Overview of the OQS Drug Quality Sampling and Testing (DQST) Program

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Overview

- OQS Vision and Mission
- DQST Program
- Types of Sampling and Testing Assignments
- DQST Risk-Based Assessment Process
- DQST Key Collaborators
- DQST Chem and Micro Testing Selection
- Future Goals

OQS Vision and Mission

Vision	To be the global benchmark for pharmaceutical quality surveillance
Mission	OQS turns intelligence into insights and actions to promote the availability of quality medicines for the American public.

Sleuths for Drug Quality!

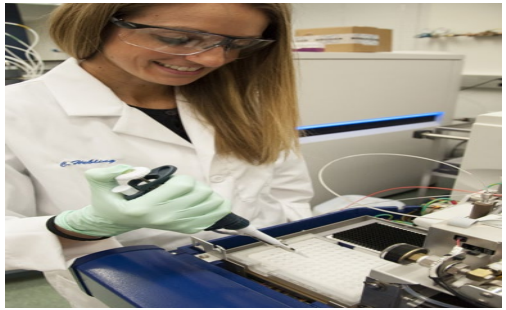
OQS leverages pharmaceutical intelligence, knowledge of GMP regulations/guidance, and analytics to help the Office of Pharmaceutical Quality (OPQ) assure drug quality and availability:

- Surveil quality throughout the product lifecycle
- Understand and model pharmaceutical supply chains
- Advance the science of quality surveillance
- Promote industry adoption of mature quality management practices

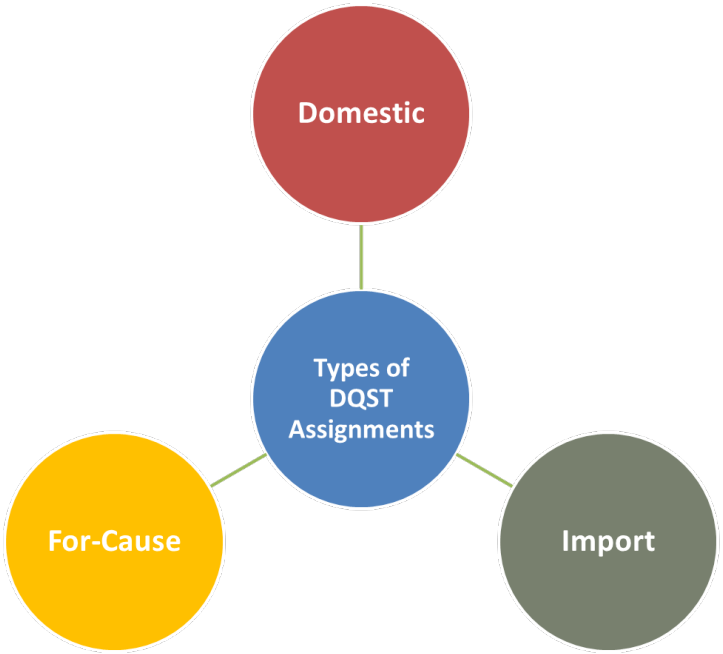
Drug Quality Sampling and Testing Program (DQST)

The DQST program is an integral part of the FDA's post-market surveillance program. DQST covers prescription drug products, over-the-counter drug products, and active pharmaceutical ingredients. It includes domestic and foreign manufacturers for products distributed in the U.S market.

The objective of the DQST program is to assess drug product quality through a risk-based sampling and testing assignments to aid the detection of drug substances and drug products that may pose quality and safety risks to the U.S patients and consumers.



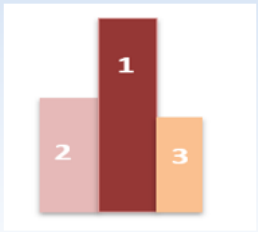
Types of Sampling and Testing Assignments



1. **Domestic Sampling & Testing**
   - Samples collected in the U.S.
   - Identified from risk-based assessment.
2. **Import Sampling & Testing**
   - Samples collected at the port of entry.
   - Identified from risk-based assessment.
3. **For-Cause Sampling & Testing**
   - Targets products and/or firms based on known or potential significant public health risks.

DQST Risk-Based Assessment Process

STEP 1a
Firm Assessment



Assess firms based on historical inspection outcomes, products manufactured, and other risk factors.

STEP 1b
Shipment Assessment (Foreign Firms)

FDA Import Alerts

Assess shipment patterns and status of Import alerts

Firm Ranking

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STEP 2
Evaluation of Postmarket Reports

Evaluate postmarket quality reports for defects, signals, and trends

STEP 3
Recall & Drug Shortage Assessment

FDA Recalls
Drug Shortages

Assess FDA databases for recalls and drug shortages to identify products of interest and confirm the effectiveness of corrective actions.

Product Ranking

DQST Key Collaborators

Quality Signal Contributors	Sample Collection	Sample Testing
OPQ Sub-Offices (OLDP, OPMA, etc.)	Office of Regulatory Affairs (ORA)	Office of Regulatory Science (ORS/ORA)
Office of Compliance	Office of Drug Security, Integrity, and Response (ODSIR/CDER/OC)	Office of Testing and Research (OTR/OPQ)
Office of Generic Drugs		
Office of New Drugs		
Consumer Complaints		

DQST Chem and Micro Testing Selection

The testing selection is based on quality defect signals identified during the risk-based assessment.

Standard product quality performance tests and/or specific tests for chemistry and microbiology selected for each of the product are from USP-NF monographs and/or USP general chapters.

In the absence of the USP monographs the firm's test methods are selected or a validated test method is used.

FDA also can conduct more specialized testing if needed.

Future Goals for the DQST Program

- Further enhance and streamline triage process for quality defect signals.
- Incorporate additional data pipelines to make better informed firm and product selections.
- Further develop algorithms to detect quality defect signals occurring in the market.

DQST Website

- FDA annually publishes test results from the DQST program:
  - CDER Drug Quality Sampling and Testing website

U.S. FOOD & DRUG ADMINISTRATION

Questions?

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