



*Office of In Vitro Diagnostic
Device Evaluation and Safety*

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FDA/CDRH/OIVD**



Topics of Discussion

- **New office (what is different)**
 - **Structure**
 - **Goals**
 - **What have we done so far**
- **In-process items of interest**



How are we Structured

- **Established – November 2002**
- **Single Organizational Unit**
- **Premarket/Compliance/Postmarket**
- **One Stop Shopping to better serve all stakeholders**

Who's who

- **Director, OIVD – Steve Gutman**
 - Deputy Director – Don St,Pierre
- **3 Divisions**
 - Chemistry & Toxicology (Jean Cooper)
 - Immunology & Hematology (Josie Bautista)
 - Microbiology (Freddie Poole)
- **Number of vacant/acting positions**

Office Goals

- **Increase Transparency**
- **Uniform Least Burdensome Approach**
- **Expedite Technology Transfer**
- **Improve Connectivity & Quality of Work**
- **Knowledge & Understanding are Key**

What have we done

- IVD webpage
 - Move to more education (lab safety tip)
 - <http://www.fda.gov/cdrh/oivd/index.html>
- Standardized review format
 - Move to posting for transparency
- Patient safety team
 - Looking for new ways to identify and resolve problems
 - Active surveillance

In the works

- **Posting FDA review summaries and labeling, if possible**
- **Shift from premarket to quality systems**
- **Open ASR rule - NPRM**
 - Rethink basic tenets
 - Expand authorities -- risk based approach
 - Address level playing field arguments
- **Drafting multiplex testing guidance**