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Final Report

Ten trainees have attended the one month study course, arriving from five different African countries South of the Sahara as follows:

1. Tanzania Ms. Margareth Ndomondo-Sigonda
 Mr. Peter G. R. Anthony
2. Eritrea Ms. Zemzem Mohamed Taha
 Mr. Isaac Tecleab
3. Ethiopia Mr. Amare Bedasso
 Mr. Ferede Yitbarek
4. Uganda Mr. Deus Mubangizi
 Mr. Apollo Angole
5. Zimbabwe Mr. Percy Muzorori
 Mr. Archibald T. Chimuka

After the selection of the participants we had to ask help from the Hungarian UNIDO representatives at the Ministry of Economy in Budapest, to organise the entry papers for them. The residence permit was issued upon arrival to the country at the airport. We had to change the ticket for Mr. Deus Mubangizi from British Airways to Sabena, because he had no transit visa for London. Finally everyone arrived in time to Budapest. The hotel's driver collected them from the airport with the Hostess of Meditop. The representative kept a daily contact with the participants to assist them with the every day's problems in Hungary. She even participated in all of the social programs, which helped them a lot according to our experience.

The lectures have taken place at Hotel Aura (***) Pilisborosjenő, where all the participants had the accommodation full board.

The Opening Ceremony was organised at the Hotel, where the following persons represented their Organisations:

- Mr. Peter Hónig, Vice Branch Secretary, Chairman of the Hungarian National Committee for UNIDO
- Dr. Barnabás Fáy and Dr. Ernő Partl from the Hungarian National Committee for UNIDO, Ministry of Economy
- Dr. Bernardo Calzadilla-Sarmiento, UNIDO Quality, Standardisation and Metrology Branch
- Dr. János Pogány, UNIDO consultant of international experts
- Dr. István Orbán. Chairman of the Association of Hungarian Pharmaceutical Manufacturers as the patron of the course.
- Dr. Dávid Greskovits, Managing Director, Meditop Ltd.
- Mr. Zoltán Ács Managing Director, Meditop Ltd.

The representatives of the Hungarian Press were present also to give the necessary publicity to the Training.

The Training was settled down according to the Terms of References and our original proposal (The detailed Training program is on the CD-ROM). During the Training program

Annex to the
Final Report of the International Expert

1. FINAL TEST RESULTS OF TRAINEES

Nine trainees have participated in the final test of the training seminar because Mr. A. T. Chimuka from Zimbabwe left Hungary after completing two weeks of the training program.

Attachment 1. details the unedited questions grouped into 16 subjects. The questions were prepared by the speakers and arranged into groups by the subcontractor. There were six (6) questions in each group —identified by a combination Roman an Arab numbers— to be answered in 8 minutes. There may have been more than one correct answer for some questions (without an opportunity for getting extra points). The correct answer(s) had to be clearly circled. In case of a mistake, trainees were requested to draw a line through the incorrect answer and circle the correct one.

Attachment 2. shows the statistical evaluation of test results. From the possible total number of 96 points an average 73 (75.6%) was achieved ranging from a maximum of 82 points (85.4%) to a minimum of 61 points (63.5%).

Each participant answered correctly the following questions: I/1, I/4, I/5, III/6, IV/1, IV/3, V/3, VII/9, VIII/2, VIII/4, VIII/5, IX/1, IX/2, IX/4, X/2, X/4, X/6, XI/2, XI/3, XII/1, XII/3, XII/4, XII/5, XII/6, XIII/5, XIII/6, XIV/1, XIV/2, XIV/6, XV/3, XVI/1, XVI/2 and XVI/3.

The zero-answers deserve substantive comments.

II/2 “Which is the primary document required for packaging?” gave three options to answer and the correct answer could have been given by formal logical approach. Namely, answer a) “master formula” does not play a role in the packaging process, whereas answer c) “specification of components” is a group of documents rather than a primary document, which is the batch record.

Zero answers IV/4 and IV/5 reveal that the trainees have not understood fundamental aspects of polymorphism (which can be a critical variable of the efficacy of a solid pharmaceutical dosage form and the tablet-manufacturing process) and the methods to study this material property. The right answer (“same chemical structure and different crystal structure”) to question IV/4 should automatically come from undergraduate studies; it is also noted that answers starting with “different chemical structure” cannot be good. Again, the correct answer a) for question IV/2 “particle size measurement” (as a method not suitable to study polymorphism) could have been arrived at after a few moments of meditation.

The correct continuation “an appropriate infrastructure and systemic actions” to the statement XIII/1 “The basic elements of a quality management system are” was not found by the trainees although the sentence comes verbally from the presentation. Wrong options for continuation a) and b) deal only with the appropriate infrastructure and wrong option d) focuses on systemic action and lists only a few principal elements of the infrastructure omitting others like procedures, processes, and so on.

2. TRAINEES' EVALUATION OF SEMINAR

Attachment 3. shows the questions of the subcontractor to assess the opinion of the trainees about the substantive aspects and management of the program. It was not compulsory to reply to the questions and only five participants took advantage of the opportunity. The analysis of their answers follows the number of questions.

1. Validation was considered to be the most useful theme of the seminar. Quality management, GMP, GLP and design and refurbishment of facilities received more than one vote.
2. The majority of the answers considered each theme as a part of the training, although one comment said that “microemulsion and NIR analysis are not of immediate impact” possibly on GMP.
3. Very different views ranged from “need for more practical work” to “everything was all right”.
4. All answers were positive and can be summarized as the “attitude to GMP compliance significantly changed”.
5. All answers recommend participation in such training to colleagues but some feel that the program should be “tailor-made to own country” and “complemented by practical shows”.
6. The opinions on best features of the training include the interactive sessions and experienced speakers from industry.
7. The critics all consider that the interactive sessions and practical industrial work components of the program should be increased.
8. Basically the same answers were given as criticized before: more case studies, group discussions and country experience.
9. Everybody crossed “contended” with the organization and supply of the training.
10. Everybody made recommendations along the above lines as well as suggested that “make it annual”, arrange for “follow-up courses for specialization” include “industrial pharmacists as regular participants”.

3. SUMMARY ASSESSMENT

This evaluation is based on the attachments and on my personal experience gathered during the implementation of the training program.

The trainees had to pass a difficult, 96-question test in about two hours. The statistical evaluation of the final test results shows a mean of 76 per cent of good answers, which demonstrates a good performance of both the subcontractor and the speakers.

The trainees evaluated the seminar as useful that gave them an insight into GMP and validation. Critical comments were focused on the relatively low number of interactive sessions and industry demonstrations of theory in practice. Recommendations include the annual repetition of the one-month training program for industrial pharmacists.

US/RAF/98/075 - Statistical evaluation of test results

Question	ER1	ER2	ET1	ET2	TA1	TA2	UG1	UG2	ZI1	Good answers
I. 1	1	1	1	1	1	1	1	1	1	9
2	1	1	0	1	1	0	1	1	1	7
3	0	0	0	0	1	0	0	1	0	2
4	1	1	1	1	1	1	1	1	1	9
5	1	1	1	1	1	1	1	1	1	9
6	1	1	1	0	1	1	1	1	1	8
II. 1	0	1	1	0	1	0	1	1	1	6
2	0	0	0	0	0	0	0	0	0	0
3	1	0	0	0	1	1	1	1	1	6
4	0	0	0	1	0	1	1	1	1	5
5	1	1	1	0	1	1	1	1	1	8
6	0	0	0	0	1	1	1	0	0	3
III. 1	0	0	1	0	1	1	1	1	0	5
2	0	0	1	1	1	1	1	0	0	5
3	1	1	1	1	0	1	1	1	0	7
4	0	0	1	0	0	1	1	1	1	5
5	1	1	1	1	1	1	0	1	1	8
6	1	1	1	1	1	1	1	1	1	9
IV. 1	1	1	1	1	1	1	1	1	1	9
2	0	0	0	1	1	0	1	1	1	5
3	1	1	1	1	1	1	1	1	1	9
4	0	0	0	0	0	0	0	0	0	0
5	0	0	0	0	0	0	0	0	0	0
6	1	1	1	1	1	1	1	1	0	8
V. 1	0	0	1	1	0	1	0	0	0	3
2	1	1	1	1	1	1	0	0	0	6
3	1	1	1	1	1	1	1	1	1	9
4	1	1	1	0	1	1	1	1	1	8
5	1	1	1	1	1	1	1	1	1	9
6	1	1	0	0	1	1	1	1	1	7
VI. 1	0	0	1	1	1	1	1	1	1	7
2	0	0	0	1	1	1	1	1	1	6
3	1	1	1	0	1	1	0	1	0	6
4	1	1	1	0	0	0	0	0	0	3
5	1	1	1	1	1	0	1	0	1	7
6	0	0	1	1	1	1	1	1	0	6

Subtotal I: 219

Question	ER1	ER2	ET1	ET2	TA1	TA2	UG1	UG2	ZI1	Good
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US/RAF/98/075 - Statistical evaluation of test results

Question	ER1	ER2	ET1	ET2	TA1	TA2	UG1	UG2	ZI1	Good answers
VII. 1	0	0	1	1	1	1	1	1	1	7
2	0	0	1	0	1	1	1	1	1	6
3	1	0	1	1	1	1	1	0	1	7
4	1	0	1	1	1	0	1	1	1	7
5	1	1	1	0	1	1	1	1	1	8
6	1	1	1	1	1	1	1	1	1	9
VIII. 1	1	1	0	1	1	1	1	1	1	8
2	1	1	1	1	1	1	1	1	1	9
3	1	1	0	1	1	1	0	0	0	5
4	1	1	1	1	1	1	1	1	1	9
5	1	1	1	1	1	1	1	1	1	9
6	0	0	0	0	1	1	0	0	0	2
IX. 1	1	1	1	1	1	1	1	1	1	9
1	1	1	1	1	1	1	1	1	1	9
3	1	1	0	1	1	1	1	1	1	8
4	1	1	1	1	1	1	1	1	1	9
5	1	1	0	1	1	1	0	0	0	5
6	1	1	0	1	1	1	0	0	1	6
X. 1	0	0	0	0	1	1	1	1	1	5
2	1	1	1	1	1	1	1	1	1	9
3	1	1	0	1	0	1	1	1	1	7
4	1	1	1	1	1	1	1	1	1	9
5	1	0	1	1	1	1	0	0	1	6
6	1	1	1	1	1	1	1	1	1	9
XI. 1	1	1	1	1	0	0	1	1	1	7
2	1	1	1	1	1	1	1	1	1	9
3	1	1	1	1	1	1	1	1	1	9
4	0	0	1	0	1	1	0	1	1	5
5	0	0	0	0	1	1	0	0	0	2
6	1	1	0	1	1	0	0	0	0	4
XII. 1	1	1	1	1	1	1	1	1	1	9
2	1	1	1	0	1	1	1	1	1	8
3	1	1	1	1	1	1	1	1	1	9
4	1	1	1	1	1	1	1	1	1	9
5	1	1	1	1	1	1	1	1	1	9
6	1	1	1	1	1	1	1	1	1	9
Subtotal 2:										266
Question	ER1	ER2	ET1	ET2	TA1	TA2	UG1	UG2	ZI1	Good answers

US/RAF/98/075 - Statistical evaluation of test results

XIII.	1	0	0	0	0	0	0	0	0	0	0
	2	0	0	1	1	1	1	1	1	0	6
	3	0	0	1	1	1	1	1	1	0	6
	4	0	0	1	1	1	1	1	1	1	7
	5	1	1	1	1	1	1	1	1	1	9
	6	1	1	1	1	1	1	1	1	1	9
XIV.	1	1	1	1	1	1	1	1	1	1	9
	2	1	1	1	1	1	1	1	1	1	9
	3	1	0	1	1	1	1	1	1	1	8
	4	1	0	1	1	1	1	1	1	1	8
	5	1	1	1	0	1	0	1	1	1	7
	6	1	1	1	1	1	1	1	1	1	9
XV.	1	1	1	1	1	1	0	1	1	1	8
	2	0	0	1	0	1	1	1	1	1	6
	3	1	1	1	1	1	1	1	1	1	9
	4	0	0	0	0	1	1	1	1	1	5
	5	0	0	1	1	1	1	1	1	1	7
	6	0	0	0	0	0	1	1	0	1	3
XVI.	1	1	1	1	1	1	1	1	1	1	9
	2	1	1	1	1	1	1	1	1	1	9
	3	1	1	1	1	1	1	1	1	1	9
	4	1	1	0	1	0	1	0	0	0	4
	5	0	0	1	1	0	0	1	0	1	4
	6	1	1	1	1	1	0	1	1	1	8

Subtotal 3: 168

Grand total: 653

										<u>Average</u>
Total points:	66	61	71	69	82	79	77	75	73	73
Percentage:	68,8	63,5	74,0	71,9	85,4	82,3	80,2	78,1	76,0	75,6

Average control: 73

Average percentage control: 75,6

Készült : 2000.04.25. 166. 48p.

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Mr. Amare Bedasso Balcha	56,300	NETTO :	56,300	<i>Amare</i>
Mr. Apollo Angole	56,300	NETTO :	56,300	<i>Angole</i>
Mr. Archibald Taurayi Chimuka	56,300	NETTO :	56,300	<i>Chimuka</i>
Mr. Deusdedit Mubangizi	56,300	NETTO :	56,300	<i>Mubangizi</i>
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Mrs. Margareth Ndomondo-Sigondo	56,300	NETTO :	56,300	<i>Sigondo</i>
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2000 Ft:	0 db	200 Ft:	10 db	20 Ft:	0 db	2 Ft:	0 db		

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*Amare**Angole**Chimuka**Mubangizi**Yitbarek**Tecleab**Muzoroni**Risha Anthony**Sigondo**Taha*

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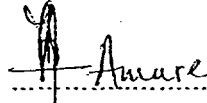
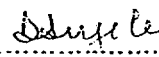




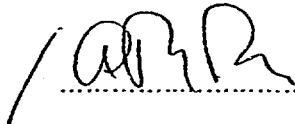
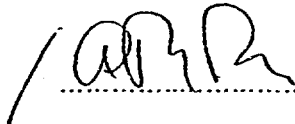
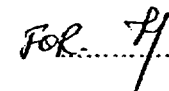
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