Pan American Health Organization

Regional Office of the
World Health Organization

Study of the current conditions of the Official Medicine Control Laboratories (OMCL) in Latin America and the Caribbean

PHARMACEUTICAL QUALITY ASSURANCE
ESSENTIAL MEDICINES AND HEALTH TECHNOLOGY UNIT (WDC)

(February 5, 2008)

References:

1. Guía para Evaluación de Labs de Control de Calidad en Centro América y Rep. Dominicana, OPS/OMS, 1999
2. Good Manufacturers Practices for Pharmaceutical Products, 32^{0} Report WHO, 1992 (WHO Report Series, N^{0} 823)
3. Quality assurance of pharmaceuticals, Vol 1, WHO 1997
4. Quality assurance of pharmaceuticals, Vol 2, WHO 1999
5. Pautas sobre Buenas Prácticas de Laboratorio, Red Latinoamericana de Laboratorios Oficiales de Control de Calidad de medicamentos (PNSP/89-07)
6. Estudio sobre las condiciones actuales de los Laboratorios Oficiales de Control de Calidad de Medicamentos en América Latina, PAHO (THS-EV, 2000)
7. Good Practices for National Pharmaceutical Control Laboratories, 36^{0} Report WHO, 2002 (WHO Report Series, N^{0} 902)
8. Prequalification of Quality Control Laboratories, 41st Report WHO, 2007 (WHO Report Series, N^{0} 943)

1. Identification of the Laboratory

1.1	Name
1.2	Country
1.3	Name of the Director
1.4	Mailing Address
1.5	Telephone
1.6	Fax
1.7	E-mail
1.8	Date of the visit/ filling out the questionnaire
1.9	Name of the staff member who was the host
1.10	Function within the Organization
1.11	Quantity of samples processed annually:
1.11.1	Medicines
1.11.2	Cosmetics
1.11.3	Raw Materials
1.11.4	Medical devices
1.11.5	Other (specify)
1.12	Quantity of sample product per year
1.12.1	Chemical
1.12.2	Physical
1.12.3	Biological
1.12.4	Microbiological
1.12.5	Other (specify)

2. Organization

2.1	Type and number of personnel (indicate quantity)
2.1.1	Pharmacists
2.1.2	Biochemists
2.1.3	Chemists
2.1.4	Microbiologists
2.1.5	Technical analysts
2.1.6	Technical laboratory
2.1.7	Student intern and / or fellows
2.1.8	Administrative assistance
2.1.9	Maintenance (electrical, mechanical, etc.)
2.1.10	Housekeeping
2.1.11	Driver, motorist:
2.1.12	Other (specify)
2.2	Attach structural and functional Organizational Chart of the Laboratory.
2.3	Does the laboratory have economic capacity that ensures its sustainability?
2.3.1	Direct allocation of the Government (%)
2.3.2	Allocation of the Ministry of Health (%)
2.3.3	Sale of services (%)
2.3.4	Other (%)
2.4	Does it subcontract tests?
2.4.1	Which ones?
2.4.2	How many? (monthly average)
2.4.3	How is the quality of the results of the contracted laboratory guaranteed?

2.5	Are research projects carried out? (indicate those studies)
2.5.1	What new methods of research have been developed?
2.5.2	Where do they publish the results of the tests carried out?
2.5.3	Do they have a bulletin or journal?

3. Premises

(Describe briefly pointing out construction materials)

		Material	Characteristic	Condition
3.1.1	walls			
3.1.2	Floors			
3.1.3	Ceiling			
3.1.4	Corridors			
3.1.5	Roof			
3.1.6	Windows			
3.1.7	Doors			
3.1.8	Other			

3.2	It owns the building sectors individualized for:	YES - NO	DESCRIBE
3.2.1	Administrative Office		
3.2.2	Bathroom / toilets		
3.2.3	Wardrobes		
3.2.4	Kitchen / Cafeteria		

3.2.5	Library		
3.2.6	Warehouse		
3.2.7	Other		

4. Materials and Equipment

4.1	**Physical chemical analysis sector** (mark the items that have the same quantity)	
4.1.1	Fume hoods	
4.1.2	Weighing-in sector	
4.1.3	Anti-vibrating table	
4.1.4	HPLC (High Performance Liquid Chromatography)	
4.1.5	UV Spectrophotometer	
4.1.6	IR Spectrophotometer	
4.1.7	Gas Chromatograph	
4.1.8	Dissolution test equipment (according with the USP-NF)	
4.1.9	Karl-Fischer titrator	
4.1.10	Refrigerators with 0°C storage with -20°C storage with -70°C storage	

4.2.	**Microbiological sector**	
4.2.1	Is there a microbiological analyses sector?	
4.2.2	Is it classified as a "clean area"? (class of air: 100.000)	
4.2.3	Equipment (mark the items and the number that the lab has):	
4.2.3.1	Autoclave	
4.2.3.2	Sterilization stove	
4.2.3.3	Culture ovens	
4.2.3.4	Water deionizing equipment	
4.2.3.5	Water distilling apparatus	
4.2.3.6	Laminar air flow unit	
4.2.3.7	LAL test for bacterial endotoxines	
4.2.3.8	Is testing on animals carried out? If so, where do these animals come from?	
4.3	**Storage conditions (Specify)**	
4.3.1	Standards and reference materials	
4.3.2	Drugs and reagents	
4.3.3	Flammable reagents and hazardous materials	
4.3.4	Samples	
4.3.5	Glass materials	

5. PERSONNEL

5.1	Are there sufficient personnel sufficient with technical knowledge and experience for their assigned functions? (Indicate %)	
5.2	Are the received training records, including in-service training, maintained with data and names of personnel involved?	
5.3	What % of the annual budget is allocated to staff training?	
5.4	Are the personnel provided with clothing and elements of safety consonant with the tasks that are developed? (Indicate %)	
5.5	What medical controls are carried out by the personnel? With what frequency?	
5.6	In what courses have the personnel participated during the last 12 months?	

6. QUALITY SYSTEM

6.1	Does the laboratory have a Quality Manual that includes the functions and responsibilities for the technical management of the quality in compliance with norms and standards?
6.2	Has some accreditation system been set up?
6.3.1	How are the qualifications of equipment and the calibration of analytical apparatus carried out?

6.3.2	Does the laboratory have a reference procedure of the highest metrological order and / or primary reference material?
6.4	Is there a maintenance plan of equipment / instruments?
6.5	Have procedures been establish to the scope of its activities, including the following:
6.5.1	Procedures to control and review all quality documents
6.5.2	Procedures to control technical records
6.5.3	A flow-chart for samples
6.5.4	A procedure for dealing with complaints
6.5.5	Initial and in-service training of staff
6.5.6	Internal and external audits
6.5.7	Control of non conformity
6.5.8	A program of possible corrective and preventive actions
6.5.9	Whether or not the sample complies with the requirements Providing, reviewing, and modifying quality records
6.5.10	Measurement procedures of the highest metrological order
6.5.11	What standards and reference materials does the laboratory have in use?
6.6	Information on participation in appropriate proficiency testing schemes

7. DOCUMENTS AND REGISTRIES

7.1	Does the laboratory have any mechanism of document approval and modification? Which one?
7.2	Check the information that the technical report contains:
7.2.1	Name and address of the analytical laboratory
7.2.2	Name and address of the client
7.2.3	Date of reception of the sample
7.2.4	Date of performance of the analysis
7.2.5	Description and identification of the sample
7.2.6	Identification number of the sample
7.2.7	Analysis requested
7.2.8	Method/ test used
7.2.9	Test equipment used
7.2.10	Result obtained
7.2.11	Fulfillment or not of criteria for acceptance
7.2.12	Comments
7.2.13	Name and signature of the analyst
7.3	Are procedures established and implemented for making, documenting and controlling changes to information maintained in computerized systems?
7.4	Is any data-processing equipment (PC) in use?
7.5	Is the INTERNET available and easy to access?

8. SAFETY

8.1	Are only authorized personnel allowed to be on the premises, to ensure the correct and efficient functioning of the laboratory?
8.2	Are flammable reagents and hazardous materials kept separately?
8.3	Are there general rules for safe practices in accordance with handling hazardous materials?
8.4	How is the handling and disposal of wastes?
8.5	Are neutralized fuming and concentrated acids and bases, volatile amines, etc. to reduce contamination of the laboratory environment?
8.6	Are general and specific safety instructions available to each staff member explaining how to proceed in unexpected situations?

9. QUALITY AUDITS

9.1	Has the laboratory defined the conditions to carry out internal quality audits? What are the key criteria?
9.2	Indicate by whom the audits are carried out.
9.3	If the audits concern personnel of the laboratory, indicate position and function:
9.4	If the audits concern external Audits, indicate by whom they are carried out
9.5	Are the suppliers evaluated especially those of critical supplies (antibiotics, vitamins, cytostatics)? What criteria?
9.6	Are the corrective actions implemented? Indicate their verification