



Meeting the Unmet Need in Regulatory Affairs: Rx Drug Advertising and Promotion

REGULATORY AFFAIRS

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AFFAIRS, INTELLIGENCE, LABELING, and ADVERTISING & PROMOTION

Agenda

Current State of Affairs in Regulatory Affairs - Vacancies

Introduction/Bio

Redress

Academic Education with Professional Training Sponsored by Industry

GIBBS Pharma Solutions (Rx Advertising and Promotion Training)

How do we create a Win, Win, Win, Win?

Introducing Iris Gibbs, JD, LL.M., RAC

20+ years in regulatory positions in the medical device, pharmaceutical, biotech industry

Entered the industry after law school to support a patent infringement lawsuit for a US-based German medical device laser company start-up

Work History: Dornier Surgical Products, Horizon Medical Products, Abbott Laboratories, Medtronic, Johnson and Johnson, Stryker, Eli Lilly Pharmaceuticals, GE Healthcare, Genzyme-Sanofi, Regeneron, Sage Therapeutics and Karyopharm Therapeutics

Specialize in the regulation of Rx drug/biologics/device advertising and promotion

Experienced in Treatment Areas:

Bariatric Surgery

Diabetes

Pain Management

Artificial Limbs

Rare Diseases

MS

Oncology

CNS/Mental Health

Nuclear Imaging

Degenerative Eye Disease

Cardiovascular Disease

Minimally Invasive Surgery

Drug Delivery/Movement Disorders

Electric Stimulation

Education

- Undergraduate: University of Michigan, Bachelors of Arts in History
- Graduate: Atlanta's John Marshall Law School (2)
(1) Doctor of Jurisprudence
(2) Master of Laws - Employment Law with Honors
- Post-graduate: Harvard University, Post-Graduate Certificate -Business Management
- Post-graduate: Villanova University, Post-Graduate Certificate -Six Sigma
- Doctorate: Massachusetts University of Pharmacy and Health Sciences
(On Hold)

Current State of Affairs in Regulatory Affairs Staffing

Increasing shortage of well-trained personnel in:

- Regulatory Advertising and Promotion
- Regulatory Global Strategy
- Clinical Strategy
- Clinical, Manufacturing, Controls
- Regulatory Operations
- Regulatory Labeling

The Immediate, Unmet Need

Research shows that the industry has a talent gap and will need to fill ~100,000 regulatory specialist and manager positions over the next 10 years

University Master's programs in Regulatory Affairs graduate only ~ 500 professionals per year*.

There is a clear, immediate, unmet need for professional training.

*Graduate Training Capacity for Regulatory Professionals at US Universities: Are We Facing a Talent Crisis?
Richmond FJ, Church TD

Off the Radar

There is a particular immediate unmet need for Regulatory Affairs professionals who are Promotional and Advertising content reviewers, editors and monitors

The challenge for industry is finding experienced people who are able to perform well in this role and responsibility at the time of hire

The challenge for professionals is that the needed expertise is challenging. They must know:

- the FDA and other laws and regulations, including enforcement actions
- the science of how drugs/biologics/devices are developed and how they work
- the clinical testing process
- how medical care is delivered
- how drugs are dispensed
- how Rx products are marketed and priced

How do we flatten the curve?

Let's Collaborate Together to create a qualified pool of RA Ad Promo Regulatory Professionals,

Universities provide the students

- Universities offer the professional training as part of a specialized course under the curriculum

Industry identifies the opportunities

- Industry benefits from the offering with access to a pool of new job candidates who are ready to work

Professional Training provides the needed education to Graduate Students

GIBBS AD PROMO REGULATORY TRAINING



GIBBS RX AD PROMO REGULATORY TRAINING

Customized Regulatory Promotional Training to Professionals Whose Responsibilities Are or Include the Advertising/Promotion and/or Marketing of Branded Products Commercialized by Pharmaceutical, Medical Device and Biologics Companies

FDA Regulations for Advertising and Promotion Compliance

FDA Regulations

In a two-day session, we will provide an overview of how FDA regulates the advertising/promotion and marketing of medical products.

Included will be a history of regulation, a summary of the rules and regulations, enforcement, how companies and individuals can comply, and other topics.



Gibbs Pharma Solutions- Rx Advertising and Promotion Strategies

Industry Case Studies

Day One of the two-day session will cover an in-depth education about the FDA rules and regulations and how they are enforced.

Included will be the role of other agencies, and a course in Regulatory Strategies which focuses on how to create innovative and impactful advertising and promotional materials for marketing commercialized branded therapeutic products.



Gibbs Pharma Solutions – Rx Ad Promo Training:

Best Practices

Advertising and Promotion Tools and Tactics

Day Two focuses on learning how to excel as a Regulatory Advertising and Promotion Professional.



Academia/Industry/Gibbs Pharma

We create the Win/Win/Win/Win through...

- Collaborative relationships with key Universities and Industry Partners
- Opportunities to partner with other Industry/Recruitment leaders, such as through participation at Industry conferences or direct connections like LinkedIn
- Combined efforts of Academia/Industry/Gibbs Pharma Solutions for training opportunities of Interns, Graduates and Professionals

In Short

The value proposition is to have a combined effort among universities, industry and professional training to meet an unmet, immediate need for regulatory professionals in the Rx drug/biologics/device area

Questions?

Next steps?

How to?

Business model:

Structure a compensation and fee schedule on a semester basis to train, certify and employ RA Ad Prom professionals:

Per campus/per student: 2 presentations over 1 weekend; 20 student limit/\$2600 per student

How can Gibbs Pharma Solutions provide Certification after completion of the Professional training?

How do we expedite this solution to address the current unmet need with the graduating class of 2020/21?

GIBBS Pharma Solutions

Training Master of Science RA, Pharmacy and Law Students in Regulatory Affairs
Advertising and Promotion

Two-Day Workshop to be held 3 quarters of the year over the weekends.

Providing Overview of the Role and the Industry Day One/Two

Providing Tools, Tactics and Case Study Day Two

Disrupter - Current Trainers target Professionals

GIBBS Rx AD PROMO TRAINING seeks to educate students in their last year of
Master's Programs University/Professional Schools as well as Professionals

Contact Information

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