

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

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Pharmaceutical Quality Symposium 2023 – Nov 1st, 2023

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)

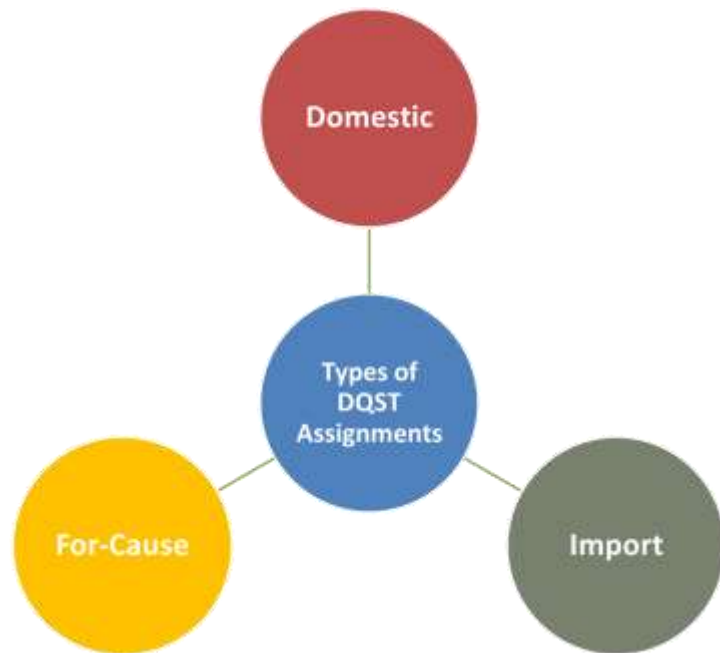


The DQST program is an integral part of the FDA's post-market surveillance program. DQST covers prescription drug products, over-the-counter drug products, and active pharmaceutical ingredients. It includes domestic and foreign manufacturers for products distributed in the U.S market.

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.

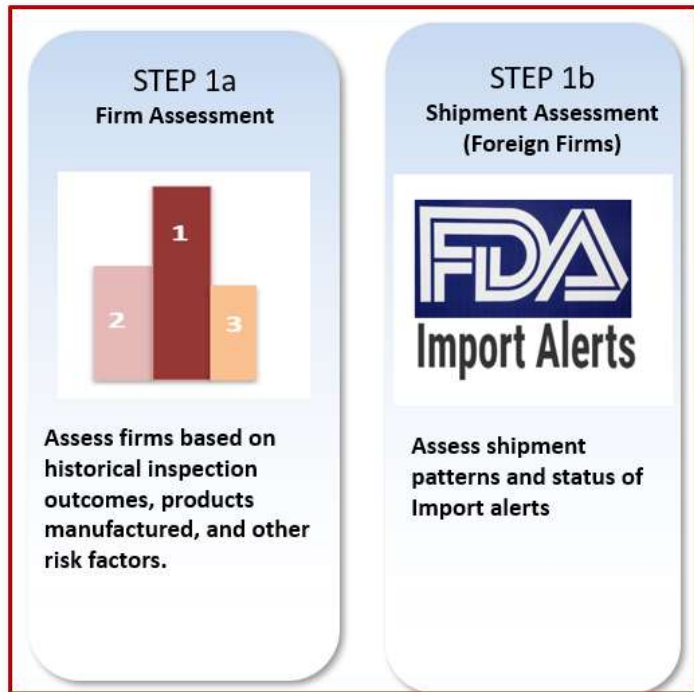
2. Import Sampling & Testing

- Samples collected at the port of entry.
- Identified from risk-based assessment.

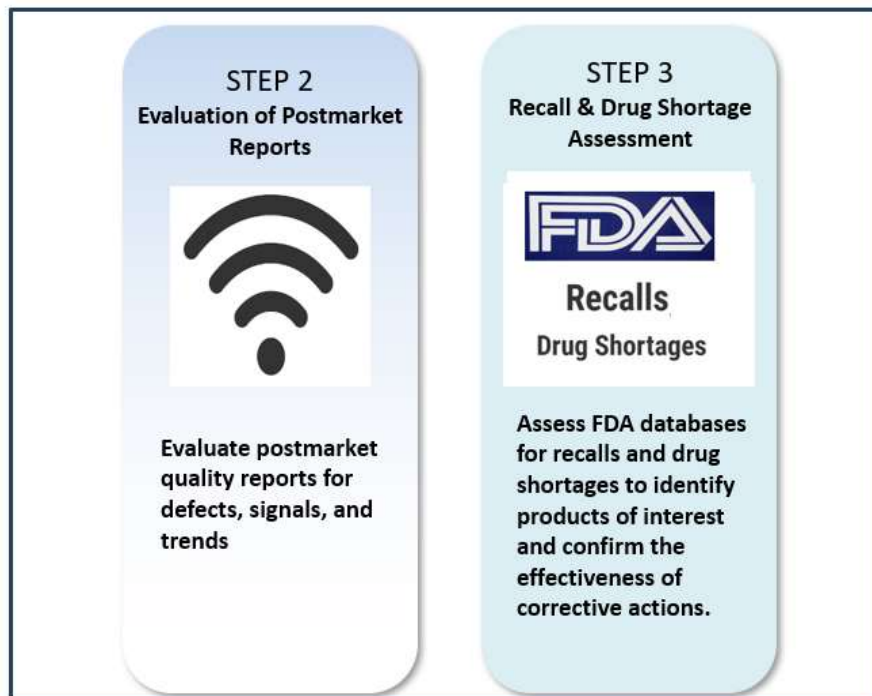
3. For-Cause Sampling & Testing

- Targets products and/or firms based on known or potential significant public health risks.

DQST Risk-Based Assessment Process



Firm Ranking



Product Ranking

DQST Key Collaborators

Quality Signal Contributors

OPQ Sub-Offices (OLDP, OPMA, etc.)

Office of Compliance

Office of Generic Drugs

Office of New Drugs

Consumer Complaints

Sample Collection

Office of Regulatory Affairs (ORA)

Office of Drug Security, Integrity, and
Response (ODSIR/CDER/OC)

Sample Testing

Office of Regulatory Science
(ORS/ORA)

Office of Testing and Research
(OTR/OPQ)



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

Home / Drugs / Science and Research / Drugs / Drug Quality Sampling and Testing Programs

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Regulated Product(s): Drugs



Drug Quality Sampling and Testing Program

FDA's requirements for [approval of new](#) and [generic drugs](#) and biologics are among the highest standards across the globe. Prior to FDA approval, manufacturers must prove that their products are high quality, safe, effective, and free of contamination and defects. In addition, manufacturers of non-application products,

Learn about CDER's regulatory science programs of research.

[Learn More](#)

- FDA annually publishes test results from the DQST program:
 - [CDER Drug Quality Sampling and Testing website](#)

Questions?

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