Singapore RA Academy
Regulatory forum meeting minutes

ARPA
Asia Regulatory Professional Association

Date: 9 Dec 2011
Time: 3-5:30pm
Venue: Faculty of Engineering, National University of Singapore, Blk EA, level 6 unit 02 (EA-06-02), Engineering Drive 1
Chair: Prof. Teoh (NUS)
Secretariat: Mr. Kelvin Koh
Facilitator: Prof. Jack Wong
Guest: Dr. Raymond Chua (Deputy Group Director, Health Products Regulation Group, HSA); Ms Sabrina Chan (Executive Director, Hong Kong Association of Pharmaceutical Industry)
Participants: About 40 participants from universities, governments, industries and consultants

Topics presented:

1. History and Background of ARPA and achievements in different countries was presented by Prof. Jack Wong

2. Presentation by ARPA Singapore Academy Chair (Prof. Teoh): Objectives of Asia Regulatory Professional Association - Singapore Regulatory Affairs Academy, discuss the needs of Regulatory Affairs Professionals in Singapore The Recent Advances in Bone Bioengineering: from Lab to Clinical Applications

3. Guest presentation (Communication and negotiation skill with government) – by Sabrina Chan (executive Director of Hong Kong Pharmaceutical Industry Association)

4. Discussion and summaries

- The team agreed we should have this forum of discussion every 3-4 months.

- Dr. Raymond Chua mentioned the workload in HSA is very high and manpower is tight (currently 18 reviewers).

- Dr. Raymond Chua also stressed the importance of communication among government, industry and other stakeholders. He shared the idea of having 1 day per week consultation session in HSA for industry. From other countries' experience, we suggest to have the consultation on a first come first serve basis rather than advance booking basis in order to avoid abuse

- Vincent Cheung shared a government project that a survey will be circulated to understand the training needs of RA professionals in Singapore. ARPA (with Good Regulatory Practice Research Centre) will

support/assist the survey.

- During Sabrina's presentation, 2 Singapore related registration issues were discussed and explore how to avoid duplicate workload to HSA and also industry:
  - A product registration of 2 products with the same specification and design but only different manufacturing site. Industry may need to submit 2 applications with many duplicate documents. Raymond commented that HSA do allow company to register these 2 product under same license, with only one set of documentation shared between the 2 products (design, specifications, certification for the legal owner)
  - A product registration of 2 products with the same specification and design, same manufacturing site but different legal manufacturers. Industry may submit 2 applications with many duplicate documents in this case as well. Raymond commented that the same approach above also apply, such that HSA would allow industry to submit documentation showing the difference between the 2 products only (certification for the legal owner, quality manual, labeling). It was understood that Industry may need to do this registration a lot in order to ensure no stop product supply during legal manufacturer change, many duplicate documentation as the products concerned have the same specification and design, same manufacturing site etc. This approach can avoid too many duplicate documentation submitted to HSA and industry should be aware.

- Prof. Teoh suggested that we should have a training committee to fine tune the training course to RA professionals in Singapore. Dr. Raymond Chua accepted the invitation to be part of committee. Prof. Teoh will invite more representatives from different sectors and organize the first committee meeting during 1Q 2012.

- Asia RA textbook
  - Our goal in creating a book on medical device regulation in Asia Market to present the insights on regulatory affairs in different countries. Book covers topics ranging from medical device regulatory system in different counties, ISO standard for medical devices, clinical trial and regulatory requirement and documentation for application. The book covers latest regulatory information. Each chapter provides substantial background materials relevant to the particular area. We want these to be the books every medical device company interest in Asia medical device companies. Undergraduate and postgraduate students related to medical devices will be used as a textbook in order to guide them to start to launch medical devices products in Asia and also start their career in this field. The book will be expected to be published in 2012. The book size is in 9 by 6 inches and consist of approximately 200-300 pages.