

Attend the President's Malaria Initiative Malaria Operational Plan Meeting and Present PQM Activities and Strategic Plans for Quality Assurance and Quality Control of Antimalarials in Ghana

**Accra, Ghana
June 7-11 2010**

Trip Report

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Promoting the Quality of Medicines Program

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About PQM

The Promoting the Quality of Medicines (PQM) program, funded by the U.S. Agency for International Development (USAID), is the successor of the Drug Quality and Information (DQI) program implemented by the United States Pharmacopeia (USP). PQM is USAID's response to the growing challenge posed by the proliferation of counterfeit and substandard medicines. By providing technical leadership to developing countries, PQM helps build local capacity in medicine quality assurance systems, increase the supply of quality medicines to priority USAID health programs, and ensure the quality and safety of medicines globally. This document does not necessarily represent the views or opinions of USAID or the United States Government. It may be reproduced if credit is given to PQM and USP.

Abstract

The PQM director travelled to Accra, Ghana to present the program's accomplishments against FY 10 goals and to present a strategic plan to improve the quality of antimalarials in Ghana as well as to strengthen the capacity of the Food and Drug Board (FDB) of Ghana for quality control of medicines in general.

In meeting with the PMI Malaria Operational Plan (MOP) team, Dr. Lukulay identified key areas of focus for support of FDB and ways to increase public advocacy and awareness about medicines quality in the country.

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Key Words

Ghana, Food and Drug Board, antimalarial, medicine quality

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I would like to acknowledge the support provided by the Ghana Food and Drug Board (FDB) for making my stay in Ghana successful. Their partnership over the last few years has been very rewarding.

I also would like to thank Paul Psychas, the President's Malaria Initiative (PMI) representative for the U.S. Centers for Disease Control and Prevention (CDC) in Ghana for his support of PQM and for facilitating my trip to Ghana. My thanks also go to Lisa Kramer, USAID PMI Advisor, and Laurel Fain, HPN Office Chief, for their support of the PQM program in Ghana. I value the useful discussions we had during the Malaria Operational Plan meetings about how to improve medicine quality in Ghana and ways to increase PQM's contributions to the efforts of the FDB in ensuring a safe medicine supply chain in Ghana.

My thanks also go to:

- Tony Boni and Veerle Coignez, USAID/Washington, for their support and guidance
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ACRONYMS

CDC	U.S. Centers for Disease Control and Prevention
DQI	Drug Quality and Information Program
FDB	Food and Drug Board
GF	Global Fund
GMP	Good Manufacturing Practices
MOP	Malaria Operational Plan
PMI	President's Malaria Initiative
PQM	Promoting the Quality of Medicines Program
USAID	United States Agency for International Development
USP	United States Pharmacopeia
WHO	World Health Organization

Background

The Promoting the Quality of Medicines (PQM) Program first started supporting the Ghana Food and Drug Board (FDB) in 2005, and continued supporting them beginning in 2008 with funding from the President's Malaria Initiative (PMI). PQM support focuses on providing technical assistance to FDB to establish a functional post-marketing surveillance program throughout the country. This has involved training the central FDB staff, World Health Organization (WHO) and regional FDB office staff in medicine quality testing using Global Pharma Health Fund (GPHF) Minilabs[®], and conducting confirmatory testing using pharmacopeial testing procedures.

Since 2008, PMI funds have been used to equip five sentinel sites with Minilabs[®], reagents, and chemicals needed to conduct testing of antimalarials in five regions in the country. The Minilabs[®] are housed at FDB regional offices and local staff conduct preliminary screening tests; confirmatory testing of failed or doubtful samples are done at the national laboratory in Accra. A second round of sampling and testing is ongoing at the five sentinel sites, and results are expected by September 2010. The sentinel sites have helped the FDB carry out their regulatory functions in a timely manner to promote medicine quality in Ghana. Regional offices are now able to conduct screening tests of antimalarials and are able to carry out sampling and testing in accordance with the protocol established by PQM.

The FDB laboratory has been testing medicines procured by Global Fund (GF). However, a GF policy that went into effect as of July 2010 stipulates that testing of all GF-procured medicines imported into a country must be done throughout the life cycle of the products and only laboratories that are WHO prequalified or ISO 17025 accredited can conduct testing. Because the FDB laboratory does not meet that restriction, it can no longer conduct testing of GF samples. The FDB has identified a qualified laboratory in South Africa to conduct the testing. Testing GF samples abroad represents lost revenue for the FDB laboratory.

Purpose of Trip

- Present PQM accomplishments against FY10 goals to the Malaria Operational Plan (MOP) team, discuss planned activities, and explore the possibility of PQM assisting FDB toward ISO 17025 accreditation or WHO prequalification
- Work with FDB and the Malaria Control Program to develop a strategy to conduct limited testing of GF samples in-country while the majority occurs abroad
- Review the architectural, mechanical, and electrical design of the new laboratory and offer suggestions for a better functioning laboratory

Source of Funding

This trip was funded by USAID/Ghana through PMI funds.

Overview of Activities

Meeting at USAID/Ghana

Dr. Lukulay gave a presentation (included in *Annex I*) to the MOP team titled "USP Update, Accomplishments, and Future Direction." The highlights of the presentation are:

- A new round of antimalarial quality monitoring is underway with results expected in September. The MOP team would like to see the program focus on antimalarials that are

on the national treatment guidelines. Previously, other antimalarials, such as Chloroquine, had been collected and tested because they are still being sold in the market

- Because the FDB laboratory will no longer be able to test GF samples, PQM proposes to provide technical assistance to aid them in becoming ISO 17025 accredited or WHO prequalified
- Future PQM activities should include raising awareness about drug quality in Ghana through public service announcements and television and other media campaigns.

Meeting at the Food and Drug Board of Ghana

Present: Dr. S. K. Opuni, Chief Executive Officer, Ghana Food and Drug Board; Mr. Eric Kakari, Acting Head, FDB Laboratory; Dr. Patrick Lukulay, Director, PQM

The group discussed PQM activities in support of PMI in Ghana and how to develop a plan for assisting the FDB laboratory toward ISO accreditation in the next two years. The following points were discussed:

- PQM will visit Ghana in fall 2010 to review results of the current medicines quality monitoring round and to seek regulatory action from the FDB for products found to be substandard or counterfeit
- Dr. Opuni asked for PQM support to assist the FDB laboratory to become ISO accredited or WHO prequalified in the next two years
- Dr. Lukulay accepted an invitation to visit the site of the new FDB laboratory, which is under construction, and to provide feedback about the suitability of the architectural, mechanical, and electrical designs
- Dr. Lukulay briefed Dr. Opuni about the presentation to the MOP team and gave him a copy of the presentation



Dr. Opuni and Dr. Lukulay review flyers

Tour of the site of the new FDB Laboratory

Dr. Lukulay and Mr. Eric Kakari visited the site of the new laboratory and met with the building architects and construction team. The objective of the tour was to assess the suitability of the building to meet ISO 17025 accreditation.

FDB staff at workstations in current lab



FDB staff in the instrument room of the current lab

The building houses administration and laboratory wings. The laboratory wing has three floors for Microbiology, Medical Devices, and Physicochemical Analyses laboratories. Dr. Lukulay made some

preliminary observations regarding the small space for physicochemical testing, building safety requirements, and sample, hazardous, and non-hazardous chemicals storage. A full evaluation is provided in *Annex 2*.

PMI Stakeholders Meeting

D. Lukulay accepted the invitation to participate in the stakeholder meeting which was held on June 10 in Accra, Ghana. USAID/Ghana, USAID/Washington, and CDC staff gave presentations about PMI accomplishments in Ghana and worldwide and highlighted challenges that still remain. Also in attendance were the Ghana Malaria Control Program, Ghana Health Service, and other Ministry of Health officials. USAID Cooperative Agreements and bilaterals also participated in the discussions. The director of the Malaria Control Program highlighted issues about quality and tolerability of the antimalarials being used and also the inappropriate use of long lasting insecticide treated nets for fishing. She stressed the need for the country to have a strategic plan that all donors work within.

Conclusions

The medicine quality monitoring program put in place by PQM with support from PMI and in collaboration with country partners has been very effective in monitoring the quality of antimalarials in circulation in Ghana. Hundreds of samples have been collected and tested, and the results have been used by FDB management to take enforcement action, as was the case when several antimalarials were removed from the market last year. More support is now needed to raise public awareness and increase advocacy about drug quality in the country.

PQM support to FDB has not been limited to medicine quality monitoring but also includes the provision of technical assistance to improve quality assurance systems in general. For example, support is being provided to the laboratory to develop quality systems that would be required for ISO accreditation. Future assistance to FDB must include stepping up support to guide the laboratory toward accreditation. The lab is losing needed funds because they can no longer receive revenue for testing medicines procured by GF.

The exposure of the Ghanaian population to substandard medicines is a threat to the efficacy of antimalarials, including those used by PMI. The poor Good Manufacturing Practices (GMP) compliance of local manufactures and inadequate training in formulation development is leading to local manufacture of substandard medicines. Providing technical assistance to help FDB conduct GMP training for manufacturers is needed in the near future. This assistance will help to improve the quality of antimalarials manufactured locally and may avert the development of resistance to the key antimalarials in circulation.

Next Steps

- PQM will return to Ghana in August or September to review the results of the current round of medicines quality monitoring
- With FDB management, PQM will discuss possible enforcement actions, based on findings
- PQM will provide an architectural layout of typical laboratory space to the FDB architects to help guide them as they plan to partition the lab
- PQM will explore possibilities for a local consultant to help coordinate work in Ghana and follow up promptly on ongoing activities



PMI Partners Meeting
Accra, Ghana ♦ June 7, 2010

USP Update

Accomplishments and Future Direction

Patrick Lukulay, Ph.D.

Director

Promoting the Quality of Medicines Program



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Outline

Promoting the Quality of Medicines Program

- ◆ USP accomplishments and results to date
- ◆ Current activities
- ◆ Issues and challenges
- ◆ Looking ahead—recommendations for sustainable impact



Program Overview

Promoting the Quality of Medicines Program

Promoting the Quality of Medicines Program

- ◆ Five-year Program (2009–2014);
\$35 million ceiling
- ◆ Focus on strengthening medicines quality assurance systems in developing countries
- ◆ Implementing partner: U.S. Pharmacopeia
- ◆ USP sets FDA-enforceable quality standards for medicines on US market
- ◆ Program is active in ~30 countries in Latin America, Asia, Africa, and Eurasia



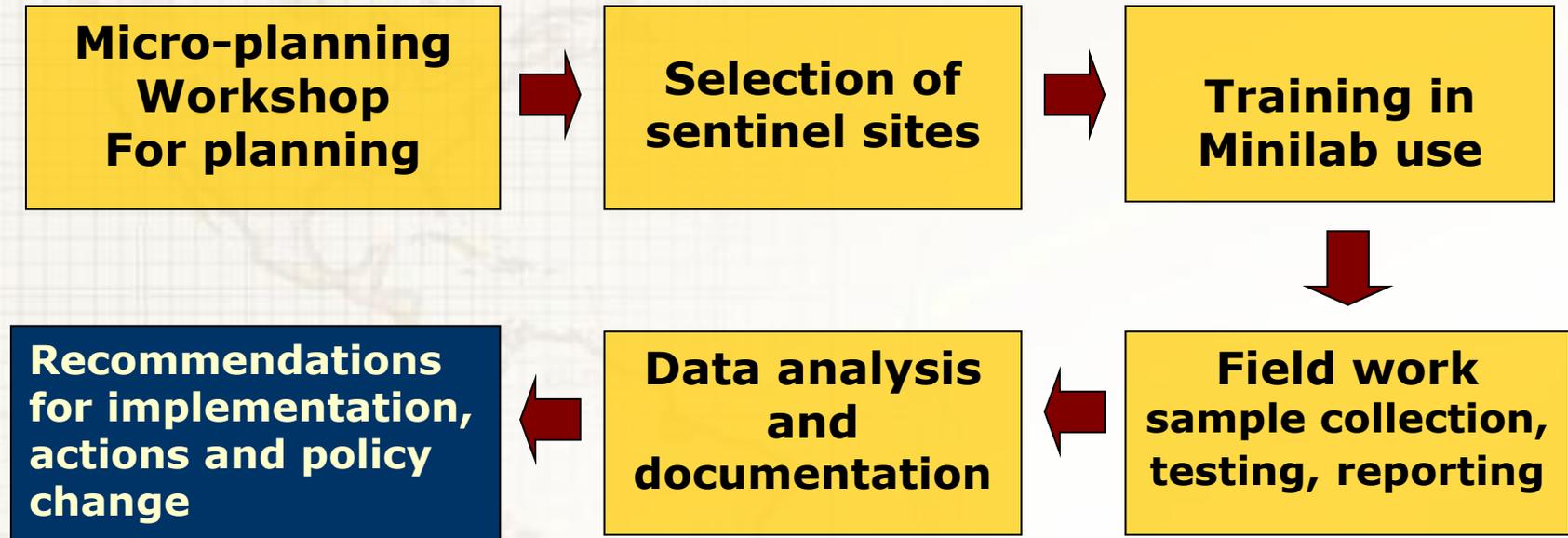
Program Targets for Ghana

- ◆ Develop and implement a postmarket surveillance program for the quality of antimalarials in Ghana
- ◆ Strengthen the capacity of FDB and FDB Laboratory for quality assurance and quality control of antimalarials



Framework for Drug Quality Monitoring

Promoting the Quality of Medicines Program



PQM also trains quality control labs on compendial analytical methods, such as HPLC, dissolution, and UV-spectrophotometry.



Medicine quality monitoring in Ghana

Accomplishments to date

Promoting the Quality of Medicines Program

- ◆ A team (>20) comprised of NMCP, FDB and regional FDB staff trained in field testing
- ◆ Protocol and monitoring framework established
- ◆ Five sentinel sites established for routine monitoring (Bolgatanga, Kumasi, Ho, Accra, Tarkwa)
- ◆ Following antimalarials are routinely tested (AS+AQ, SP, AR+LU, Quinine, Chloroquine)

A system has been put in place



Drug Quality Monitoring in Ghana

Promoting the Quality of Medicines Program



Sentinel Sites

- ▶ Bolgatanga
- ▶ Kumasi
- ▶ Ho
- ▶ Accra
- ▶ Tarkwa



Medicine quality monitoring in Ghana Accomplishments to date

Promoting the Quality of Medicines Program

- ◆ Monitoring collected & tested 447 samples: 128 failed basic testing (28%)
- ◆ Monitoring led to FDB withdrawing 22 products from the market
- ◆ Monitoring led to detection of counterfeit Coartem (no active ingredient) in Kumasi and subsequent withdrawal from the market

Counterfeit



Genuine



FY 10 Highlights

Promoting the Quality of Medicines Program

- ◆ Ghana was selected for the launching of NAMCOL (National Quality Control Laboratory) network
 - ▶ Promote south-south collaboration
 - ▶ Share information across countries
 - ▶ Mutual training in QC procedures





FY 10 Workplan

Promoting the Quality of Medicines Program

PROPOSED ACTIVITIES	DESCRIPTION	DELIVERABLES	TIMELINE
Conduct medicine quality monitoring in five sentinel sites	<ul style="list-style-type: none">• Collect samples of antimalarial• Carry basic tests at sentinel sites• Carry confirmatory testing in FDB lab• Draft and share final data report• Promote enforcement actions to be taken by FBD based on PMS data	<ul style="list-style-type: none">➤ Detailed data report issued and shared with stakeholders➤ Specific enforcement actions recommended to FDB	March - June 2010
Technical assistance toward ISO accreditation	<ul style="list-style-type: none">• Develop a workflow for ISO accreditation• Identify gaps in systems and procedures• Develop a list of needed SOPs• Assist the lab to draft missing or ill-prepared SOPs	<ul style="list-style-type: none">➤ A process map developed for ISO accreditation➤ List of SOPs developed and template SOPs provided to the laboratory	June – August 2010



Issues / Challenges

- ◆ Limited laboratory space at the FDB lab to handle more samples
- ◆ Lack of public standards for certain FDC antimalarials
- ◆ Need for on-the ground follow up of PQM activities
- ◆ Need to expand sentinel sites for better coverage



Looking Ahead

Promoting the Quality of Medicines Program

Continue Medicine Quality Monitoring

- ◆ Continue to support the monitoring program but make plans for sustainability
- ◆ Expand the sentinel sites to other strategic districts



Build Capacity of FDB Laboratory

- ◆ Advance to comply with Global Fund policy
- ◆ New Global Fund policy

“Recipient countries are required to test all samples upon receipt and monitor quality throughout the life of the product in a WHO-prequalified or ISO 17025 laboratory....”
- ◆ FDB Lab to develop implementation plan for WHO prequalification and ISO 17025



Looking Ahead

Promoting the Quality of Medicines Program

Support FDB Lab participation in NAMCOL

- ◆ Staff participation in NAMCOL workshop
- ◆ Support lab participation in proficiency testing



Build Capacity of local Manufacturers

- ◆ Provide better oversight of local manufacturers
- ◆ After product withdrawal, training should follow
- ◆ Training of manufacturers to be done through FDB
 - ▶ Process validation- consistent quality
 - ▶ Stability testing



Looking Ahead

Promoting the Quality of Medicines Program

Donor Coordination and Collaboration

- ◆ Collaborate with other donors to assist local manufacturers toward WHO prequalification
- ◆ Form working group of all donors and stakeholders in medicines quality assurance and quality control
- ◆ Map out key players in quality assurance (USAID, World Bank, Clinton Foundation, MeTA)



Request for Immediate Value-added Activities (opportunities for reprogramming)

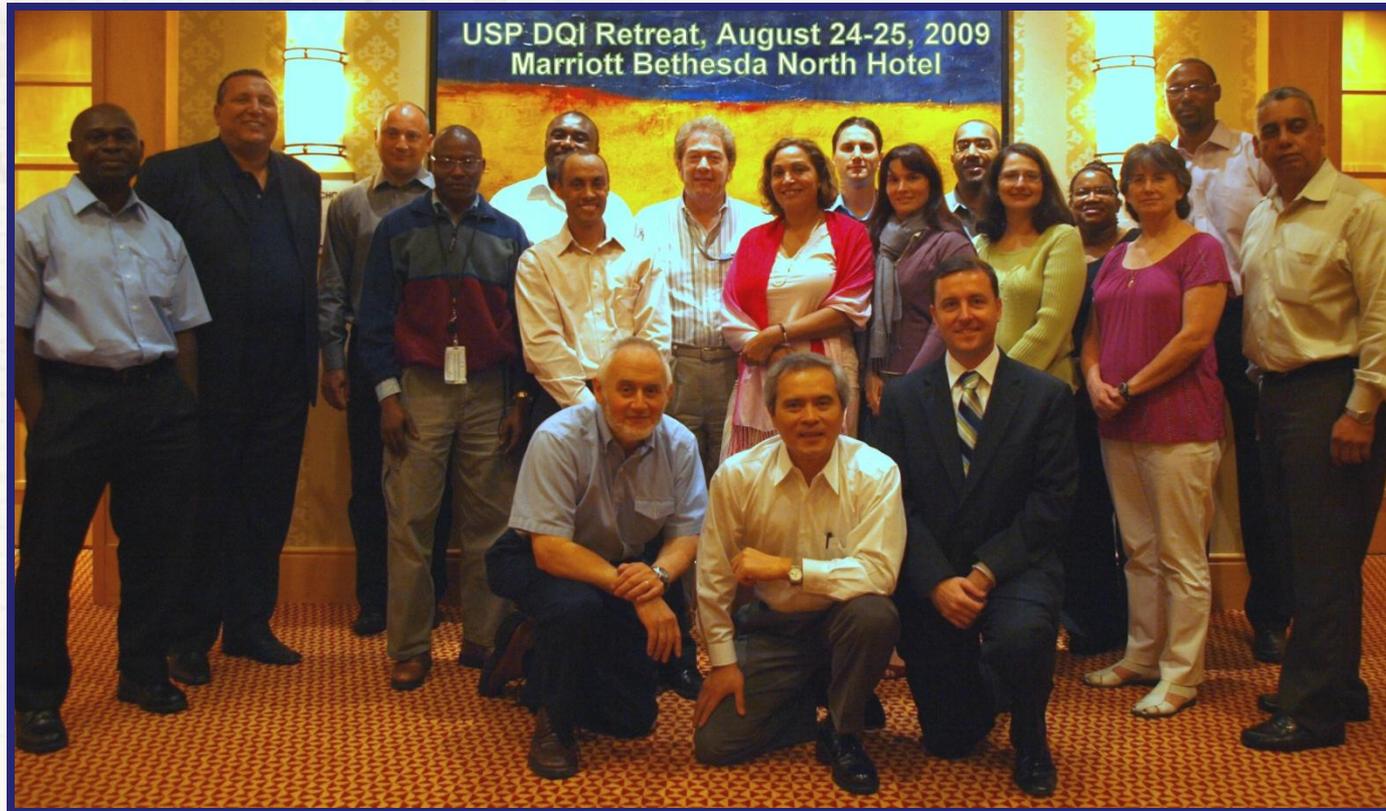
Promoting the Quality of Medicines Program

- ◆ Advocate and Raise Awareness
 - ▶ Public service announcement (PSA)
 - ▶ TV spots to inform the public about counterfeits and substandard medicines
- ◆ Local consultant to facilitate PQM work in Ghana
- ◆ Review laboratory blue print for the new FDB laboratory



PQM Staff

Promoting the Quality of Medicines Program



Where we're from: Argentina, Cambodia, Democratic Republic of the Congo, Ethiopia, Ghana, Jamaica, Laos, Mexico, Morocco, Philippines, Russia, Sierra Leone, Switzerland, United States, Zambia

Languages we speak: Akan, Arabic, Cambodian (Khmer), Chinese, English, French, German, Hebrew, Krio, Lao, Mende, Portuguese, Russian, Spanish



Thank You



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Questions?



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1st Design and Evaluation Report

Laboratory for Food and Drug Quality Control

Comment Laboratory Facility in General:

- Elevator is too small for goods transportation
- Laboratories must have 2 exits at opposite sides
- Doors from Laboratories should open to the corridor
- No electrical or mechanical Installation (riser) is shown
- Not to mix Offices and Laboratories on the same building side (fire coding)
- No supply for gases shown in the layout –Comment: Flammable and non-flammable gases to be separated
- Sizes and width of the Laboratories are not according to international Standard
- Maybe it is better to centralize the washing facilities and have only restrooms in each floor -> further investigation
- Doors to Laboratories have to be fire resistant minimum 30 minutes and equipped with a glass cut out that allows to see what is happening inside the laboratory.
- Live load should be ,75 kN /square meter

Comments to specific Laboratories:

Ground floor

- Sample Reception
 - no storage facilities (fridges, cold room, etc.)
- Medical Devices Lab
 - Lab should be a closed area / door is missing (What is happening here?)
 - the distances between laboratory benches is too small, the space at the walls can not be used for further laboratory furniture installation
- Doors to storage rooms should not be squeezed in the corner (missing area)

1st floor

- Sterility Testing Lab
 - gown missing, airlock missing,
 - no pass through chamber for materials –
 - class A / B / C / D – non classified
- door width -> laminar airflow workbench not able to pass
- Microbiology Lab
 - category Bio Safety Level – air lock missing
 - no second emergency exit
 - not enough space between benches / wall bench
 - no typical lab layout shown / fume cupboards, laminar airflow workbenches etc.
- Preparation lab should be next to main laboratory
- Inactivation of biological material – Autoclave? / in Washing Area?

2nd floor

- Physiochemical Laboratory
 - is placed on the Corridor -> so we loose the save corridor for emergency evacuation
 - not enough space
- Food Lab
 - no storage facilities
 - door opens to the wrong side
 - no second emergency exit
 - not enough space between benches

- no typical lab layout shown / fume cupboards, laminar airflow workbenches etc.
- Drug Lab
 - no storage facilities
 - door opens to the wrong side
 - no second emergency exit
 - not enough space between benches
 - no typical lab layout shown / fume cupboards, laminar airflow workbenches etc.
- Chemical Storage
 - Flammable and non-flammable reagents / Solvent can not be stored in the same room except for the fact that we put the flammable solvents into special cabinets. Generally the door has to open to the outside. Fire resistant walls 90 minutes.
- Instrument Lab
 - door opens to the wrong side
 - bigger door
 - second exit
 - analytical equipment needs special gases

The actual design does not qualify for a National Laboratory for Drug Quality Control. We strongly advise to analyze the flow of work in the different areas and design the designated areas according to international standards.

If you have any questions, please do not hesitate to contact us.

Regards,



Christian Schnitzer