Generic Drug Registration

Preparing for Successful Submissions in the New Millenium

December 13-14, 1999
The Ritz Carlton Pentagon City • Arlington, VA

Take a Proactive Approach to Accelerate the Approval to Market by:

- Understanding FDA guidelines and requirements
- Determining what data is needed to support the ANDA
- Exploring electronic submission documentation for bioequivalence studies
- Reviewing the latest developments of SUPAC and IVIVC

To Register Call (888) 670-8200 *US; (941) 951-7885 INT'L*
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Presented by the Institute for International Research
Pharmaceutical Division

Why You Must Attend

Generic Drug Registration:
Preparing for Successful Submissions in the New Millenium

Since the FDA anticipates a dramatic increase of ANDA submissions over the next decade, it is critical for the application process to proceed as expeditiously as possible in order to remain competitive in the market. Each year, an average of 10 pioneer drugs lose their patent protection. This virtually eliminates their market exclusivity and thereby opens the door for generic alternatives. Attention to this area is expected to rise based on the number of important patent expirations along with the increased focus on health-care cost containment.

The FDA has increased its effort in ensuring that the generic products are indeed meeting the required standards. Any insufficient or inaccurate data ultimately delays the approval process. Timing therefore, becomes a critical factor. Electronic generic drug submissions are gaining precedence in resolving this issue. When properly executed, this process can expedite the evaluation and review process. If not, it can greatly hinder the review causing delays to market. Lastly, bioavailability and bioequivalence continue to be one of the most important issues for approval. Proper study execution and documentation are key to the successful approval of the application.

The Institute for International Research, is proud to present **Generic Drug Registration: Preparing for Successful Submissions in the New Millenium** seminar. This program has been specifically designed to address the challenges and concerns facing generic drug submissions and avoiding pitfalls. We provide hands-on examples of how to execute successful ANDA submissions for generic products. **Day One** comprises a practical course covering all aspects of FDA filing. **Day Two** includes a variety of current topics affecting generic products.

Our seminar leaders bring years of expertise to the table. Together they provide you with information on the guidelines and processes used to file generic drug submissions. Join us for two days of detailed education and training. You'll take back information guaranteed to benefit your special product needs. Don't miss this opportunity to discuss critical concerns one-on-one with the presenters.

Register today. Space is limited. Please use the registration form on the back of this brochure. Or, if you prefer, phone us at **(888) 670-8200 US; (941) 951-7885 Int'l;** or fax us at: **(941) 365-2507**. We look forward to greeting you on December 13th in Arlington.

To Register Call (888) 670-8200 *US; (941) 951-7885 INT'L*
Fax (941) 365-2507

Day One Monday, December 13, 1999

8:00	***Registration & Continental Breakfast***
9:00	**Day One Begins**
10:30-11:00	**Morning Refreshment Break**
12:30-1:45	**Luncheon**
3:15-3:30	**Afternoon Refreshment Break**
4:30	**Conclusion of Day One**

Seminar Leaders Welcome and Opening Remarks

Deborah R. Miran
President
MIRAN CONSULTING, INC.

Ken Muhvich, Ph.D.
Senior Regulatory Consultant
THE VALIDATION GROUP

Generic Drug Registration

I. **Signed Application Form**
1. Determining when to use Form FDA 356h or Form FDA 3439
2. Original Signature

II **Basis for ANDA Submission**

III. **Patent Certification**

IV **Comparing Generic Drug and Reference Listed Drug**
1. Conditions of Use
2. Active ingredients and supporting information
3. Inactive ingredients as appropriate
4. Route of administration, dosage form, and strength

V. **Labeling**

VI. **Bioavailability/Bioequivalence**
1. Financial certification/disclosure statement
2. In vivo study protocols
3. In vivo study results
4. Request for waiver of in vivo studies
5. In vitro dissolution data
6. Formulation data-comparison of all strengths

VII. **Components and Composition Statements**

VIII. **Raw Materials—Active and Inactive Ingredients**
1. Synthesis listing manufacturer and/or supplier
2. Certificates of analysis specifications
3. Test results from drug substance manufacturers
4. Testing specs and data from drug product manufacturers
5. Spectra and chromatograms for reference standards and test samples

IX. Description of Manufacturing Facility and Outside Firms
1. Facility Description
2. CGMP certification
3. Central File Number (CFNs)

Day Two Tuesday, December 14, 1999

8:00	**Registration & Continental Breakfast**
9:00	**Day Two Begins**
10:15-10:30	**Morning Refreshment Break & Hotel Check-Out**
12:00-1:45	**Luncheon and Featured Presentation**
3:00-3:15	**Afternoon Refreshment Break**
4:30	**Conclusion of Day Two**

Featured Luncheon Presentation

Countering the LCM Strategies of Branded Pharmaceuticals

Generic Drug Registration

X. **Manufacturing and Processing Instructions**
1. Manufacturing process description
2. Microbiological verification

XI. **In-Process Information**
1. Batch records
2. Specifications and in-process controls

XII. **Packaging Materials Controls**
1. Summary of packaging system
2. Components specification and test data

XIII. **Controls for the Finished Dosage Form**
1. Test procedures
2. Testing specifications and data (COA)

XIV. **Analytical Methods**
1. Methods for drug substance and product
   * Method validation
   * Test specifications and data

XV. **Stability of Finished Dosage Form**
1. Protocol
2. Post-approval commitments
3. Expiration dating period
2. Stability data of test samples
   * Normal stability data
   * Various stress conditions

XVI. **Sample Availability and Identification**

XVII. **Environmental Assessment (EA)**

XVIII. **Sterilization Assurance Information and Data**

A Symposium on Current Generic Product Topics

I. SUPAC-IR and MR Guidances
1. Mission of Regulatory Guidances
2. Overview of SUPAC-IR
3. Levels of compositional changes
4. Biopharmaceutical classification system
5. University of Maryland Research

II. IVIVC Guidelines
1. IVIVC in product development
2. Development of an IVIVC
3. Validation of an IVIVC
4. IVIVC in support of biowaivers
5. Implementation of an IVIVC in product development and optimization

III. Electronic Submission Document for Bioequivalence Studies
1. Explore the early stages and development of electronic submissions
2. Describe the current submission standards
3. Identify the challenges facing electronic submissions and how to overcome them
4. Understand the limitations of electronic documentation
5. Meet FDA requirements for electronic data submission
6. Implement plans to improve integrity and efficiency of electronic submission documents

IIR would like to thank everyone who has dedicated their time and effort with the research and organization of this event; especially the speakers for their enthusiasm, insights and commitment.

Distinguished Seminar Faculty

Natalie D. Eddington, Ph.D. is an Associate Professor of Pharmaceutics in the **School of Pharmacy at the University of Maryland, Baltimore.** Dr. Eddington received her Ph.D. from the Department of Pharmaceutics, University of Maryland, specializing in pharmacokinetics. Prior to joining the faculty of the University of Maryland, she served as an Assistant Director of Drug Development at Pfizer Pharmaceuticals. Research interests include examining factors that influence drug delivery and pharmacokinetics of drugs across biological membranes using in vitro cell culture, animal models, and healthy volunteers so as to elucidate structure-pharmacokinetic and pharmacodynamic relationships. Current efforts are directed toward the examination of the biopharmaceutical factors influencing oral absorption including: development of in-vitro in vivo correlation models to predict in vivo behavior, and evaluation of input rate and first pass metabolism on in vitro in vivo correlation. This research is relevant to drug disposition and the results are important in the design of drug delivery systems. Drug classes under investigation include HIV agents, anti-convulsants and anti-cancer agents.

Marie Lai is currently Operations Manager, Pharmacokinetics at **Phoenix International Life Sciences.** She worked as a biometrician at the South African Medical Research Council in collaboration with researchers in analyzing data related to hyperlipidemia in man and primates. Ms. Lai also worked at the Centre for AIDS studies, affiliated with the Montreal General Hospital, where she conducted epidemiological studies in the population of childbearing women, incarcerated women and injection drug users. She has held positions of Project Manager and Senior Project Manger in the Pharmacokinetics Department at Phoenix International Life Sciences, Inc., conducting and managing Phase I and bioequivalence studies. Ms. Lai obtained her degrees in Statistics at the University of Cape Town and in Communications & Linguistics at the University of South Africa.

Deborah R. Miran is founder and President of **Miran Consulting, Inc.,** where she advises both brand and generic drug makers on the FDA approval process. She previously served as Senior Director of Regulatory Affairs for Alpharma, where she coordinated all activities relating to NDAs. She was the firm's liaison to various state formularies and served on several industry and FDA committees aimed at improving the drug approval process. After starting her drug industry career at Syntex, Ms. Miran served as Senior Regulatory Officer at Geneva Pharmaceuticals

Ken Muhvich, Ph.D., is a Senior Regulatory Consultant with **The Validation Group.** Dr. Muhvich is a Registered Medical Technologist and has held the position of Technical Supervisor in the Clinical Microbiology Laboratory at Sinai Hospital in Baltimore, Maryland. His research interest center on the study of different treatment modalities tested in animal models of infectious diseases, e.g.,bacterial sepsis. He was awarded the Callendar Binford fellowship at the Armed forces Institute of Pathology located on the Walter Reed campus in Washington, D.C. He then joined the FDA's Office of Generic Drugs as a Review Microbiologist. While at the FDA, he performed 625 sterility assurance reviews (ANDAs, AADAs, and Supplements). Dr. Muhvich was recognized as a FDA expert in Advanced Aseptic Processing of sterile drug products and was the recipient of the FDA Scientific Achievement Award for Excellence in Review Science from the Office of Pharmaceutical Sciences. He earned his B.S. in Health Sciences from the University of Delaware, a M.S. degree in Clinical Microbiology from West Virginia University Medical School, and a Ph.D. in Experimental Pathology from University of Maryland.

Patrick Noonan, Ph.D. is Vice President of **Pharmacokinetics at PPD Development** and has 23 years of experience in Drug Metabolism, Pharmacokinetics, Biopharmaceutics, Drug Delivery and Regulatory Affairs. His areas of expertise include dosage form development, pharmacokinetics of oral (IR and ER) and transdermal drug delivery systems, cutaneous metabolism, bioanalytical assay development and regulatory aspects/CMC (Chemistry and Manufacturing Controls) of ANDAs and NDAs. Prior to joining PPD, Dr. Noonan held R&D and Regulatory positions at Mylan Pharmaceuticals, Key Pharmaceuticals (Schering Research, Miami) and G.D. Searle. Dr. Noonan is active in the National Pharmaceutical Alliance; his professional affiliations include AAPS, ASCPT, the Controlled Release Society and The Drug Information Association.

Luncheon Speaker

Richard DiCicco is President of **Technology Catalysts International,** a multinational consulting organization servicing the pharmaceutical and chemicals industries in licensing and business development. TCI's expertise includes assisting generic companies both domestic and international, with first launched generic to brand product introduction and establishing tactics to counter life-cycle management strategies implemented by original patent holders.

Achieve These Competitive Advantages by Attending this Seminar

- Understand the requirements for an approveable ANDA.
- Gain knowledge of the FDA guidelines and requirements
- Determine the key elements necessary for a successful submission
- Implement a successful application strategy to ensure approval
- Examine the role of electronic submissions and how it can expedite the review process
- Explore the latest information on bioavailability and how it impacts the submission process
- Identify how to interpret and respond to regulatory guidelines
- Review the latest trends and opportunities affecting the generic industry

Who Should Attend

Generic Drug Registration: Preparing for Successful Submissions in the New Millenium is designed for pharmaceutical and biotech professionals who are involved in writing and generating data for an Abbreviated New Drug Application. These include:

- **Regulatory Affairs**
- **Formulation**
- **Technical Services**
- **Regulatory Consultants**
- **Analytical Chemistry**
- **Quality Assurance/Quality Control**
- **Legal Council**
- **Third Party Manufacturers**

Do You Want to Reach the Audience at this Event?

Generic Drug Registration: Preparing for Successful Submissions in the New Millenium offers an excellent opportunity to showcase your product in front of key decision-makers.

Morning and afternoon breaks are carefully designed to ensure maximum networking opportunities, and all the exhibits are strategically positioned to ensure excellent traffic.

Maximize your marketing dollars by exhibiting at the conference, or increase your exposure even further by sponsoring a cocktail reception, luncheon or breakfast.

To learn more about **sponsorship** opportunities: **Todd Nakasato at (800) 345-8016 ext. 3215, email at takasato@iirny.com**

To learn more about **exhibit** opportunities: **Dan Schmidt at (800) 345-8016 ext. 3029, email at dschmidt@iirny.com**

Rave Reviews from Past IIR Conferences

"This conference is essential for companies embarking on electronic document management systems both for internal use and for electronic filings. The contacts I made at this conference are truly valuable-I now have peers at other companies to share ideas with, and through their experiences, will be able to avoid certain pitfalls throughout our project."

Suzanne Abeyta, Supervisor, Regulatory Document Management
GENEVA PHARMACEUTICALS

"Overall, this seminar was very well presented. I look forward to attending future seminars."

Shelly Holt, Regulatory Affairs Associate
PFIZER, INC.

"Very informative to learn about what others in the pharmaceutical industry are doing to meet the ever changing qualification and validation needs."

Stephen H. Decker, Senior TGL-Metrology
BARR LABORATORIES, INC.

"The conference was a great opportunity to exchange ideas with colleagues in the industry concerning current issues. It is an opportunity to see how other pharmaceutical companies are addressing similar problems and to assess the approaches we are currently pursuing."

Maryanne Quinn, Manager, Worldwide Regulatory Operations
MERCK & CO., INC.

Five Ways to Register

	FAX:	**(941) 365-2507**
	CALL:	**(888) 670-8200 *US* or (941) 951-7885 *Int'l***
	MAIL:	**Institute for International Research–NY Conference Administrator P.O. Box 102914 Atlanta, GA 30368-2914**
	E-MAIL:	**register@iir-ny.com**
	WEB:	**http://www.iir-ny.com**

Including the seminar materials, lunch and refreshments, your investment for attending Generic Drug Registration: Preparing for Successful Submissions in the New Millenium is $1295.

GROUP DISCOUNTS AVAILABLE — SEND YOUR WHOLE TEAM!
Send 3 individuals from the same company and the 4th attends at no charge!

Payments must be received by December 6,1999. You may pay by check, Visa, MasterCard, Diner's Club or American Express. Please make checks payable to **"Institute for International Research, Inc."** and write the name of the delegate(s) and our reference **#P0488** on the face of the check. If payment has not been received prior to registration on December 13,1999, a credit card hold will be required and will be processed 2 weeks following the conference.

DATES: December 13-14, 1999

VENUE: The Ritz Carlton, Pentagon City
1250 Hayes Street
Arlington, VA 22202
Phone: (703) 415-5000
Fax: (703) 415-5060

BOOK EARLY — HOTEL WILL SELL OUT!

To secure hotel accommodations at a discount rate, please call the hotel prior to November 13, 1999 and tell them you are an Institute for International Research delegate for the ***Generic Drug Registration: Preparing for Successful Submissions in the New Millenium*** seminar.

CANCELLATIONS: Should you be unable to attend for any reason, please inform us IN WRITING prior to December 6, 1999 and a credit voucher for the full amount will be issued. If you prefer, a full refund, less a $195 non-refundable deposit will be issued. No refunds or credits will be given for cancellations received after December 6,1999.

Substitutions of enrolled delegates may be made at any time. Please indicate upon registration whether you are eligible for a discount. No two discounts can be combined. If for any reason, IIR decides to cancel this conference, we are not responsible for covering airfare, hotel or other costs incurred by conference registrants. Program content is subject to change without notice.

All speakers and topics listed are confirmed as of press time. When substitutions must be made due to speaker cancellations, IIR makes every effort to find a replacement of equal caliber to present the scheduled topic.

Press permission must be obtained prior to the event and is dependent upon the speakers' approval. The press may not quote speakers or delegates unless getting their approval in writing.

AIR TRAVEL RESERVATIONS: IIR has negotiated discount fares with several airlines for conference attendees; Saturday night stays are not required. To learn more about these savings, please call IIR's designated travel agency, Advanced Travel Management, 489 Fifth Avenue, New York, NY 10017 at 212/867-6112; 800/592-1097 (outside New York State); or 212/867-6118 (fax); or (email) iir@advtravel.com between 8:30am-6:00pm EST and advise them that you are attending an IIR conference.

Any disabled individual desiring an auxiliary aid for this conference should notify IIR at least three weeks prior to the conference. Please call 212-661-6045.

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Send 3 individuals and the 4th attends at NO CHARGE

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