REPORT TO

IUPAC-UNESCO-UNIDO- COMMITTE
International Union of Pure and Applied Chemistry
United Nations Educational, Scientific, and Cultural Organization
United Nations Industrial Development Organization

in

Safety, Health, and Environmental Training Fellowship Programme

At Astrazeneca Pharmaceutical Company
Alderley Park, Macclesfield, Cheshire SK10 4TF Brixham
ENGLAND
31st October -16th November 2005

BY

Prof. Dr. Said Mohamed Mahmoud Bayomi

ACKNOWLEDGEMENTS

First of all, I would like to thank the top management of the AstraZeneca Company for having accepted to host me for two weeks under the IUPAN/UNESCO/UNIDO Safety, Health and Environmental Program.

Special thanks go to ***Dr. Kevin Connelly*** for his strong administrative, hard work and support throughout the entire exercise he did for my visit.

I gratefully acknowledge to all the members of AstraZeneca for that I met for their cooperation and support during my short stay in UK.

I'm particularly thankful to ***Dr. Mark Cesa,*** who was the link with IUPAC, for his faithful support and hard work man, and for answering all questions in connection with this training program since 2001.

Introduction

The gap between the developed and developing countries in safety education, research and implementation of technical measures is widening day by day. In the meantime the increase in chemical production and consumption in the developing world makes it essential to promote interactions to disseminate state of the art knowledge on safety and environment protection in chemical production. Thus, IUPAC- UNESCO- and UNIDO developed a joint training program for safety and environmental protection, which allows safety experts from developing countries to learn about safety and environmental protective measures by visiting and working with plants of IUPAC company associates in the industrialized world.

I was privileged to be selected for the safety training program which started in 31st October 2005 to 16th November 2005 and was accepted by AstraZeneca Pharmaceutical Company in the United kingdom.

Safety, Health and Environmental Program:

Places of Visit:

A- **AstraZeneca Alderly Park**
B- **AstraZeneca Macclesfiled site**
C- **AstraZeneca Brixham site**

A -Training topics in AstraZeneca Alderley Park :

Topics	Host
Risk Assessment Training course. An introduction to how SHE risks are identified, assessed and managed within AstraZeneca	Roger Preston & Jay Vaja
Review of Egypt Project Presentation of a new facility being developed by AstraZeneca in Egypt	Bill Tennant
Tour Chemistry Laboratories Mereside	Arnold Ratcliffe
Radiation and Control of Substances Hazardous to Health – An introduction to the UK approach to managing safety of chemical and radioactive substances in laboratories	Mike Smith
Spillage Control – How accidental spills are managed. Chemistry SHE Committee – The role of the SHE committee in promoting good practice and improving performance	Stwart Bowden
Tour of Bioscience Laboratories	Gary Burns
Biosafety and European Biosafety Association – An introduction to how Biosafety is managed in the UK and EU	Gary Burns
Biosafety SHE committee and laboratory – The role of the Biosafety SHE committee in promoting and sharing good practice and improving performance Animal allergens – How they are managed in AstraZeneca	Martin Rayer
Fire Safety and Safe System of Work – An introduction to managing fire safety in laboratories and systems for controlling change and maintenance Chemical Hazards and Risk Management – How chemical hazards and associated risks are managed in AstraZeneca's laboratories	Stewart MacBryde Arnold Ratcliffe
Safety Data Sheets HAZRD Safety Data Sheets, Dangerous Goods An introduction to safety data sheet production in AstraZeneca	Mair Oliver, Abena Achampong Sue Howson

B -Training topics in Macclesfield site

Tour to production research and Process Development laboratories	Martin Jones
Chemical Hazards – An introduction to the assessment and management of chemical reaction hazards and operations hazards such as static, fire and explosion	Steve Hallam

D- **Training topics in Brixham site**

Topics	Host
SHE discussions How SHE is managed in the Brixham environmental Laboratory	Richard Stanly, Rob Cumming Alec Page & Doug Morgan
Environmental Foresight – AstraZeneca's programme for tracking future issues Ecotoxicology & Husbandry – The work of the laboratory	David Taylor Nadine Pounds
Environmental Fate and Modeling – AstraZeneca's capability and experience in environmental monitoring Research & collaboration – How AstraZeneca works with universities	Gary Roberts Alan Sharpe & Paul Robinson Malcolm Hetheridge
Support to AstraZeneca Products – How the Global SHE organization supports the product portfolio	Sarah Barrett & team
SHE Information Support – Systems to provide corporate SHE information	Claire Coleman
Support to process Development & Manufacture – The role of Global SHE in supporting new product development	Chris Tickle & Team

Training Topics Highlights

- **Training Highlights on Safety, Health and Environment (SHE)**

AstraZeneca use a two-step risk assessment process. Preliminary risk assessment identifies the significant hazards and defines the control philosophy to manage those hazards. Detailed risk assessment challenges the design to make sure the controls are in place and adequate. The output is a Basis of She that describes the safe operating envelope. This is maintained and reviewed regularly. Risk assessments are facilitated by trained leaders.

The principles for safety, health and environment (SHE) risk management within AstraZeneca is to provide a guidance document for use by Risk Assessment Leaders and to include details on the key steps in managing SHE risks for a product or facility, from the Preliminary Risk Assessment to the regular Reviews of the Basis of SHE. This Guidance is not mandatory and should be viewed as a tool kit. It represents the core methodology for SHE risk assessment across AstraZeneca and describes techniques

which may be used in a wide range of activities such as warehousing, distribution, laboratories, pilot plants and chemical plants.

The methodology described is applicable across all functions, processes and activities within AstraZeneca and is not prescriptive. It is recognized that the depth of risk assessment required is likely to vary from project to project and between different functions. As a result, it is not practical to provide universal guidance on how this is best achieved. In areas such as Research & Development processes and activities, a pragmatic approach can be taken and local procedures and best practice should be used to carry out risk assessments, e.g., for individual experiments on the bench. Many different methods have been developed by the various industries for SHE risk assessment, and the techniques most widely applied in AstraZeneca. Risk Assessment teams have the freedom to decide the most appropriate depth of evaluation required for specific situations and to use alternative techniques where appropriate.

Basis of SHE document should be produced consisting of the following recommended sections:

a) Description of the facility, process, etc., to which the Basis of SHE refers. The boundaries of the Basis of SHE should be defined.

b) Reference should be made to the industry standards, codes of practice and regulatory / project specific requirements that will have to be satisfied by the project.

c) A list of all the hazards identified and the SHE philosophies agreed for each hazard.

d) A Revision Table showing the brief description of amendments carried out and the date.

e) Cross reference can be made to the relevant documentation such as project specification, engineering drawings, etc

f) The name of the person responsible for keeping the Basis of SHE up to date (at this stage this will normally be the project manager).

Conclusions from Detailed Risk Assessment

The Detailed Risk Assessment should have assessed the risks arising from the identified hazards and verified that the control features provided are adequate for credible deviations from design intent. It is important that the findings of the risk assessment are recorded in such a way that people who have not been directly involved

will be able to understand them. It is important that the documentation clearly shows that all actions identified during the risk assessment have been completed or gives reasons as to why they have not been completed.

The Basis of SHE document forms the basis for ongoing risk management as described in the following sections on Pre Start-up and Periodic Reviews; therefore, it is important that the Project Manager hands over the completed Basis of SHE and other relevant documents to the manager of the facility, equipment, process or activity.

Other documents generated during the Detailed Risk Assessment, e.g. record of HAZOP study, action review sheets, activity / line diagrams, etc., should be retained as reference material by the manager who is responsible for the facility, equipment, process or activity.

AstraZeneca have provided me with the training material and the guideline and will be willing to answer any further questions I have in using the material in my situation.

Material Safety Data Sheets (MSDS)

Material Safety data sheet is a means of transferring essential hazard information (including information on transport, handling storage and emergency actions) from the supplier of a chemical product to the recipient of the product. It may also be used to transfer this information to institutions, services and other bodies that play a role in dealing with the chemical product.

In order to establish uniformity, certain requirements have been laid down as to how information on the chemical product shall be given (for instance the wording, numbering and sequence of the headings). All products have a chemical abstract service (CAS) number and provide the chemical product information under the following 16 standard headings, the wording, numbering and sequence of which shall not be altered.

Hazard Identification Risk Assessment (HIRA)

This is a risk assessment tool that identifies hazards and enables risk to be plotted on a matrix. It operates with the following steps:

1. Subdivide division in logical units, for instance, identification of different sections in a department and various work carried taking note of the equipment, accessories etc.
2. List the hazards in each of these logic units using the check list.

3. Determine the consequence factor (worst case scenario).

4. Determine frequency from injury/incident and near incident history.

5. Note all the above information on a risk register (control measures, actions required, responsible person and target date).

6. Plot the risks on the risk matrix.

7. Finally review the process yearly or after any serious accidents /incidents. Usually a risk value is given which is normally the product of frequency of occurrence and the consequence. Both the frequency and consequence have a number score which is dependent on the severity of the consequence and frequency respectively. The higher the probability of an occurrence, the higher the number and the bigger the consequence of the accident which ultimately results to a higher risk value. Generally, risks are classified into Low, Medium and High.

The risk matrix enables effective decision to be taken in order to give priority to higher risk areas. This tool is very effective in enforcing best practice on Safety, Health and Environment (SHE) and can be used to address any/all of S, H or E. It helps put controls in place to reduce risk to a level as low as reasonably practicable, with a target date and responsible persons in place to action required control measures. It is a good tool to get agreement on what is important

Provision of Information

AstraZeneca have provided me with information about SHE management systems they use to manage the many SHE risks in Laboratories. They have also provided me with training material that I can use internally and externally.

Plans for my University

1. Departmental Laboratories:

- An SHE Team should be established
- Lab/Process Unit Safety, Health and Environmental Information binders for each experiment or research work.

Including:

- Instructions of using the binder
- Standard operating procedures
- MSDS (Material Safety Data Sheets) for each chemical used

- Process and Instrumental Drawings
- Utility Drawings
- Inspections
- Hazard Labels
- Personal Protective Equipment
- Audits
- Manuals
- Calibration Charts
  - Training Technicians
  - Safety Recall Interviews
  - Planned Task Observations
  - Quarterly Lab Tours
  - Safety Inspections
  - Weekly Safety Checklist
  - Safety Meetings
  - Lab Safety Program Sheets
  - Chemical Hygiene Plan
  - Safety Sampling
  - Emergency Response Team

2. Campus Site Safety:

- SHE Committee (should have a member from each faculty)
- Safety Council (members of each department – including fire and medical)
- Emergency Response Teams (for each department)
- Evacuation Procedures and Charts for each Building
- Drills (for fire and earthquake emergencies)

3. Plans for The Industry

Series of seminars and training programs

Suggestion for Program Improvement:

- This training is a useful tool for scientist in the developing World and I hope that IUPACUNESCO-UNIDO will make a follow up on this investment by maintaining contacts with trainees and using them where necessary to fill gaps in future projects apart from regular updating of the knowledge of trainees.

- In order to standardize and compare the health and safety course issues between countries and be able to determine the scope and desired level of coverage for the trainees, I wish to suggest that IUPAC develops both the course content and training materials for the trainees and the host company in advance so that the two parties are guided on what is expected of them. This will reduce the task of the host company to that of practical exposure as opposed to both theoretical discussions and field visits.

- Certificates should be issued to all Health and Safety Trainees and should bear the logos of IUPAC, UNIDO, and UNESCO.

- The course period should be extended from the current 2 weeks to at least 2 months. This will be sufficient to cover all the important issues of health and safety.
- Trainees should be supported financially and materially to undertake work shops, seminars, conferences, training sessions, demonstration projects on Health and Safety after their training. This way the impact will be immediate and bigger.
- Drills (for fire and earthquake emergencies)

Additional Information provided after completion of the report:

In AstraZeneca there are sophisticated Safety measures covering Operational, health and Environmental aspects in close relation with UK law and publics which gave my faithful strength for development and establishing better Safety, Health and Environmental issues.

My training and practicing in Astrazeneca covered the following topics which I am looking for to gain:

1. An introduction to how SHE risks are identified, assessed and managed within AstraZeneca.
2. An introduction to the UK approach to managing safety of chemical and radioactive substances in laboratories.
3. An introduction to how Biosafety is managed in the UK and EU.
4. An introduction to managing fire safety in laboratories and systems for controlling change and maintenance.
5. How chemical hazards and associated risks are managed in AstraZeneca's laboratories.
6. An introduction to safety data sheet production in AstraZeneca.
7. An introduction to the assessment and management of chemical reaction hazards and operations hazards such as static, fire and explosion.
8. Environmental Foresight and AstraZeneca's programme for tracking future issues.
9. Research & collaboration and how AstraZeneca works with universities.

As a trainer of IUPAC safety training, I have responsibility to :

1. Give seminars in he following topics:
   i) Risk Assessment Training Course,
   ii) Chemical Hazards and Material safety Data Sheets,
   iii) Radiation and Control of Substances Hazardous to Health,
   iv) And Others
2. Carry out as a result of more insights gained from of IUPAC –UNESCO-UNIDO safety training in AstraZeneca to Universities and industry in my country.
3. Organizing an obligatory training program for all laboratory technicians and teaching assistant staff members.
4. Include in the syllabus of the special courses of the Master degree studies, some of the SHE topics with Practical training program.

The training practice is a worthwhile investment and has sensitized me to greater commitment to Safety, Health and Environmental issues. An exposure that has left me an impression on me that it is possible to have an indigenous Universities and industrial companies operate within acceptable and best practices according to the international standers because of IUPAC-UNESCO-UNIDO Safety training program initiation. "Thank you to All of you".

Professor Dr. Said Mohamed Mahmoud Bayomi

Department of Medicinal Chemistry
Faculty of Pharmacy
Mansoura University
EGYPT

sbayomi@mans.edu.eg

top left: Dr. Kevin Connelly (AstraZeneca) and Dr. Said
top right: Dr Said Mohamed Mahmoud Bayomi in Manchester Square
bottom: Dr. Mike Smith and Dr. Said