

## Quality control in a qualified laboratory - An essential element to safeguard good quality medicines

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Quality control of medicines is a cornerstone of post-marketing surveillance. Drug supply organisations of the Ecumenical Pharmaceutical Network with the support of the German Institute for Medical Mission (Difaem) have investigated the quality of medicines at the WHO pre-qualified laboratory of MEDS (mission for essential drugs & supplies), Nairobi.

**Methods:** The DSOs could send five specific samples of medicines to be tested by MEDS ("pooled sampling/pooled testing arrangement"). The tests were based on USP requirements.

**Results:** From 2009 to 2012 in total 17 DSOs and Difaem partners from 14 different countries provided 234 samples of 27 different medicines/dosage forms for testing. Altogether, 234 samples were manufactured by 108 different companies in 28 different countries. 56% of the samples were from Asia, 32% from Africa, the rest from other continents. 76 samples had been manufactured in Africa, 130 originated in Asia, others from Europe and elsewhere. 98 (42%) samples came from 40 different companies in India; 33 (14%) from 6 companies in Kenya; 26 (11%) from 15 companies in China.

41 samples (17%) failed USP requirements - in turn this means that 83% of all medicines that were tested were of good quality. The main problems with substandard medicines were dissolution problems (17 of 41 samples). Out of 41 samples that failed USP requirements, 24 came from Asia.

**Conclusion:** Quality control is an important element to safeguard good medicines supplied to the health facilities. A well equipped laboratory like the one at MEDS can perform the required tests using USP required methods including HPLC.

### Biography

Andreas Wiegand has completed his Ph.D. in 1991 from the University of Freiburg. He gained experience in hospital pharmacy in Namibia and in Germany over nine years and joined the generic industry for ten years in various functions including regulatory affairs. Since the beginning of 2012, he is working as a programme officer at the secretariat of the Ecumenical Pharmaceutical Network in Nairobi, Kenya.

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