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SUMMARY

Title of Project:- Global Workshop on GMP in the Pharmaceutical Sector.

Duration of Workshop:- 19th-30th June, 1995.

Purpose of Project:- To create and improve awareness of GMP compliance in the Pharmaceutical Industry.

Main Conclusions:- The course was very successful, each participant was provided with a course evaluation form and the technical content was rated at greater than 95% consistently by every participant. The participants preferred a much more central location for the hotel and were somewhat disappointed with the quality of food and service of the hotel. The cost of single room, full board and refreshments was 99.00 USD per day.

A complete overview of the fundamental principles of GMP compliance was provided during the course. Invited speakers were asked to give some of the course lectures to provide participants with different viewpoints. Additionally to help understand the GMP concepts especially with respect to design and cleanliness, four different sites visits were arranged to multipurpose Pharmaceutical factories. These included generic Pharmaceuticals which included fill and finish (secondary manufacturing) as their primary function, a primary manufacturing company, research and development pharmaceutical company and the last one which exclusively made materials for clinical trials. The site visits were extremely helpful in highlighting GMP compliance. The course also covered audio visual presentations which are described in the text.

It was clear from participants discussions and feedback, that there was different level of maturity with respect of GMP compliance depending on the regions of the world. South America showed the strongest understanding of GMP compliance and Validation followed by Asia, Middle East and finally Africa. Africa needed the most support and resources to bring the level of GMP understanding to that of the rest of the world. It must be borne in mind that these conclusions are quite general and are based on the discussions and feedback of individual participants and may not necessarily reflect official status of each country.

The most important recommendations which arose from this workshop was as follows:-From the view point of limited resources UNIDO faces today and based on the feedback obtained from the individual countries, the major recommendation which arises from this workshop was to concentrate the limited UNIDO resources in the Middle Eastern countries such as Syria and Jordon and Asian countries such as India and China. The rationale behind this conclusion is that these countries supply not only their own needs but export to nearby countries too. For example, it is evident that Jordan and Syria supply Pharmaceuticals to the Middle East at large, China and India supply South America and Africa and other Asian regions. Therefore by concentrating resources of UNIDO to these areas,

many immediate advantages arise. For example, these areas are quite heavily populated and therefore having factories which are more GMP compliant in this region enables the fact that a larger population or greater per capita of quality drugs are distributed to the population , secondly the impact of adverse reactions due to non GMP compliance can be felt at a greater magnitude in more densely populated areas, and finally these countries export to other countries and therefore many more are exposed to the potential of adverse reactions due to non GMP compliance.
The participants all strongly believed in the value of one week on site GMP training of inspectors or designated individuals at the National Control Authority who could then in turn train their own local inspectors. The need for being in an environment with other participants and be able to share their experiences and problems with each other and the experts present for a period of time with interactive discussion and workshops on how to solve daily problems was one of the most beneficial aspects that the participants found and urged the UNIDO representative on site (Dr. Sanchez) to design more such courses for specific regions.

INTRODUCTION

This report is based on activities of the workshop carried out under the auspices of UNIDO. It was held at the Best Western Hotel, Montreal, Canada. The workshop Director was Rosemina Merchant of BioVentures Alberta Inc.

The workshop was held from 19th June to 30 th June 1995 incl.

The entire project was designed in a workshop format and included visits to four pharmaceutical factories. The activities carried out with this project so that all factory visits were preceded by inhouse lectures. Additionally, most invited speakers were asked to join the workshop during the second week to allow participants to reach a level playing field.

The objectives of the workshop were to:-

1. To visit some key pharmaceutical manufacturing installations
2. Direct workshop in GMP programs for the pharmaceutical Industry.
3. Direct the workshop on commercialization issues associated with the pharmaceutical industry.

The majority of the activity associated with this project is presented in the form of Workshop Manuals. A total of four (4) volumes accompany this report. These are essentially the workshop contents presented to the participants on the form of slides and course notes.

Where appropriate, additional supplementary literature in the form of published papers, brochures, technical reports and general information was supplied. All workshop material was supplied to each and every participant. Some participants requested additional copies and these were provided as well.