



Stop TB Partnership
GLOBAL DRUG
FACILITY



THE GDF QUALITY MONITORING PROGRAM (QMP)

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ACRONYMS

CoA	Certificate of Analysis
CoC	Certificate of Conformity
CRF	Clean Report of Findings
DP	Direct Procurement
EMA	European Medicines Agency
ERP	Expert Review Panel
FLM	First Line antituberculosis Medicines
FPP	Finished Pharmaceutical Product
GDF	Global Drug Facility
GDF QA	Global Drug Facility Quality Assurance (team)
GDP	Good Distribution Practice
GHTF	Global Harmonization Task Force on Medical Devices
GMP	Good Manufacturing Practice
GLP	Good Laboratory Practice
GSP	Good Storage Practice
ICH	International Conference on Harmonization
ISO	International Organization for Standardization
IMDRF	International Medical Device Regulators Forum
IVD	In-Vitro Diagnostics
MD	Medical Device
MT	Method Transfer
NRA	National Regulatory Authority
OoS	Out of Specification
PA	Procurement Agent
PIC/S	Pharmaceutical Inspection Cooperation Scheme
PSI	Pre-Shipment Inspection
QA	Quality Assurance
QC	Quality Control
QCA	Quality Control Agent
QMP	Quality Monitoring Programme
QMS	Quality Management System
SLM	Second Line antituberculosis Medicines
SOP	Standard Operating Procedure
SRA	Stringent Regulatory Authority
TB	Tuberculosis
WHO	World Health Organization
MQAS	Model Quality Assurance System for Procurement Agencies
WHO PQP	World Health Organization Prequalification Programme

DEFINITIONS

Antituberculosis Medicines: Medicines that are recommended for the prevention and treatment of tuberculosis (TB) as per the latest WHO treatment guidelines, and related medicines such as Pyridoxine Hydrochloride (Vitamin B6).

Certificate of Analysis: The list of test procedures applied to a particular sample with the results obtained and the acceptance criteria applied. It indicates whether the sample complies with the specification.

Consignment: The quantity of pharmaceutical products supplied at one time in response to a particular request or order. A consignment may be comprised of one or more packages or containers and may include pharmaceutical products belonging to more than one batch.

Direct Procurement: A product shipment that is dispatched directly from the manufacturer/supplier location to the client destination.

Diagnostic Products: Products used for the screening, diagnosis, and/or surveillance and monitoring of TB. Diagnostic products include medical devices (MD), in-vitro diagnostics (IVD), and medical software, as well as laboratory equipment, reagents, chemicals, and consumables.

Finished Pharmaceutical Product (FPP): A medicine presented in its finished dosage form that has undergone all stages of production, including packaging in its final container and labeling.

Good Manufacturing Practices (GMP): The practices which ensure that pharmaceutical products are consistently produced and controlled according to quality standards appropriate to their intended use and as required by marketing authorization.

International Conference on Harmonization (ICH) of Technical Requirements for the Registration of Pharmaceuticals for Human Use: An initiative involving regulatory authorities and pharmaceutical industry experts that was established to make recommendations on ways to achieve greater harmonization worldwide to ensure that safe, effective, and high-quality medicines are developed, registered, and maintained in the most resource-efficient manner whilst meeting high standards. ICH member countries are specified on its website: <http://www.ich.org>.

International Medical Device Regulators Forum (IMDRF): A voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices (GHTF). IMDRF aims to accelerate international medical device regulatory harmonization and convergence. More information is available on the IMDRF website: <https://www.imdrf.org/>.

International Organization for Standardization (ISO): An independent non-governmental organization with a membership of 167 national standard bodies which brings together experts to share knowledge and develop voluntary, consensus-based, market-relevant international standards that support innovation and provide solutions to global challenges. These include generic standards (e.g., ISO 9000 series) or product-specific requirements for implementing a quality management system (e.g., ISO 13485 for medical devices). More information is available on the ISO website: <https://www.iso.org/home.html>.

Manufacturer: A company that carries out operations such as production, packaging, repackaging, labelling, and re-labelling of medicines and/or diagnostic products.

Pharmaceutical Inspection Cooperation Scheme (PIC/S): A non-binding, informal co-operative arrangement between regulatory authorities in the field of GMP of medicinal products for human or veterinary use. It is open to any authority having a comparable GMP inspection system. PIC/S presently comprises 54 participating authorities from all over the world. PIC/S member countries are specified on its website: www.picscheme.org.

Product batch: A defined quantity of pharmaceutical products processed in a single process or series of processes so that it is expected to be homogeneous.

Product Formulation: The active pharmaceutical ingredient (or combination of ingredients), dosage form, and strength of a pharmaceutical product. Multiple FPPs may exist for the same product formulation.

Quality Assurance: A wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the objective of ensuring that pharmaceutical products are of the quality required for their intended use.

Quality Control: All measures taken including the setting of specification sampling, testing, and analytical clearance, to ensure that starting material, intermediate material, packaging material, and FPPs conform with established specifications for identity, strength, purity, and other characteristics.

Quality Control Agent: A third party company contracted to carry out inspection services for consignments prior to shipment and/or quality control testing activities of the product batch based on a predetermined and defined criterion.

Quality Management System: A management system encompassing the organizational structure, procedures, processes, resources, and systematic actions necessary to ensure adequate confidence that a product or service will satisfy the given requirements for quality.

Quality Monitoring: All activities undertaken to ensure that medicines and diagnostic products continue to conform with the manufacturer's established quality specifications during the storage, distribution, and use of such product (e.g., lot testing, reporting of deficient products, surveillance) as part of a QA system.

Stringent Drug Regulatory Authority (SRA): A regulatory authority which is either (a) an ICH member, (b) an ICH observer, or (c) a regulatory authority associated with an ICH member through a legally binding mutual recognition agreement as before 23 October 2015. Refer to the list of current members, observers, and associated authorities as specified on the ICH website: www.ich.org.

Supplier: A person, business, or entity that provides products, materials, or services on request. Suppliers may be agents, brokers, distributors, manufacturers, or traders. Where possible, suppliers should be authorized by a competent authority.

WHO Prequalification Programme (WHO PQP): The programme managed by WHO which prequalifies those medical products which are acceptable for procurement by the United Nations and specialized agencies and quality control laboratories for medicines.

1. INTRODUCTION

Stop TB Partnership is a global multistakeholder partnership that seeks to achieve a tuberculosis-free world by facilitating, catalyzing, and coordinating the work of its partners through its secretariat in Geneva. A key initiative of the Stop TB Partnership is the Global Drug Facility (GDF).

The mission of GDF, an ISO:9001 certified entity, is to ensure worldwide, equitable access to quality-assured and affordable antituberculosis medicines, diagnostics, and other supplies. GDF seeks to achieve this mission by employing innovative business approaches, efficient knowledge management of evidence-driven leadership in market shaping, and strategic and high-quality procurement and supply services.

GDF facilitates the procurement of all medicine and diagnostic products that are recommended by WHO for the screening, prevention, diagnosis, treatment, and surveillance and monitoring of all forms of TB in adults and children. When procuring through GDF, clients are guaranteed to receive quality-assured TB products in accordance with the quality standards described in GDF's [Quality Assurance \(QA\) Policy](#). The GDF Quality Assurance Policy is based on international and WHO guidelines applicable to medicines, medical devices, and in-vitro diagnostics (IVD) and is aligned with the QA policies of key United Nations agencies, the Global Fund, Unitaaid, and other international organizations.

2. BACKGROUND

GDF has a rigorous quality management system to monitor the quality of TB products procured by GDF. For quality monitoring, GDF contracts the services of both a Procurement Agent (PA) and a Quality Control Agent (QCA) and applies both established international standards and internal standard operating procedures (SOPs).

The first GDF Quality Monitoring Program (QMP) was developed in 2010 but its scope covered only the quality monitoring of first line antituberculosis medicines (FLMs). Since then, the scope has been extended to cover second line antituberculosis medicines (SLMs) and diagnostic products.

3. PURPOSE AND SCOPE

The GDF [Quality Assurance Policy](#) sets out the principles and requirements for the selection, procurement, and supply of all TB products used for the screening, prevention, diagnosis, and treatment of tuberculosis. The purpose of GDF's QMP is to surveil and monitor the quality and safety of TB products procured and delivered by GDF to its clients.

The scope of the updated QMP covers all TB products and includes the following activities:

- Pre-shipment inspection (PSI)
- Sampling of the product batch for quality control (QC) testing before shipment of the consignment
- Quality control testing of the product batch before shipment of the consignment
- Review of Certificate of Analysis (CoA) of the product batch before shipment of the consignment

4. EFFECTIVE DATE

The updated GDF QMP takes effect on 01 April 2023 and supersedes the GDF's drug monitoring program of July 2010.

The QMP will be updated every five years, or when warranted by changes in the quality requirements as specified by the GDF Quality Assurance team (GDF QA).

5. DESCRIPTION OF THE QMP ACTIVITIES

5.1 Pre-Shipment Inspection

For consignment of finished pharmaceutical products (FPPs), PSI is organized by GDF and its contracted PA in accordance with the criteria set forth by the QMP. PSI is conducted by a QCA contracted by GDF/PA.

For consignment of diagnostic products, PSI is organized by GDF as per country request and conducted by a QCA contracted either by the country, UNOPs (the GDF hosting organization), or other UN agencies in line with GDF SOPs for PSI.

5.1.1 **PSI for Consignment of FPPs**

5.1.1.1 *GDF's Criteria for Conducting PSI*

GDF's criteria for conducting PSI for consignment of FPPs are:

- a. All shipments with a value above US \$2,000 going directly from a manufacturer/supplier to a client-authorized destination (i.e., direct procurement).
- b. All shipments containing ERP-recommended FPPs for which routine QC testing is required.
- c. All shipments from a manufacturer/supplier for which at least two major PSI deviations (those resulted in shipment rejection) were reported by the inspection agency or the client during the last six months regardless of the shipment value or the destination (i.e., regardless of whether the shipment was sent to the client or to the warehouse of GDF's contracted PA).
- d. All shipments for which PSI is required by the client as per country importation regulations.

PSI of a consignment is waived for an order/shipment if:

- a. The order/shipment value is less than or equal to US \$2,000.
- b. The order/shipment destination is the GDF-contracted PA warehouse, unless specifically requested by GDF.

The above criteria may be modified by GDF and the QCA based on an analysis of available product and service quality data collected at any given time in the supply chain.

5.1.1.2 *GDF's Specifications Requirements for PSI*

The QCA conducts PSI per GDF's specifications requirements which include—but are not limited to—the following:

- a. Verification of compliance with respect to the quantity and integrity of all FPPs within the consignment in the purchase order of the PA, including the availability of a patient information leaflet (PIL), a patient kit booklet, and any additional inserts as specified per GDF technical specifications (e.g., a safety box, treatment monitoring cards, etc.).
- b. Verification of compliance with respect to artwork of all FPPs in the consignment with the latest approved GDF artwork related to language, labelling, or packaging.

- c. Verification of compliance with respect to the quantity, product batch numbers, and expiry dates of all FPPs in the consignment with those specified in the supplier's packing list, as well as verification that their remaining shelf life is in line with GDF requirements.
- d. Verification of compliance of packed FPPs in the consignment with respect to the packaging requirements as specified in the purchase order of the PA.
- e. Verification of the compliance of the shipping marks of the consignment with those specified in the purchase order of the PA.
- f. Verification of the presence of a Global Trade Item Number (GTIN) on the secondary and tertiary packaging for all FPPs in the consignment.
- g. Verification of the compliance of the consignee's name and address with the purchase order of the PA.
- h. Verification of the completeness and accuracy of the manufacturer/supplier documents required to accompany each consignment (e.g., invoice, packing list, CoA, or any other document as specified in the purchase order of the PA).

5.1.1.3 Management of PSI

The QCA organizes and conducts the PSI at the premises of the manufacturer/supplier. If it is not possible to conduct a PSI at the premises of the manufacturer/supplier, a virtual PSI will be performed by the QCA.

If no deviation is observed, the QCA will issue a Clean Report of Findings (CRF) and share it with the supplier and the PA.

If deviations are observed, the QCA will issue a deviation report and share it with the supplier, PA, and GDF QA. GDF QA and the PA will request the supplier to implement corrective actions as per agreed timelines. A CRF will be issued by the QCA once deviations are corrected. If the supplier cannot correct the deviations, GDF QA and the PA will reject the shipment and the supplier will be requested to replace the consignment.

5.1.1.4 Documents Used for PSI

- a. A Request for Inspection form duly filled by the supplier.
- b. A purchase order from the PA to the manufacturer/supplier.
- c. GDF's latest approved product artworks for medicines, which include artwork for product inserts, cartons, and foils.
- d. A manufacturer/supplier shipment packing list.
- e. GDF QA List of Eligible Products.
- f. GDF/PA packing and labelling instructions.
- g. QCA inspection form and report.
- h. Country-specific forms if PSI is requested by the client.

5.1.1.5 Management of Consignments Not Subject to PSI

Shipments delivered from the manufacturer/supplier premises to the warehouse of GDF's contracted PA are not subjected to PSI. As the PA's warehouse is compliant with Good Distribution Practices (GDP), receipt, storage, consolidation, and dispatch of FPPs at and from the PA's warehouse is compliant with the relevant pharmaceutical regulations and applicable standards. Therefore, inspection by the QCA of

shipments from the PA's warehouse to the client is not required by GF. If clients require PSI of shipments from the PA's warehouse, PSI will be organized.

Shipments delivered directly from the manufacturer/supplier to the client with a value less than or equal to US \$2,000 are not subjected to PSI. In this case, the PA must verify the completeness and accuracy of manufacturer/supplier documents required to accompany each consignment, shipping marks, consignee addresses, compliance of product packaging, and remaining shelf-life of all FPPs in the consignment before dispatching the shipment.

5.1.2 PSI for Consignment of Diagnostics

5.1.2.1 GDF's Criteria for Conducting PSI

GDF's criteria for conducting PSI for the consignment of diagnostics are

- a. All shipments for which PSI is required by the client as per country importation regulations.
- b. All shipments for which PSI is requested by GDF prior to dispatch if warranted by circumstances without prior approval from the client.

These criteria may be modified by GDF and the QCA based on analysis of available product and service quality data collected at any given time in the supply chain.

5.1.2.2 GDF's Specifications Requirements for PSI

The QCA conducts PSI as per GDF's specifications requirements.

When PSI is required by the client, PSI specifications requirements will be those required by the guidelines of the country of destination. These guidelines are published on the website of the relevant regulatory authority and available to the QCA.

When PSI is requested by GDF, the QCA performs PSI as per GDF's PSI specifications requirements which include—but are not limited to—the following:

- a. Verification of quantity and integrity of all products in the consignment as per GDF's purchase order.
- b. Verification of compliance of quantity, product batch/series number, and expiry dates of all products in the consignment with those specified in the supplier's packing list.
- c. Verification that remaining shelf life is in line with GDF requirements.
- d. Verification of compliance of the packing of all products in the consignment with the packing requirements specified in GDF's purchase order.
- e. Verification of compliance of the shipping marks of the consignment with those specified in GDF's purchase order.
- f. Verification of the presence of a GTIN on the secondary and tertiary packaging in the consignment.
- g. Verification of compliance and accuracy of the manufacturer/supplier documents required to accompany each consignment (e.g., invoice, packing list, CoA, or any other document specified in GDF's purchase order).

5.1.2.3 Management of PSI

- a. When PSI is required by the client, GDF uses an internationally recognized QCA appointed by the regulatory agency of destination country to perform PSI.

- b. If the QCA is not selected by the client, or if PSI is requested by GDF, GDF selects the QCA from a valid agreement in place through UNOPs (GDF's hosting organization) or another UN agency.
- c. The QCA conducts PSI at the manufacturer/supplier premises or, if a physical PSI is not possible, conducts a remote PSI.
- d. If no deviation is observed, the QCA will issue a Certificate of Conformity or a CRF and share it with the manufacturer/supplier and GDF QA.
- e. If deviations are observed, the QCA will issue a deviation report and share it with the supplier and GDF QA. GDF QA will request the supplier to implement corrective actions within an agreed timeline. A CRF will be issued by the QCA once deviations are corrected. If the supplier cannot correct the deviations, GDF QA will reject the shipment and the supplier will be requested to replace the consignment.

5.1.2.4 Documents Used for PSI

- a. Documentation of a client request and client instructions.
- b. Country importation regulations and guidelines.
- c. A purchase order from GDF placed with the manufacturer/supplier.
- d. A manufacturer/supplier shipment packing list.
- e. GDF shipping documentation, including packing and labelling instructions.
- f. A QCA inspection form and report.
- g. Other country-specific forms if PSI is requested by the client.

5.2 **Sampling of FPPs for QC Testing Before Shipment of Consignment**

5.2.1 **Criteria for the Sampling of FPPs for QC Testing**

- a. All orders/shipments containing ERP-recommended FPPs for which routine QC testing is required.
- b. All orders/shipments with WHO-prequalified or SRA-authorized FPPs for which two quality complaints were submitted to GDF QA in the last six months and thus subjected to QC testing.
- c. When required by the client as per country importation regulations.

Sampling of FPPs for QC testing is not applicable for orders/shipments with only WHO-prequalified or SRA-authorized FPPs, unless specifically requested by GDF.

5.2.2 **Sampling Requirements**

The methodology used by the QCA to conduct sampling is based on GDF specifications requirements for the sampling of FPPs.

For all ERP-recommended FPPs:

- a. Sampling of the first five product batches; this applies even if five product batches are not available in the first instance.
- b. In case of either the discontinuity of QC testing for FPPs (i.e., no of product batch tested during the last six months), or a tested product batch found to be non-compliant with specifications, or a change by the manufacturer/supplier in the method of analysis, the QCA may decide to sample

more than 20% of product batches. This will depend on the availability of product batches at the manufacturing site and the number of batches for the same product that have already been tested by the QCA with the same manufacturer/supplier procedures (i.e., the skip-lot approach).

- c. Only after satisfactory testing of the first five product batches (or, alternately, more than 20% of batches as described in the previous paragraph), a randomization protocol is applied for the sampling of the same product, strength dosage form, and manufacturer. The subsequent sampling shall be done as per the following:
- ✓ On 20% of ERP-recommended product batches are compliant with specifications within the last six months.
 - ✓ With further reduction to 10% of ERP-recommended product batches, if no Out of Specifications (OoS) are reported for the previously tested product batches.

This randomization scheme may be modified by GDF and the QCA at any given time following the analysis of available product quality data.

For all WHO-prequalified or SRA-authorized FPPs: when these are subjected to ad-hoc QC testing, the methodology for the sampling and QC testing will be defined jointly by GDF QA, the PA, and the QCA once the magnitude of quality concerns is assessed and confirmed.

When required by the client as per country importation regulations: the client requirements will be applied.

5.2.3 Management of the Sampling of FPPs

The QCA conducts the FPP batch sampling at either the manufacturer/supplier premises or at the PA's warehouse.

5.3 Quality Control (QC) Testing of FPPs Before Consignment Shipment

5.3.1 Requirements for QC Testing of FPPs

The QCA laboratory conducts QC testing of FPPs based on GDF requirements which are to test the FPP as per the manufacturer/supplier specifications/methods for analysis as approved by WHO PQP, SRAs, or the ERP.

5.3.1.1 As Per Official Monographs of the Pharmacopoeia

Where the approved specifications/methods for analysis of the FPP refer to official monographs of a pharmacopoeia, the QCA shall refer to the latest editions. Pharmacopoeia used by manufacturers for specifications/methods for analysis of antituberculosis medicines eligible for GDF procurement are:

- ✓ U.S. Pharmacopoeia
- ✓ British Pharmacopoeia
- ✓ International Pharmacopoeia
- ✓ European Pharmacopoeia

5.3.1.2 As Per In-House Manufacturer/Supplier Specifications/Methods of Analysis (Method Transfer)

Where the approved specifications/methods of analysis for an FPP refer to an in-house manufacturer/supplier's specifications/methods of analysis, the QCA laboratory shall conduct a method transfer (MT) of the manufacturer/supplier's analytical tests before starting routine QC testing. The QCA

laboratory will implement an analytical test and issue an MT report as per an agreed upon and approved MT protocol.

The QCA will start route QC testing of an FPP only after the satisfactory completion of the MT and the issuance of a report.

Unless variations to specifications/methods of analysis for new methods are set up by the manufacturer/supplier, the MT for an FPP is done only once.

For ERP-recommended products, the implementation of the manufacturer/supplier MT to the QCA laboratory will be requested, managed, and paid for by the Global Fund upon request from GDF QA.

5.3.2 Parameters and Methods Used for QC Testing

The QCA laboratory contracted by the GDF/PA is required to perform the analysis of the product batch as per approved manufacturer/supplier specifications.

A. Physical/Chemical Analysis
pH, density, optical rotation, refractometry, viscosity, loss on drying, water content, disintegration, dissolution, uniformity of dosage units (mass, content), friability, tablet hardness, particulate matter test
B. Identification
HPLC (fluorescence, UV-Vis, RI detection, conductivity detection), GC (FID, TCD), TLC, capillary electrophoresis, UV-Vis spectrophotometry, FTIR, AAS
C. Assay, Impurities, and Related Substances
HPLC (UV-Vis, RI, conductivity detection), GC (FID, TCD), TLC, UV-Vis spectrophotometry, AAS, fluorimetry, volumetric titrations, potentiometry, coulometry
D. Microbiological Tests
sterility test, microbial limit tests, bacterial endotoxins test (LAL), microbial assay of antibiotics
E. Stability Studies
ICH conditions

5.3.3 Management of QC Testing

As per the contract between the GDF/PA and the QCA laboratory, the QCA laboratory is responsible to conduct QC testing and shall not subcontract any services and/or tests to another service provider at any time during the period of the signed contract. The QCA laboratory can only subcontract work required to third party companies subject to prior written approval by GDF. The QCA laboratory shall ensure that any subcontracted entities are duly certified according to GDF requirements and follow the signed contract.

The QCA laboratory will request the following technical documentation from the manufacturer for testing purposes when an FPP is tested for the first time and/or the methods of testing are per in-house manufacturer/supplier’s specifications/methods of analysis:

- a. Manufacturer/supplier testing SOPs.

- b. Manufacturer/supplier validation report for test methods.
- c. Characterized standards and reference materials in sufficient quantities for method optimization and final MT testing, with certificates containing information on, at minimum, content, purity, water content, and expiry date.
- d. Manufacturer/supplier specification sheets for each product formulation with testing parameters and acceptance limits.
- e. Sufficient samples from three different batches of each product formulation to perform testing for MT.
- f. CoAs of the product batches involved in MT.
- g. List of QC/QA focal persons for each manufacturer for technical discussions on analytical methods.

All documentation provided must be in English.

If the results of parameters tested by the QCA laboratory are not within the expected specifications, the product batch is considered OoS. The QCA laboratory's procedures and reporting timelines shall be applied to investigate and report on the OoS together with the manufacturer.

The QCA laboratory and manufacturer's shared method of analysis, approved specification/methods, and CoAs must be kept strictly confidential by the QCA laboratory, archived for at least five years, and be provide to GDF if requested.

5.4 Review of Certificates of Analysis (CoA) of the Product Batch Before Shipment of Consignment

CoA review of the product batch is conducted by the GDF/PA-contracted QCA.

5.4.1 Criteria for CoA review

The QCA conducts CoA review:

- a. Only for antituberculosis medicines.
- b. For all product batches procured by GDF/PA, including those that are not subject to testing or that skipped testing due to the randomization protocol.

For all consignments consisting of over 20 batches of the same antituberculosis medicine, in the absence of deviations, review of additional CoAs may be skipped.

5.4.2 CoA Review Management

CoAs of all TB medicine batches supplied to GDF are reviewed by the QCA for conformity against approved specifications. The QCA shall alert GDF QA and the PA of any detected deviations to the approved specifications/methods. GDF QA, the PA, and the QCA will jointly address all deviations with the manufacturer/supplier.

5.5 Post-Delivery Quality Surveillance

Quality monitoring activities can also be organized post-delivery by recipient countries as part of their medicine and diagnostic products monitoring program. Some countries conduct systematic laboratory

testing upon receipt of medicines or diagnostic products, while other countries sample batches at different points of the supply chain during a product's shelf life.

5.6 Handling of Product Complaints

GDF's clients, suppliers, or the QCA can report a product complaint to GDF for both medicines and diagnostics. Currently, two reporting systems exist at GDF to submit product complaints. The complainant can fill out a complaint form which is available on the [GDF QA website](#). Alternately, the complainant can submit feedback via a GDF customer satisfaction survey. GDF conducts customer satisfaction surveys on a regular basis to collect clients' feedback on their level of satisfaction with GDF's processes, products, and performance.

All complaints concerning potentially defective products procured through GDF are reviewed by GDF QA so that appropriate actions can be taken, including potential recall. Product complaints received are duly recorded and investigated by GDF and/or the PA as per internal procedures.

- a. All complaints received concerning the quality of ERP-recommended TB products are shared with the Global Fund QA/ERP Secretariat for further action.
- b. For complaints related to SRA-authorized products, the manufacturer/supplier is required to inform the relevant regulatory authority as per its requirements. GDF will share these with WHO PQP for further action.
- c. Complaints related to WHO-prequalified TB products are shared with WHO PQP for further action.

Relationship and responsibilities

Technical office:

Global Drug Facility Quality Assurance Team
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