The conference organising committee of SAAPI have again excelled and organised an enormously successful two day conference. The conference, dealing with Advances in Quality, Manufacturing and eCTD submissions, was held at the CSIR international conference centre in Pretoria on 28 and 29 July 2008 and was attended by 280 delegates – a true measure of success.

Speakers, both locally and internationally, who being experts in their field were able to share their knowledge and expertise with all the delegates. Some topics alerted participants to what can be expected in terms of quality and manufacturing in the near future, and others suggested improvements to existing practices.

The conference opened with a keynote address from Prof Ronnie Green Thompson, special advisor to the previous Minister of Health and the Chair of the Ministerial Task Team, on the review of the MCC and the MRA with regards to the recommendation of a new regulatory process for health products. He outlined the proposed new structure of the South African Health Products Regulatory Authority (SAHPRA) with its overarching responsibilities for all health products but with various pillars and sub-pillars. The reasons for the review of the system, which will be done every five years, is to improve efficiencies, improve communications and to ensure all health products are controlled including those that were not included, namely the complementary medicines, the medical devices and at a later stage the traditional medicines.

Rene Doms, a pharmacist who has moved into the legal arena and is now an advocate of the High Court of South Africa, has taken a special interest in the pharmaceutical industry. He gave an insight into the roles and legal obligations of the CEO and the Responsible Pharmacist (RP). He highlighted that where there is a conflict between the professional obligations and the business then the professional issues take precedence. Another interesting point raised was that with the MCC having become a PIC/S member, the Responsible Pharmacist needs to be cognisant of all the international laws that affect the RP. In closing, he advised that Directors of pharmaceutical companies are as responsible as the Responsible Pharmacist and therefore must act with due care, caution, wakefulness and prudence.

Dr Tom Sam, from Schering Plough Corporation in the Netherlands and President of FIP’s Industrial Pharmacists Section, addressed the conference on Quality by Design, a paradigm shift for industry and health authorities. The old paradigm involved testing and inspection, and the new paradigm, Quality by Design (QbD), involves a systematic approach to development that has a predefined objective based on sound science and quality management. This leads to more efficient manufacturing reducing direct and indirect costs to the manufacturer, and products that are more “fit for purpose” allowing for better drug therapy. He also addressed criticality in the manufacture of Active Pharmaceutical Ingredients (API’s) and finished dosage forms.

Linda Hakes, Vice President of Global Quality Operations at UCB in the UK, has 30 years of experience in the pharmaceutical industry and she expanded on Dr Sam’s talk focusing on improving quality and efficiency using QbD principles and PAT.

Annette Wodrich, our home grown expert, who has had many years of experience in production and quality assurance, shared her insight into the implementation of a Change Management Strategy for the company she is presently working for, MSD (Pty) Ltd, as well as LEAN in manufacturing. She shared the challenges the company has faced with change and how thinking and emotional issues had to be dealt with in the transformation. Once overcome, the efficiency and production levels improved remarkably.

Jens Myrseth, the regional QA manager for GE Healthcare based in Oslo, discussed good distribution practices when managing the supply chain risk by managing and monitoring distribution routes. He demonstrated that by knowing the product temperature requirements, understanding distribution routes, having well trained personnel with written procedures and following GDP, the product will be well protected.

Nate Morgan, an engineer from Alcon Laboratories based in the USA, gave us a practical guide for establishing control systems to ensure pharmaceuticals are stored in temperature controlled environment. By answering key questions like:

• what temperature range must the warehouse be maintained?
• how to control heat loss and gain?
• what SOPs are required?
• what do the staff know and understand?

the correct measures can be put in place to maintain the warehouse temperature.

The final day was dedicated to the fundamentals of eCTD compation, submission and evaluation. A route that our authorities want to follow. SAAPI was privileged to have a specialist in the preparation of the eCTD and the problems the EU and the UK are facing with these types of submissions. Dr Olaf Schoepeke, the managing director of Extendo, a company that specialises in submission management, labelling, pharmacovigilence and product submission and tracking, gave an insight into how to prepare companies for eCTD submissions. It became very clear that both the industry and the SA Regulatory Authority have a huge learning curve in understanding how to compile the data and the handling of the submissions. It will involve a move to the next level as far as IT and computer skills are concerned for a large number of the regulatory departments throughout the country.

This conference certainly whetted participants’ appetites for what is happening in the local industry both on the regulatory and on the legislative sides. There will be a number of SAAPI workshops expanding on what was learnt at this conference.

This conference also saw the launch of the SAAPI website so please visit it on www.saapi.org.za. One can also see what workshops were planned in 2008 and early 2009. There are a number of very interesting features and SAAPI would love to hear from pharmacists about what they would like to see on the site.

Congratulations to the SAAPI conference committee and the conference organisers for yet another well organised two day conference.