Pharmatech
TRAINING

Report of the QA/GMP project in Ulaanbaatar.

1 Short description.

On 6 and 7 October 2016 a QA/GMP course was organised together with the Association of Mongolian Pharmaceutical Professionals (AMPP). The venue of the course was the School of Pharmaceutical Biomedical Sciences in Ulaanbaatar.

2 Introduction.

The Dutch Foundation Farmacie Mondiaal (FM) approached Pharmatech Training with the question to organise a QA/GMP course for industrial pharmacists in Mongolia. The contents of the course should be defined together with the AMPP, section Industrial Pharmacy. Course leader from the side of Pharmatech was Simon Arnoldussen, PharmD. On behalf of the AMPP mrs. Munkhzul Mishig, QA manager of IVCO JVC, and secretary of the AMPP, was acting as contact to discuss the course contents.

The main goal of the AMPP is to improve the professional standard of pharmacists, in the public pharmacy as well as in the industrial pharmacy. At this moment, the AMPP is involved with the implementation of guidelines for the delivery and distribution of medicinal products in Mongolia.

Financially, the course was a real joined project in this sense, that Pharmatech considerably reduced the course fee to make it payable for AMPP, and FM accounted for the traveling and accommodation cost involved.

3 The project.

We arrived on Wednesday 5 October around 6 o'clock in the morning. Mrs. Zuzaan Zulzaga from AMPP, and her husband, very kindly picked us up from the airport, notwithstanding the early hour. To acclimatize we spend that first day trying to sleep off the jetlag and to discover Ulaanbaatar, which is an interesting mix of old and modern buildings. The end of the day we met with Zuzaan Zulzaga and Munkhzul Mishig to go over the final program and discuss last issues.

The first course day, Thursday 6 October, we arrived between 8 and 9 at the School of Pharmaceutical Biomedical Sciences. We were kindly invited by the Director of the Department of Pharmacy Dr. D. Davaadgva, who introduced us, together with the Zuzaan Zulzaga of the AMPP, to the attending pharmacists and other functionaries. Translations that day were taken care of by Mrs. Tsatsral Ichinkhorloo, consultant with HERA.

The contents of the first day encompassed the modern concepts of Quality system, Deviation control, Quality Risk Management, Change Control and Validation, based on WHO and ICH Guidelines. Where possible, practical examples were given to the participants. Particularly, the European concept of the

Qualified Person, legally responsible for the certification of medicinal products, received attention. The attendees thought that, at this time, such a concept would be impossible in Mongolia due to the view of management in companies towards the role of the Quality Department.

The second day the course was attended by the same participants. The second day encompassed all aspects of the subject 'validation', as well for sterile as for non-sterile processes and equipment. Technically, this part of the course was more difficult and not all subjects were equally interesting for each participant, depending on the type of product manufactured at their facilities.

The second day was completed with a session where the course certificates of participation were handed out.

4 Evaluation and follow-up.

The course was attended with enthusiasm, certainly the first day. Due to technical language difficulties, the second day was less appealing to the participants, although the subjects were closer to the day-to-day practice.

The preparation of the project started rather late, partly due to the time it took to agree on the course conditions. As the two-day course had to be prepared completely in English, and with the WHO Guidelines as reference, there was not enough time to translate all the sheets in Mongolian. Which made translation during the course more important and difficult, mainly due to the use of English pharmaceutical technical jargon.

For next courses, the preparation time should be longer, taking into account the very basic knowledge of English the participants have.

As for the subjects discussed during the course, we think that the concepts were clear to all participants. The difficult part is to implement the concept into the everyday practice of the business and the Mongolian working environment. A follow-up should be given where the subjects are discussed in more detail, with practical examples.

5 Conclusion.

The impression we have is one that is very positive towards the attitude of the Mongolian industrial pharmacists: ambitious, willing to gather knowledge necessary to improve the quality and reliability of the pharmaceutical products manufactured. Some companies have the ambition to marked their products in Europe.

The difficult part will be to make it clear to management - in all organisations - that quality is an upfront investment, which later will be earned back. A continuous effort should be made to improve and maintain quality – quality should be built into the organisation, and not seen as an inevitable burden.

Further, in Europe we know strict rules for the manufacturing of medicinal products, rules that are strictly enforced by governments, with a system of licenses that can be withdrawn EU-wide. In Mongolia such a system is far from being implemented at the moment, as we understand it. With still the realistic possibility for fraud as well.

So, not only the companies will have a task here, the enforcing government as well. We understood that for the public pharmacies guidelines are being developed together with the AMPP. Further, for industry a Mongolian national standard has already been developed (MNS 5524-2014), based on the WHO GMP Guideline. The problem is the implementation and the lack of regulatory enforcement at this moment.

6 Word of thanks.

During our stay in Mongolia we were very kindly welcomed by the AMPP. Special thanks go to Munkhzul Mishig for helping set up the course program and support during the course, and Zuzaan Zulzaga and her husband for showing us on Saturday the Gorkhi-Terelj national park - a beautiful part of Mongolia.

October 2016,

Simon Arnoldussen, PharmD