

MARY Y. JAROSZ, RPH, RAC, FTOPRA

President and Principal Consultant, Jarosz Regulatory Services, Inc.

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International Regulatory Affairs since 1991

Pharmaceutical Industry since 1987

Health Care since 1984

REGULATORY ACTIVITIES

Regulatory Support

- Regulatory strategies for new and marketed products
- Regulatory strategies and plans for clinical studies
- Regulatory research
- Interactions with Regulatory Agencies
- Regulatory advice and guidance during drug development
- Responses to questions from Health Authorities
- Regulatory interim management

Regulatory Documentation

- Clinical studies: CTA/IMPD, IND, CTX
- Dossiers: CTD, MAA, NDA, ANDA, Regional Core Dossiers, Variations, Supplements, Amendments, Annual Reports, Re-registration Applications
- Orphan Designation Applications (EU, US)
- Drug Master Files: EDMF Open and Closed Parts, FDA Type I and Type II
- Clinical Study Reports, ISE, ISS

Training

- Tutoring of entry-level Regulatory Professionals
- Workshop tutorials

THERAPEUTIC AND PRODUCT AREAS

Therapeutic Areas

- Analgesics / anesthetics
- Anti-infectives / antivirals
- Cardiovascular
- Central Nervous System
- Dental
- Dermatology
- Endocrine
- Oncology
- Pulmonary

Product Areas

- Drugs, combination products
- Branded drugs, generic drugs, orphan drugs, US over-the-counter
- Starting materials, intermediates, drug substances / API
- Drug products: oral preparations (tablet, capsule, modified-release, granules, suspension, solution), sterile injectable preparations

COMPLIANCE ACTIVITIES

- Regulatory Affairs due diligence audits
- Document review for regulatory submissions

AREAS OF THE WORLD

- Australia / New Zealand / Asia
- Canada
- Europe
- Latin America
- South Africa
- US

LEADERSHIP PHILOSOPHY

Provide leadership for Jarosz Regulatory Services, Inc. to maintain an energetic team of professionals working on regulatory submissions for pharmaceutical products. Instill pride in work. Maintain first hand knowledge of regulatory issues that span the spectrum from worldwide strategy development to post-approval activities. Continually increase the expertise in medical writing. Through these commitments, promote repeat business and form long-term relationships based on high standards, trust, and personalized attention to all projects. Maintain a network of professional associations around the world to keep current with the constant changes in regulations.

POSITIONS

<i>President and Principal Consultant</i> Jarosz Regulatory Services, Inc. Whitewater, WI USA	1996 - present
<i>Senior Regulatory Affairs Associate</i> Abbott Laboratories, Inc. Abbott Park, IL USA	1994 - 1995
<i>Regulatory Affairs Associate</i> Abbott Laboratories, Inc. Abbott Park, IL USA	1992 - 1994
<i>Regulatory Affairs Associate / Label Editor</i> Abbott Laboratories, Inc. Abbott Park, IL USA	1992 - 1992

Research Pharmacist and Project Leader 1988 - 1992
Abbott Laboratories, Inc.
Abbott Park, IL USA

- Responsible for the development and scale-up of a pediatric formulation that was approved and marketed internationally.

Pediatric Intensive Care Clinical Pharmacist 1986 - 1988
University of Wisconsin Hospital
Madison, WI USA

Clinical Pharmacist 1984 - 1986
Michael Reese Hospital
Chicago, IL USA

EDUCATION

Baccalaureate of Science in Pharmacy 1978 - 1984
University of Illinois at Chicago

PRESENTATIONS and SPECIAL PROJECTS

- EU – FDA: CMC Differences: Regulatory Requirements for International Pharmaceutical Submissions: Focus on CMC and Regional Specific Expectations, American Association of Pharmaceutical Scientists (AAPS) Chicagoland Pharmaceutical Discussion Group (CPDG), Skokie, IL, USA, April 11, 2008.
- Roundtable Facilitator, Calling all Consultants! An Ideas Exchange, RAPS 2005 Annual Conference, Baltimore, MD USA, October 28, 2005
- EU Clinical Trials – Past & Present: Preconference Workshop on the Implementation of the EU Directive on Clinical Trials, RAPS 2004 Annual Conference, Washington, D.C. USA, October 10, 2004
- Global Clinical Trials: Regulatory Strategy & Requirements: Regulatory Strategy: Strategic Thinking for the Senior Regulatory Professional (RAPS), Coral Gables, FL USA, December 8-9, 2003
- Invited Guest Lecturer, INTERNATIONAL MEDICAL REGULATIONS on-line course at San Diego State University for the Master of Science in Regulatory Affairs program, “European Clinical Trials: Current Status and Future Directions”, February 2003 and October 2004
- Roundtable Facilitator, Global Registration Success Stories, RAPS 2001 Annual Conference, Baltimore, MD USA, November 7, 2001
- Mutual Recognition Procedure: RAPS 2000 Annual Meeting, Washington, DC USA, October 2-4, 2000
- Regulatory Requirements for European Clinical Trials: Drugs Today 2000 – Integrated US and International Current Issues (RAPS), Philadelphia, PA USA, April 11-12, 2000

- Workshop moderator for the European Regulatory Processes and Initiatives: RAPS 1999 Annual Meeting, Washington, DC USA, 4-6 October 1999
- The Centralized Procedure: Henry Stewart Conference Studies – Understanding the European Regulatory Environment and Procedures in Order to gain Marketing Authorization for Medical Products in the EU, Washington, DC USA, September 29-30, 1999
- The EU Systems and Dossier Preparation: Abbott Laboratories, Inc., Abbott Park, IL USA, January 1998

PUBLICATIONS

Mary Y. Jarosz, Regulatory Affairs Focus, "Orphan drug Designation in the US and Europe: Contrasts & Comparisons" Mary 2005.

Mary Y. Jarosz, Regulatory Affairs Focus, "Clinical Trials in the European Union" April 2003.

Mary Y. Jarosz, Regulatory Affairs Focus, "BSE and the Certificate of Suitability Dossier" March 2003.

Alison Bowers, Mary Y. Jarosz, BIRA The Regulatory Review, "Horizontal and Vertical Harmonisation via the Mutual Recognition Procedure" Dec 2000; 8.

Mary Y. Jarosz, Madison Business Journal, "Europe Trade Agreement Benefits the Drug and Medical Device Industries" April 12, 1999.

Mary Y. Jarosz, ESRA Rapporteur, "Clinical Trials in Latin America" 1999; 6(6):26.

Mary Y. Jarosz, ESRA Rapporteur, "PDQ Database Listing Cancer Clinical Trials" 1999; 6(6):21.

Mary Y. Jarosz, ESRA Rapporteur, "Come Surfing with Me" 1997; 4(3):31.

PHARMACIST LICENSURE

State of Illinois	1984 - present
State of Wisconsin	1986 - present

PROFESSIONAL ORGANIZATIONS

Leadership

Head of Publications and Publicity for TOPRA North America
Leadership Team 2004 - 2007

Active Member

Drug Information Association (DIA), Worldwide
Regulatory Affairs Professional Society (RAPS), USA
The Organisation for Professionals in Regulatory Affairs (TOPRA), Europe
Madison Area Business Consultants (MABC), USA
National Association of Women Business Owners (NAWBO), USA (2003)

Alliance

Regulatory Affairs US Consultants Network	2005 – present
Regulatory Affairs European Consultants Network	1998 – present

Committee Involvement

Regulatory Affairs Special Interest Area Committee Drug Information Association	2001 - present
Web Site Development Committee; European Society of Regulatory Affairs	2000 – 2003

ACHIEVEMENTS

- Appointed a Fellow of TOPRA (FTOPRA), October 2004
- Achieved Regulatory Affairs Certification (RAC) through RAPS, 2003
- 1990 Presidential Award - Abbott Laboratories, North Chicago, IL USA

COMMUNITY SERVICE / INTERESTS

The Basics of Negotiation Workshop, September 14, 2004, The University of Chicago Graham School of General Studies, Chicago, IL, USA

Red Cross Volunteer (2004)

Speech Judge for the Wisconsin Academic Decathlon (2003)

Transcontinental Bicycle Adventure presentation to 10 community service organizations (1996-2000)

Completed self-supported U.S. transcontinental bicycle trip of 7116 miles (1995)

Reading, bicycling (1st Masters 45-49, Wisconsin State Time Trial Championship), beekeeping, kayaking, cooking, bird watching

March 18, 2008