SUMMARY SHEET

Agenda Nr.1.05-12.0	Subject	**Global Drug Facility**
For Information	For Discussion	**For Decision**

Introduction:

After 4 years of operation, the Global Drug Facility (GDF) has provided over 4 million patient treatments to more than 58 countries. The increasing number of countries supported by the GDF's grant and direct procurement service line and the rapidly growing procurement volumes have necessitated the development of an information technology (IT) based knowledge and data management system, which in turn requires a quality management and improvement system as well as the formalization and implementation of standard operating procedures (SOPS).

In order to effect the formalization and implementation of a quality management system, including SOPS, ISO Certification of the GDF is being proposed.

ISO certification refers to certification issued by the International Office for Standardization (ISO) in Geneva (http://www.iso.ch/) that sets standards which companies, agencies, or organizations should follow in order for there to be a Documented Quality Management System in place, adhered to by all staff and subject to verification. Such a management system requires that SOPs are documented and in place for every main activity, that the responsibility for every activity are assigned to a specific staff member and that there is an internal auditor who checks and can certify that tasks are done according to the SOPs.

The GDF team continues to be lean and effective, but in order for it to maintain its efficiency in the face of rapid and significant expansion of support to countries globally, appropriate tools are required. ISO certification and the implementation of the SOPs inherent to that process will not only complement and augment the IT based knowledge and data management system that has now become operational but will also improve the quality of GDF services and considerably enhance the public perception of GDF operations.

Action steps required for ISO Certification:

- Nomination of an ISO focal point within the GDF team
- Selection and contracting of an ISO consultant to assist GDF to prepare for ISO inspection and ISO status, as prerequisites to certification
- Preparation of an ISO Project Plan
- Nomination of an ISO Steering Committee
- A Gap Analysis, with the aid of a Gap Analysis Checklist: i.e. to identify the Gaps that exist between the present situation and the desired end situation, identifying what will have to be put in place to make ISO Certification possible
- Assigning responsibilities and tasks to individuals or sub teams for developing or customizing Quality System Procedures and the Quality System Procedures Manual
- Training of staff in writing/preparing text for SOPs
- Trial testing and fine tuning of new system
- Inspection by ISO Registrar

Time line for above steps: 7 to 9 months
Estimated cost: US$ 40,000 for consultancy/registration fees plus ongoing staff time

Decisions requested from the Stop TB Coordinating Board			
Discussion and approval for GDF to proceed with ISO Certification Process			
Next steps and time frame			
WHAT	**WHO**	**WHEN**	**FOCAL POINT**
ISO Certification	Secretariat	7-9 months	GDF Manager