

Strengthening Quality Assurance in Developing Countries through South - South Collaboration



India's Approach to Quality Assurance in RH Commodities

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Welcome

I am grateful to PPD Secretariat and the Ministry of Health & Family Welfare, Government. of India for inviting me to share my experience in Quality Assurance with special reference to RH Commodities.

Introduction...

As you are aware, India has a well developed Pharmaceutical Industry and is not only self sufficient in contraceptive commodities, but has also been exporting them to many countries. It has also a well established regulatory system at State and Central levels. There are four central laboratories one in each zone and at least one laboratory in each state for testing drugs. Besides these, there are a number of licensed Public Testing Laboratories, some of which have ISO or NABL Certification.

*PRODUCTION CAPACITIES AND USAGE
WITHIN THE COUNTRY*

	Production Capacity Million/annum	Usage within India Million/annum
Condoms	2000	1200
Copper T	100	7
Tubal rings	25	3
OCP's	215(cycles)	85(cycles)

CONTRACEPTIVE MANUFACTURERS

CONDOMS	COPPER T	TUBAL RINGS	OCPs
HINDUSTAN LATEX LTD*	HINDUSTAN LATEX LTD*	PREGNA INTERNATIONAL LTD*	HINDUSTAN LATEX LTD*
TTK LIG	FAMY CARE LTD*	G.SURGIWARE	FAMY CARE LTD*
TTK BIOMED	CONTECH DEVICES LTD*	CORPORATE CHANNEL	IDPL
POLAR LATEX	PREGNA INTERNATIONAL LTD*		PHARMASIA
CUPID RUBBER			EUPHARMA
SURETEX			
PASHUPATI			

* **ISO OR WHO-GMP CERTIFIED**

*GOVT. APPROVED LABORATORY FOR
TESTING OF CONTRACEPTIVE DEVICES*



SGS, CHENNAI

SHRIRAM INSTITUTE, DELHI

CIPET, CHENNAI

PRK PHARMANALYST, HYDERABAD

VIMTA LABS, HYDERABAD

Introduction....

Most of the Partners have the same goal and face similar problems in implementing population programmes. Since India has vast experience and built up a great potential for manufacture of RH commodities, it can assist the PPD secretariat in identifying manufacturers or potential suppliers of RH commodities at affordable cost and also ensure certification of these.

Introduction....

Opening up of the commerce to international trade and WTO have spurred the government and the industry to strengthen Quality Assurance of Pharmaceuticals. The Government has recently amended the Drug Rules to introduce cGMP and issued GLP guidelines for all government and public testing laboratories to follow.

Background....



In RH commodities too the government has been making concerted efforts to strengthen quality by certification of every batch of contraceptives meant for Public distribution, by independent laboratories, for wider acceptability of contraceptive methods.

Background....



The Department of Family Welfare has formulated guidelines for Storage, Packaging and Transportation of Contraceptives with the help of I. I. T., New Delhi. It has also constituted a Task Force for review of quality of contraceptives, which has prepared a draft GMP for Copper T 200B and tubal rings and recommended some amendments for rationalization of the existing standards.



Action

However it would be necessary to take the following steps to achieve availability of high quality RH commodities at affordable cost to all the Partners :

Action

1. Harmonize standards and specifications for all RH commodities.
2. Identifying independent laboratories for certification.
3. Make provision in drug regulations for one point registration of RH commodities to facilitate hassle free export and import among the Partners.
4. Identify centers for training of technical manpower.



Benefits

The above measures will ensure :

1. Wider choice for sourcing the commodities
2. Ensure availability of quality material for all Partners
3. Help make long term decisions for procurement and distribution of the commodities.



Thanks

I once again thank the PPD Secretariat and the Ministry of Health & Family Welfare, for giving me this opportunity to make this presentation.