

The slide features a dark grey background with a light grey diagonal band running from the top-left to the bottom-right. A small, bright pink triangle is located in the bottom-right corner. The text 'SAPRAA ACTIVITIES' and '2009' is centered in a pink, sans-serif font.

# SAPRAA ACTIVITIES

## 2009

# Regulatory Authority, Legal & Pharmaceutical Topics:

Feedback on P&A Comments and Update on the eCTD:  
Mrs Estelle Taute, MCC

Equivalence of Medicines: Bioequivalence & Bio-availability Studies Ms Sanet Aspinall, AddClin Research

CAM Regulations: Mr Rene Doms

Pharmacovigilance: Mr Mukesh Dheda

Down-scheduling of Medicines: Mrs Allison Vienings

# Regulatory Authority, Legal & Pharmaceutical Topics:

Strategic Health Plan and Anticipated Changes to MRA/MCC:  
Dr Joey Gouws

Continuing Professional Development for Pharmacists:  
Mrs Lorraine Osman

Intellectual Property: Mr Alexis Apostolidis

DRU Workshop Presentation: Mrs Liz Filby (SAPRAA) and Ms Fleur Hartman (SAAPI)

Consumer Protection Act: Mr Aubrey Mathope

Update on MCC Backlog and the New Regulatory Authority:  
Dr Nicolas Crisp

# Global Regulatory and Quality Assurance Activities:

WHO Activities: Focus on Prequalification of Medicines:  
Dr André van Zyl, WHO, Geneva

Quality Risk Management:  
Mrs Helena van Schalkwyk, Boehringer-Ingelheim

Quality Risk Management Methodology:  
Mr Anthony Cumberlege, Roche

Pharmaceutical Quality Systems (ICH Q10):  
Dr Chris Stubbs, Aspen Pharmacare

## Disease Entities:

Osteoporosis: Dr Mampedi Bogoshi

Swine Flu (H1N1): Prof. Barry Schoub

Diabetes: Dr Wayne Riback

## **Other Topics of Interest:**

A Survey of the Volumes of Antibiotics Used in Food  
Animals in South Africa:

Dr Hayley Eagar

## **Motivational Speaking:**

Generate Personal Potential to be REALLY Energised:

Mrs Lynette Viljoen

**2010?:**

Introduction of CPD “points” for attendance: Certification being given a trial run

Refresher Courses for Regulatory and Quality Pharmacists – input from local and overseas Subject Matter Experts

Disease entities – topical, e.g. MDR- and XDR-TB, new HIV treatment protocols

Availability of Dietary Preferences – on reply form

Suggestions for Topics please!