

5th International Conference and Exhibition on Pharmaceutical Regulatory Affairs

Date & Venue: Aug 03-05, 2015 Florida, USA

(Theme: Share and Enhance the Aspects on Novel Policies in Regulatory Affairs)

Summary:

Regulatory Affairs-2015 welcomes attendees, presenters, and exhibitors from all over the world to Florida, USA. We are delighted to invite you all to attend and register for the "5th International Conference and Exhibition on Pharmaceutical Regulatory Affairs (Regulatory Affairs-2015)" which is going to be held during August 3-5, 2015 in Florida, USA.

The organizing committee is gearing up for an exciting and informative conference program including plenary lectures, symposia, workshops on a variety of topics, poster presentations and various programs for participants from all over the world. We invite you to join us at the Regulatory Affairs-2015, where you will be sure to have a meaningful experience with scholars from around the world. All members of the Regulatory Affairs-2015 organizing committee look forward to meeting you in Florida, USA.

For more details please visit- <http://regulatoryaffairs.pharmaceuticalconferences.com/>

Importance & Scope:

Regulatory Affairs is a profession which developed from the desire of governments to protect public health by controlling the safety and efficacy of products in areas including pharmaceuticals, veterinary medicines, medical devices, cosmetics.

Regulatory Affairs importance is to provide the strategic regulatory framework for the submission, to advise on procedures and formats, to collect, evaluate and compile the scientific data and information on the product. Conference share knowledge to the Pharma Industry Professionals, Professors and Students. Both Pharma companies and Bulk drug industries can be involved.

The regulation of medical products has been expanding since early 20th century. Regulatory agencies are being established in an ever increasing number of countries across the globe. Those that have established are reorganizing their systems and attempting to harmonize with organizations of other countries. The pharmaceutical, biotechnology and medical devices are among the most highly regulated industries in the world.

Source: [Reference4](#)

Why Florida?

After years of aggressive, coordinated effort, Florida has firmly established itself as a true hub for the Pharma industries. Today, Florida is home to some of the nation's most highly regarded research centers; over 1,000 biotech, pharmaceutical and medical devices companies; industry leaders - including Actavis, Arthrex, Bristol Meyers Squibb, Johnson & Johnson, Medtronic, Noven, and Steripak.

Florida's 200+ pharmaceutical and medicine manufacturing companies specialize in the development and manufacture of novel treatments, generics, nutraceuticals and OTC drugs. They employ nearly 4,500 researchers, engineers, technicians and workers.

Florida boasts the 2 largest medical device manufacturing industry in the U.S. Nearly 19,000 Floridians work in this industry, with a majority of companies located along the I-4 Corridor in Central Florida, the Jacksonville area, and in South Florida. Florida is home to more than 250 biotech companies and world renowned R&D institutes specializing in therapeutics, diagnostics, industrial/ag biotech and other areas. Florida has the science, talent, and support structure biotech need to succeed.

Source: [Reference1](#)

Conference Highlights:

- Regulatory Affairs for Healthcare Products
- Regulatory Requirements for Pharmaceuticals
- Novel Strategies for Growth in the Pharma and Regulatory Environment
- Biologics and Other Special Categories
- Best Industry Practices
- Intellectual Property Management
- Marketing authorizations, Advertising and marketing practices
- Drug Designing & Development
- Requirements for Medical Devices

Why to attend???

A deep understanding of legal, ethical and policy context is required to effectively navigate through today's regulatory environment. The Florida focuses in pharmacy with concentration in Pharmaceutical Outcomes & Policy to enable regulatory professionals, as well as health systems and insurance administrators, pharmacists, and lawyers to effectively create, manufacture and deliver pharmaceuticals that are safe for patient use and meet the policy and laws in place.

Major Associations in Florida

- Florida Society of Health-System Pharmacists
- Central Florida Pharmacy Association
- FPA - Florida Pharmacy Association
- Escambia County Pharmacy Association
- National Alliance of State Pharmacy Associations
- Dade County Pharmacy Association
- The Asia-Pacific Professional Services Marketing Association (AP SMA)
- Association of Internet Marketing and Sales (AIMS)-Canada

Major Associations in USA

- Regulatory Affairs Professionals Society
- Regulatory Affairs-American Chemical Society

- TOPRA-The Organization for Professionals in Regulatory Affairs
- Orange County Regulatory Affairs Discussion Group (OCRA)
- The Canadian Association of Professionals in Regulatory Affairs (CAPRA)
- AAPS Regulatory Affairs
- American Bakers Association
- American Association of meat processors
- American Herbal Products Association (AHPA)

Statistical Analysis of Associations

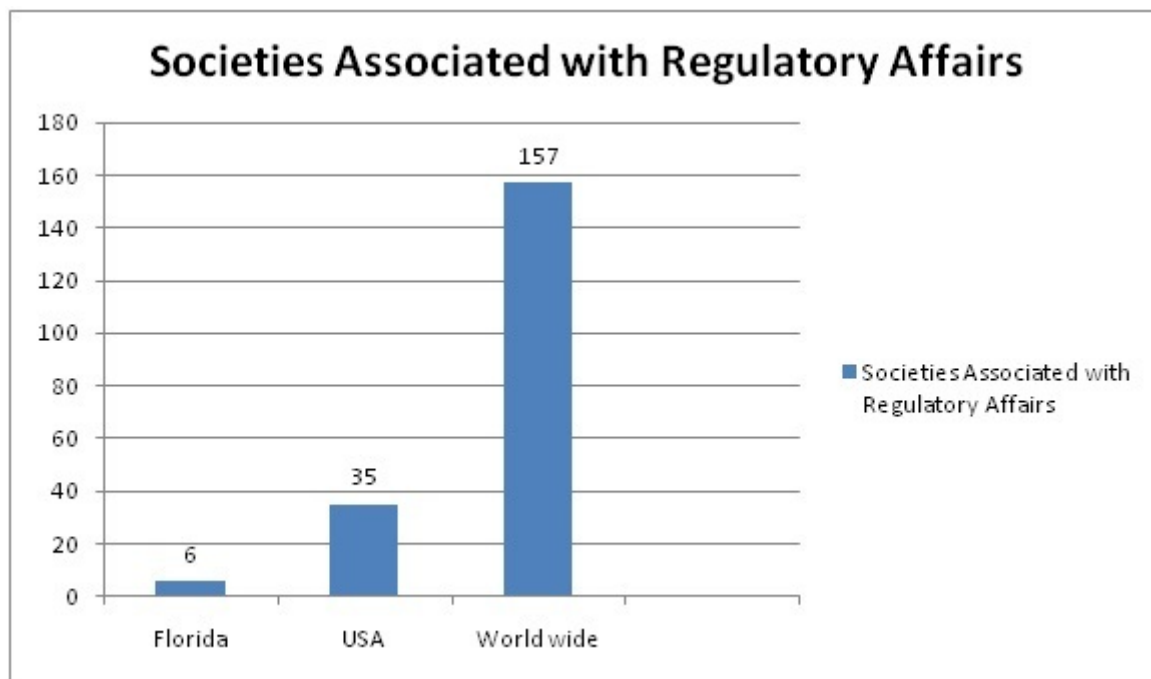


Figure 1: Statistical Analysis of Associations in Florida, USA and World wide

Target Audience:

Directors/Managers & Business Intelligence Experts, Departmental Managers, Vice Presidents/ Directors, Pharmaceutical Scientist, Scientist, Policy Analyst, Pharmaceutical Companies, Bulk drug Industries, Pharmaceutical regulatory agencies, Professors and Students from Academia in the study of Pharmaceutical regulatory affairs.

Top Universities in Florida:

- Nova Southeastern University - College of Pharmacy
- University of Florida College of Pharmacy
- University of South Florida - College of Pharmacy
- Lake Erie College of Pharmacy
- Palm Beach Atlantic University - School of Pharmacy

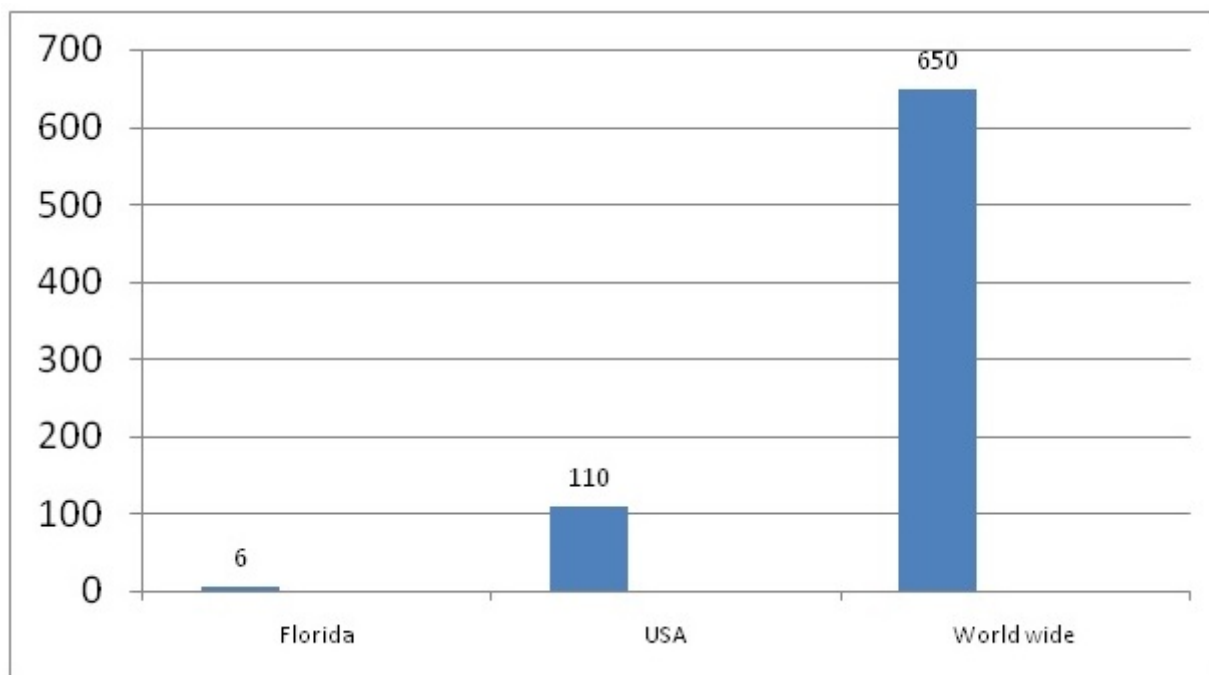


Figure 3: Statistical Analysis of universities in Florida, USA and World wide

Companies Associated with Regulatory Affairs

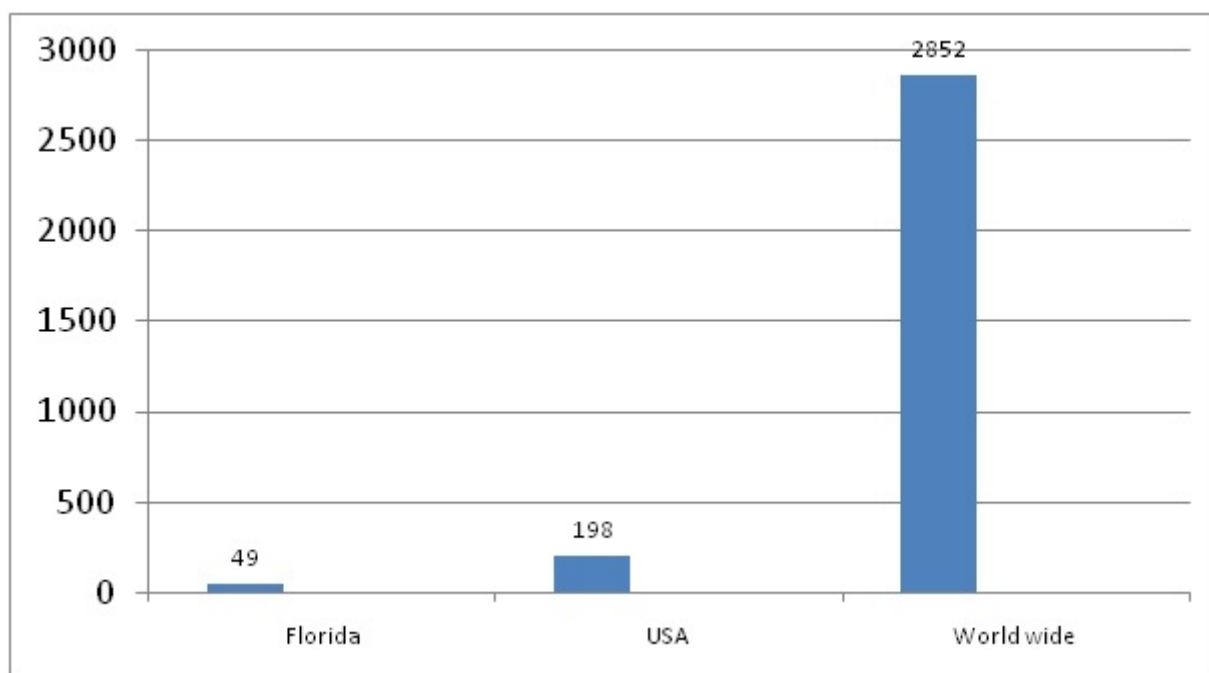


Figure 4: Companies Associated with Regulatory Affairs in Florida, USA and World wide

Marketing Analysis for Drug Approval:

Regulatory Affairs Department is the backbone of Pharmaceutical Industry. It is the revenue generator for pharmaceutical Industry. The Regulatory Affairs department is an important part of the pharmaceutical companies.

More than 15 years span is required to develop and launch a new pharmaceutical product in the market. The Regulatory Affairs

Agencies explains expenditure spent on each drug annually is \$850 million in US. The Indian Pharmaceutical industry is one of the fastest growing industries in India, with a compounded annual growth rate (CAGR) of over 13 % in last 5 years and it is expected to grow at a higher rate in coming 10 years India spends around \$300 million, united kingdom \$700 , Brazil \$200 million , France \$550, Italy \$400 As per cabinet decision in June 2010 in Japan amended a new policy i.e., Health power strategy through "Life Innovation" and expenditure spent on each drug was \$450 million .

Internally it cooperates with other department like drug development, manufacturing, marketing and clinical research. Externally, it is the key interface between the company and the regulatory authorities. Industrialized regulatory affairs is to drive compliance, speed to market, and cost efficiency.

Source: Reference3

Statistics which shows Expenditure spent on each drug for approval global, USA & Florida

Source: Reference2

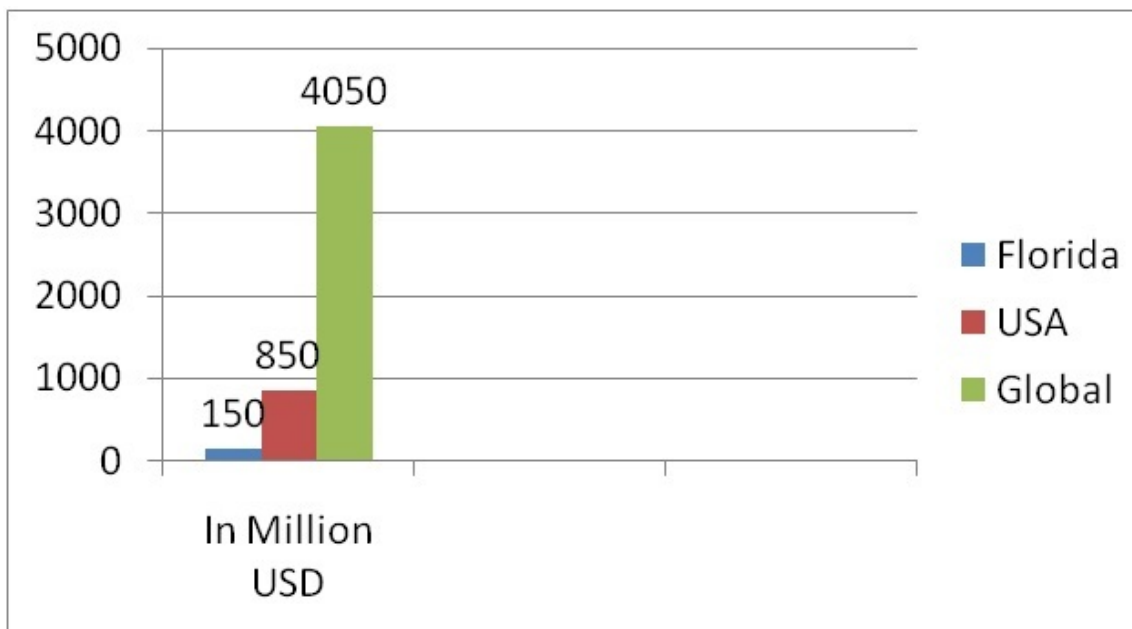


Figure 6: Expenditure spent on each drug for approval Florida, USA & global

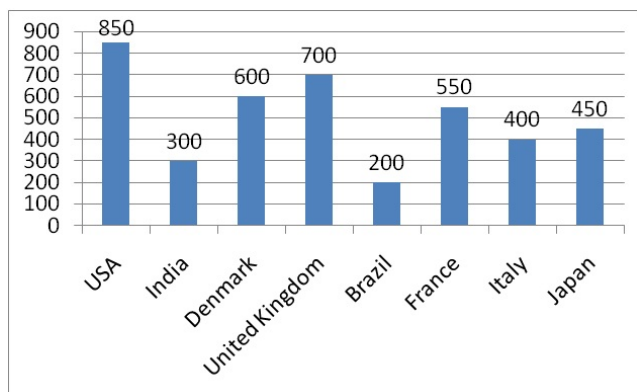


Figure 8: Expenditure spent on each drug country wise for drug approval

References:

1. <http://www.enterpriseflorida.com/industries/life-sciences/>
2. <http://www.pharmainfo.net/introduction-regulatory-affairs>
3. <http://www.hygeiajournal.com/downloads/554336197subash%20ansa.pdf>
4. <https://www.pharmatching.com/inforena/the-role-and-responsibility-of-the-regulatory-affairs-department>