Final Report

Assessment of GMP-training at:

"State Training Centre for Good Manufacturing and Distribution Practice", State Inspectorate for Quality Control of Medicines of the Ministry of Healthcare of Ukraine – hereafter the “Branch”

28-29 November 2012

Scope

To evaluate and develop recommendations for further improvement of the GMP training conducted at the State Training Centre.

Subjects to be audited at a field visit

1. Course development
2. Scope
3. Programme
4. Methodologies
5. Performance
6. Competences of trainers
7. Course materials
8. Training records and certificates
9. Evaluation
10. Quality management

Phase 1

Pharmakon receives written information about the 10 subjects translated to English not later than 26 October.

Received 25 October.

Phase 2

Real GMP training has to be conducted during the audit. The assessment will include interviews with trainers, trainees and managers and observation of one day of training.

An internal one day training course “Current approaches to Process Validation with 5 participants were observed.

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Director and Deputy Director in common, each of the two trainers and all five trainees as a group were interviewed.

Phase 3

A report with observations will follow the field visit. The report is confidential between the Institute and Pharmakon. A copy is given to WHO, if the Institute agree.

Director Mr. Denys Gurak has agreed, that a copy of the report is given to WHO.

Phase 4

Development of recommendations for the further improvement of the GMP training centre. Follow up on corrective actions.

The recommendations were presented to the Senior Management on the final meeting and later on to Mr. Oleksiy Solovyov, Head of state administration of medicinal products.

Director Mr. Denys Gurak has agreed to follow up on the recommendations and sending their response on corrective actions to Pharmakon.

Director Ms. Ella Ulbak, Pharmakon has agreed on continuing cooperation on transferring the concept of Pharmakons Training and certification of Pharmaceutical Inspectors assuming that the Institute fulfill the training with module 2 and module 3 during 2013.

Practical issues

The two senior consultants from Pharmakon conducted the assessment.

- Director, Training Division Ella Ulbak
- Lead Auditor Michael Møller

The interpreter for the field visit/audit should be certified by Pharmakon.

Mr. Oleg Lutsenko.

Audit Programme - see Appendix 1.
Conclusion of the field visit /Audit:

The overall impression of the observed activities is very good.

We have reviewed the Quality Management System (QMS) and have made spot-checks on the implementation of and compliance to the system.

We have observed an internal one day training course “Current approaches to Process Validation” set up for Inspectors. Our experience by observing this course is that the professional level is of a high quality. From our point of view the pedagogical and communicative skills should be subject to improvement.

Regarding course facilities, these are considered suitable for the intended use, in terms of the number of participants attending the actual course (5). We were informed by the “Head of the Training and Methodology Department” that the maximum number of participants is limited to 24. It is advisable not to exceed this number. Equipment as described in the QMS (3.5 page 12 of 61) in the course room was in place prior to commencement of the course.

Our review of the QMS was based on the course “GMP theory and Practice” held on September 10.-14 Th 2012. During this review we found traceability, transparency and coherence in all crosschecked matters. In addition, interview of trainers, managers and participants were conducted in order to support our assessment.

More in detail and in relation to the 10 Quality parameters listed above in the Audit plan, we have assessed the following issues:

1. Course development: According to the QMS (3.2 page 9 of 61) this process is well described. However we experienced that a 2½ day PIC/S seminar organised in October 2012, was compressed to a 1 day course. Likewise we observed that 75 % of the original PIC/S seminar content was presented based on unedited material from this PIC/S seminar. In the QMS we found no guidance as to develop course material.

2. Scope (Learning objectives): This term seems to be non-existing in the QMS. The issue is addressed in details later.
3. Programme (Curriculum) OK.

4. Methodology/Pedagogical skills: We recommend improvement as to further development of course structure, methods and interaction. This implies ongoing training in different ways of chairing workshops, and methods of engaging the participants in solving cases presented at the courses.

5. Performance: Based on the fact that the presentations were departing from slides made of other people, we recognise the challenge it is to reuse others’ work. Clearly the appurtenant cases were easier to introduce to the participants and the trainers obviously appeared more comfortable in this situation.

6. Competences of trainers: Professional skills: Excellent 
Communicative skills: Should be improved

7. Course Materials: The readability of the slides used was of a bad standard both with respect to readability on the screen and in the printed material. It was a scanned PDF of the original PIC/S material.

8. Training records and certificates: OK.

9. Evaluation: The system for evaluation is excellent and well functioning. Both the overall evaluation of a particular course and the different topics addressed as well as the trainers are evaluated with a score. The average score accumulated is calculated for each course. Forms for these evaluations are included in the QMS manual as appendices 22 and 23 and were reviewed for the course “GMP theory and Practice” held on September 10.-14Th 2012.

10. Quality Management System – QMS: The Quality Management System is fully implemented, operating and complied to. The Branch holds an ISO certificate which has expired in June 2012. A new certification is expected in December 2012 from the international certifying Body, TÜV.

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Recommendations:

1. Based on our observations during the 2 days Audit/assessment we will recommend the Branch to make a plan for, how to improve and develop the communicative and pedagogical skills of the trainers. This can be done both as individual training depending of the already achieved skills for the each trainer and as group training for all lecturers taking advantage of the exchange of experience.

2. For each individual course to develop a “Scope/Learning Objectives”. By doing this, it will serve as a help for potential participants to know about the aims of the course and to which level they expect to be trained. By elaborating Learning Objectives, this will also serve as tool as to measure whether the trainer has achieved his goal for the particular course.

3. For the future we also recommend that you pay attention to allocate adequate time for preparation for the trainers. Also for the professional lay-out of the course material, it is important to encourage the trainers to prepare their own presentations according to your design manual for PowerPoint and word documents.

4. To maintain the attention of the course participants, we recommend that you put emphasis on mixing theory and practical exercises/workshops throughout the day and build in regular breaks. Any participant is unable to keep his/hers attention for no longer than app. 1 hour without a break.

We wish to thank all of the involved staff members, trainers, participants and managers who have been readily answering our questions and provided the requested documents.

December, 11. 2012

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Director, Training Division

Michael Møller
Lead Auditor

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Appendix 1

Assessment of GMP-training

"State Training Centre for Good Manufacturing and Distribution Practice", State Inspectorate for Quality Control of Medicines of the Ministry of Healthcare of Ukraine

27-30 November 2012

Agenda

Tuesday November, 27

16:50 Arrival and pick-up at Kiev Borispol International Airport
   Transfer to and accommodation at Gintama Hotel

Wednesday November, 28

08:30-17:00 Supervising the implementation of the Seminar Current approaches to process validation.

17:00-18:00 Interviews of two participants at the Seminar

Thursday November, 29

09:00-10:30 Interviews of Course managers and trainers

10.30-15:00 Audit of the Quality system, implementation and compliance

15:00-16:00 Auditors meeting

16:00-18:00 Final meeting – observations and recommendations

Friday November, 30

? Transfer to Kiev Borispol International Airport

12:50 Departure to Copenhagen

Lead Auditor Michael Møller

Director Ella Ulbæk

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