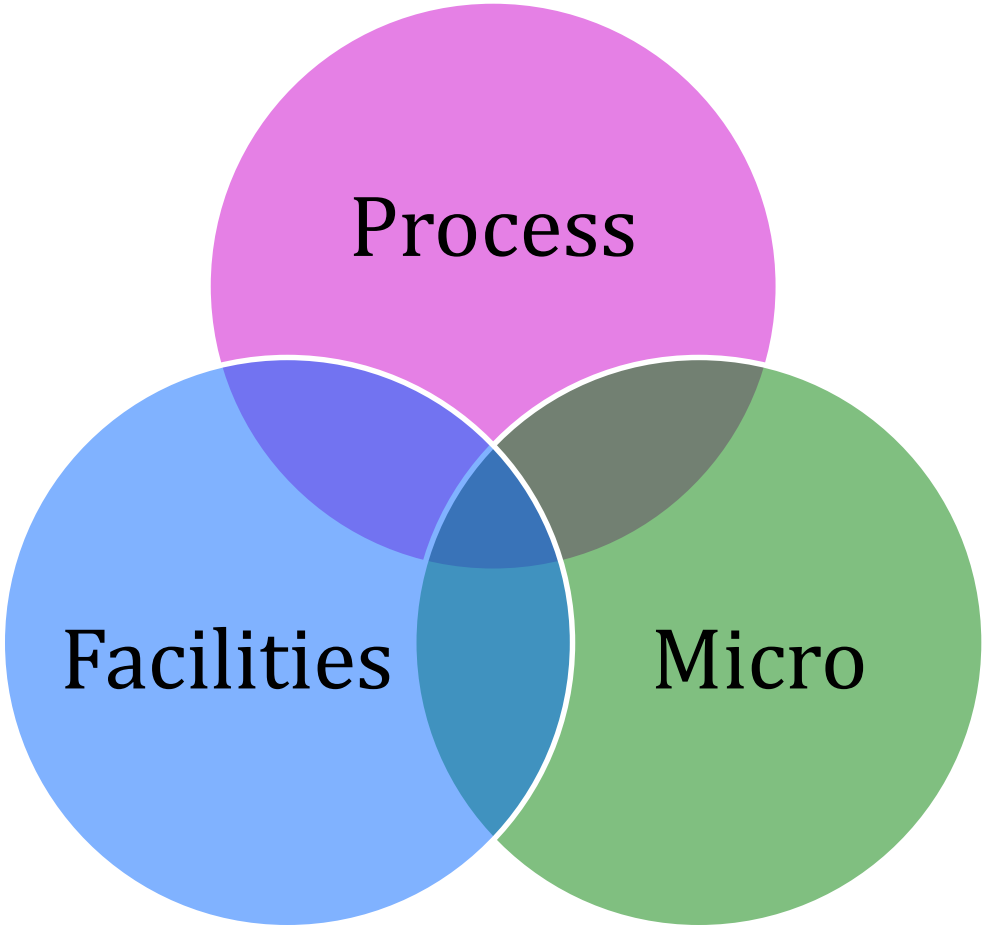
MISSION

OPF assures that quality pharmaceuticals are consistently manufactured over the product lifecycle

Why OPF?

- OPF has been designed with the necessary specialization and expertise to provide oversight to assessment of pharmaceutical manufacturing
- Traditionally, manufacturing process review has been isolated from pre-approval inspections
- A higher degree of integration between ORA and CDER is needed to deal with current challenges (e.g., emerging technologies, prioritization of medically necessary products, etc.)
- Manufacturing technologies are becoming more complex and are critical to drug product quality

OPF "Holistic Assessment"



OPF Holistic Assessment

OPF effectively and efficiently leverages its complementary expertise in process engineering and controls, quality microbiology, facility aspects and CGMPs, in the assessment of all manufacturing aspects of regulatory submissions in order to provide consistent and comprehensive approvability decisions over the product lifecycle.

Enablers

- Robust training programs
- Agreed upon quality assessment standards
- Processes and procedures that clearly link our assessment to risk
- Open and seamless communication within OPF and with our stakeholders
- Full awareness of issues related to and impacting OPF assessment roles
- Decisions that are data driven and based in current science
- Transfer of knowledge over the product lifecycle (and over the entire supply chain)

Three Disciplines – One Mission

Microbiology Assessment Division:

- Evaluates manufacturing process and facility aspects with regard to sterility assurance for all sterile drug substances and drug products in all NDAs, ANDAs and BLAs and their supplements, INDs and meeting packages
- Perform assessment of microbial controls for sterile drug substances, drug products and products components, as appropriate
- Perform microbiology assessment for other products on an as-needed or request basis

Three Disciplines – One Mission

Inspectional Assessment Division:

- Evaluates the need for pre-approval inspections (PAI) for facilities proposed in **all** ANDAs, NDAs, BLAs and certain supplements
- Make final site recommendation (Acceptable, Withhold) based on inspection team recommendation, available facility information, and data submitted to an application
- Evaluate PAI establishment inspection reports

Three Disciplines – One Mission

Process Assessment Divisions:

- Conducts manufacturing process reviews for drug products for ANDAs and NDAs, for some supplements, INDs and meeting packages, on an as-needed or request basis
- Evaluates drug substance processes for complex drug substances or complex drug substance manufacturing processes

Integrated Quality Assessment (IQA)

- IQA team will provide an aligned, patient-focused and risk-based drug product quality recommendations for BLAs, NDAs, and ANDAs, inclusive of drug substance, drug product, manufacturing, and facilities.
- **IQA Teams consist of:**
  - Application Technical Lead (ATL)
  - Regulatory Business Process Manager (RBPM)
  - Discipline Reviewers (includes OPF & ORA)
  - Advisors - Lab (OTR), Policy (OPPQ), Surveillance (OS), etc.

IQA Team Roles

Role / Task	Responsible*
Scientific Content / Initial Risk Assessment	ATL / IQA Team
Process and Timeline	RBPM
IQA Executive Summary	ATL / IQA Team
Assessment of Drug Substance / DMF	DS/DP Reviewer
Assessment of Drug Product	DP Reviewer
Assessment of the Manufacturing Process	Process Reviewer
Assessment of Facilities	Could be one person
Assessment of Biopharmaceutics	Bio pharm Reviewer
Assessment of Microbiology	Micro Reviewer
Assessment of Environmental Analysis	EA reviewer
Labeling & Package Insert	DP Reviewer
PAI Inspections	ORA Lead / SMEs participate
Lifecycle Knowledge Management	ATL/ IQA Team

* Represents General Cases

PAIs and the IQA team

- A PAI is part of the overall quality assessment performed by the Integrated Quality Assessment (IQA) team
- IQA team members (ORA, OPF, others) share knowledge (e.g., KTMs) and/or participate on PAI
- Communication during inspection to resolve overlapping quality assessment/cGMP issues
- Inspection findings are fed back to IQA team


Office of Lifecycle Drug Products
Office of New Drug Products
Office of Biotech Products
Office of Regulatory Affairs
Office of Compliance
Office of Surveillance
Office of Testing and Research
Office of Policy for Pharm Quality
Office of Program and Regulatory Operations
and Facilities
One Quality Voice

Thank you for your attention!

Please evaluate this session:

surveymonkey.com/r/PQS-D1S2

Questions will be addressed during the Q&A Panel coming shortly.

Additional Questions: CDER-OPQ-Inquiries@fda.hhs.gov