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Focusing on Regulatory Science News

FDA News

- On 27 December 2006, FDA announced that Dr. Larry Kessler, a senior FDA scientist and manager, will chair the Global Harmonization Task Force (GHTF) for the next eighteen months. GHTF is compromised of regulatory and industry representatives collectively addressing the need for international harmonization in the regulation of medical devices. See http://www.fda.gov/bbs/topics/NEWS/2006/NEW01540.html and http://www.ghtf.org/ for more details.

- On 19 January 2007, FDA announced two key personnel changes. John R. Dyer, MPH, was appointed as the agency's Deputy Commissioner for Operations and the Chief Operating Officer (COO). The newly created Office of the Chief Medical Officer will be overseen by Deputy Commissioner Dr. Janet Woodcock.
    - The Office of the Chief Medical Officer will oversee scientific and planning-related operations for FDA. Dr. Woodcock will share responsibility and collaboration with the Commissioner of FDA in planning, organizing, directing, staffing, coordinating, controlling, and evaluating the agency's scientific and medical regulatory activities in order to achieve the mission of FDA. Dr. Woodcock most recently served as the Deputy Commissioner for Operations.
    - Mr. Dyer will be a part of the senior management of the agency that supports the Commissioner in advancing his priority initiatives. Specifically, Mr. Dyer will concentrate on strengthening the management, business processes, and information technology of the agency. In addition, Mr. Dyer will work with the other Deputy Commissioners and the Chief of Staff to provide management leadership and oversight to FDA. Mr. Dyer most recently served as the Chief Operating Officer for the Centers for Medicare & Medicaid Services (CMS).

- On 30 January 2007, FDA outlined a comprehensive commitment to the safety of drugs and other medical products (see press release at http://www.fda.gov/bbs/topics/NEWS/2007/NEW01551.html). The FDA report, which responds to a set of recommendations made by the Institute of Medicine (IOM) in 2006, details a series of initial steps that aim to ensure that FDA's safety programs are the best possible. A copy of the report is available at http://www.fda.gov/oc/reports/iom013007.pdf. The FDA's "Commitment to Drug Safety" Fact Sheet is available at http://www.fda.gov/oc/factsheets/drugsafety-iom.html.

- A memorandum of understanding between FDA and the Veterans Health Administration became effective on 23 January 2007. The purpose of this MOU is to enhance knowledge and efficiency by

providing for the sharing of information and expertise related to the review and use of FDA-regulated drugs, biologics, and medical devices between the two agencies. The goals of the collaboration are to explore ways to: (i) further enhance information sharing efforts through more efficient and robust interagency activities; (ii) promote efficient utilization of tools and expertise for product risk identification, validation, and analysis; and (iii) build infrastructure and processes that meet the common needs for evaluating the safety, efficacy, and utilization of drugs, biologics, and medical devices. The MOU is available at http://www.fda.gov/OHRMS/DOCKETS/98fr/oc079-mou0001.pdf.

New Guidelines and Rules

- The IPAC-RS Supplier Quality Control Working Group, which includes representatives from OINDP manufacturers and device component suppliers, has published its ***GMP Guideline for Suppliers of OINDP Components,*** available for purchase at http://www.ipacrs.com/supplier.html. The IPAC-RS GMP Guideline, which incorporates the PS 9000 and ISO 9001 Guidelines, addresses those areas of GMP critical to OINDP that are not sufficiently addressed by existing quality Guidelines. This includes topics such as change control, cleaning, and extractables. The IPAC-RS Guideline was developed in an effort to help build quality into OINDP; encourage quality through design rather than through testing; promote quality assessment early in the supply chain; and provide OINDP suppliers and manufacturers with harmonized standards for OINDP component quality.
    - The IPAC-RS Supplier Quality Control Working Group held its Second ***OINDP Component Supplier GMP Workshop*** on Wednesday, 14 February 2007 in Chicago, Illinois to introduce the Guideline and discuss its use with OINDP manufacturers and component suppliers. The Workshop was held in conjunction with the 13 February 2007 ***IPAC-RS Symposium on Extractables in Materials for OINDP***, at which control of extractables in the OINDP supply chain was discussed. Presentations are available at http://www.ipacrs.com/supplier.html.

- On 21 December 2006, FDA announced the availability of the guidance entitled **Procedures for Handling Post-Approval Studies Imposed by PMA Order**, available at http://www.fda.gov/OHRMS/DOCKETS/98fr/2005d-0348-gdl0002.pdf. The guidance provides a standard format and content for submitting post-approval studies. The guidance is issued to help ensure that sponsors provide adequate information about the conduct of post-approval studies and that CDRH can properly track and evaluate post-approval studies. Comments can be submitted anytime to FDA Docket No. 2005D-0348 (http://www.fda.gov/dockets/ecomments).

- On 3 January 2007, FDA announced the availability of the draft guidance entitled **Draft Guidance for Industry and FDA Staff; Radio-Frequency Wireless Technology in Medical Devices**, available at http://www.fda.gov/OHRMS/DOCKETS/98fr/06d-0504-gdl0001.pdf. The draft guidance addresses issues relevant to the safe and effective use of radio frequency (RF) wireless technology in medical devices, including wireless coexistence, performance, data integrity, security, and electromagnetic compatibility (EMC). These issues involve all stages of the product life cycle and should be considered in preparing premarket submissions; identifying, documenting, and implementing product design requirements, as well as design verification and validation; and risk management processes and procedures. Written or electronic Comments are due by 2 April 2007 to FDA Docket No. 2006D-0504 (http://www.fda.gov/dockets/ecomments).

- **WITHDRAWAL**: Effective 12 January 2007. FDA published a direct final rule entitled **Medical Devices; Reprocessed Single-Use Devices; Requirement for Submission of Validation Data** that appeared in the Federal Register on September 25, 2006 (see http://www.fda.gov/OHRMS/DOCKETS/98fr/06-8166.pdf), that would have amended certain classification regulations for reprocessed single-use devices (SUDs) whose exemption from premarket notification (510(k)) requirements have been terminated and other reprocessed SUDs already subject to premarket notification for which validation data, as specified under the Medical Device User Fee and Modernization Act of 2002, are necessary in a 510(k). FDA stated in the direct final rule that, if it

received a significant adverse comment by December 11, 2006, FDA would publish a notice of withdrawal. FDA received two comments and considers at least one of these comments a significant adverse comment and, therefore, is withdrawing the direct final rule. Accordingly, the agency will consider the comments received under its usual procedures for notice and comment in connection with the notice of proposed rulemaking (see http://www.fda.gov/OHRMS/DOCKETS/98fr/06-8165.pdf) as a companion to the direct final rule.

- On 6 February 2007 FDA announced the availability of proposed and final documents that have been prepared by Study Groups 1, 2, and 4 of the Global Harmonization Task Force (GHTF). These documents represent a harmonized proposal and recommendation from the GHTF Study Groups that may be used by governments developing and updating their regulatory requirements for medical devices. These documents are intended to provide information only and do not describe current regulatory requirements; elements of these documents may not be consistent with current U.S. regulatory requirements. FDA is requesting comments on these documents.
    - Background Material Study Group 1: Role of Standards in the Assessment of Medical Devices (revised) http://www.fda.gov/OHRMS/DOCKETS/98fr/07d-0031-bkg0001-01.pdf
    - Background Material Study Group 2: Medical Devices Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices http://www.fda.gov/OHRMS/DOCKETS/98fr/07d-0031-bkg0001-02.pdf
    - Background Material GHTF Study Group 4: Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers- Part 3: Regulatory Audit Reports http://www.fda.gov/OHRMS/DOCKETS/98fr/07d-0031-bkg0001-03.pdf

  Comments on the above-listed documents are due by 7 May 2007 to FDA Docket No. 2007D-0031 (http://www.fda.gov/dockets/ecomments).

- On 28 February 2007, FDA announced the availability of a draft guidance for industry entitled **Advisory Committee Meetings--Preparation and Public Availability of Information Given to Advisory Committee Members**, available at http://www.fda.gov/OHRMS/DOCKETS/98fr/07d-0021-gdl0001.pdf. The guidance is intended to provide information to industry sponsors, applicants, and petitioners on the development, preparation, or submission of briefing materials that will be given to advisory committee members as background information prior to open FDA advisory committee meetings. The guidance will help sponsors develop, organize, and submit advisory committee briefing materials for public release and should help minimize the time and resources spent in preparing these materials for public availability. The guidance also describes the process FDA intends to follow when we make briefing materials available to the public. Comments are due by 30 April 2007 to FDA Docket No. 2007D-0021 (http://www.fda.gov/dockets/ecomments).

- Effective 5 March 2007, FDA is amending the standing advisory committees' regulations to change the name of the Advisory Committee for Pharmaceutical Science to the Advisory Committee for Pharmaceutical Science and Clinical Pharmacology. The new name more accurately describes the subject areas for which the committee is responsible. The committee shall provide advice on scientific, clinical and technical issues related to safety and effectiveness of drug products for use in the treatment of a broad spectrum of human diseases, the quality characteristics which such drugs purport or are represented to have and as required, any other product for which FDA has regulatory responsibility, and make appropriate recommendations to the Commissioner of Food and Drugs. The Committee may also review agency sponsored intramural and extramural biomedical research programs in support of FDA's drug regulatory responsibilities and its critical path initiatives related to improving the efficacy and safety of drugs and improving the efficiency of drug development.

- On 6 March 2007 FDA announced the availability of a final guidance for industry entitled **Orally Inhaled and Intranasal Corticosteroids: Evaluation of the Effects on Growth in Children**, available at http://www.fda.gov/OHRMS/DOCKETS/98fr/06d-0432-gdl0002.pdf. The guidance provides recommendations regarding the design, conduct, and evaluation of clinical trials to assess the effects of orally inhaled and intranasal corticosteroids on growth in children. For this class of drug products,

measurement of growth is considered a sensitive surrogate of, and an important sentinel for, the potential to cause systemic effects. Growth studies designed and carried out following the recommendations in this guidance can provide adequate and well-controlled data that are consistent among drug products and can be included in product labeling. This guidance finalizes the draft guidance published on November 6, 2001.

- On 7 March 2007 FDA announced the availability of a final guidance entitled **Drug Safety Information - FDA's Communication to the Public**, available at http://www.fda.gov/OHRMS/DOCKETS/98fr/05d-0062-gdl0002.pdf. The guidance describes FDA's current approach to communicating important drug safety information, including emerging drug safety information, to the public and the factors that influence when such information is communicated. The guidance was developed in connection with FDA's Drug Safety Initiative. The guidance is the final version and supersedes the previously issued draft guidance titled "FDA's Drug Watch for Emerging Drug Safety Information" (70 FR 24606, May I0, 2005). A press release is available at http://www.fda.gov/bbs/topics/NEWS/2007/NEW01577.html.

Outside of FDA

- The U.S. Pharmacopeia (USP) signed a Memorandum of Understanding (MOU) with the Pharmaceutical Export Promotion Council (PHARMEXCIL) on 15 February 2007 during the USP 6th Annual Scientific Meeting, Mumbai. The agreement recognizes the common interests of both organizations and establishes a formal relationship to develop mutually beneficial activities designed to improve the quality of medicines and dietary supplements and herbal ingredients. Specifically, the MOU calls for both organizations to: 1). promote cooperation; 2). improve transfer and exchange of information; 3). increase awareness; 4). establish the basis for a long-term relationship; and 5). develop standards.

- On 18 January 2007 The President issued an Executive Order amending Executive Order 12866 on Regulatory Planning and Review. The amendments would modify the Order to address government agency guidance documents in addition to regulations. Under the amended Order, agencies would need to provide to the Executive Office and the public justification for the creation of guidance, including assessment of the specific market failure and significance of the issue being addressed. Guidance documents covered by the Order are those that among other things would affect the economy by $100 million or more per year or "adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities." Office of Information and Regulatory Affairs in the President's Office of Management and Budget will have authority to review and approve of proposed guidance. The Order is available at http://www.whitehouse.gov/news/orders/.

- On 18 January 2007, the HHS Office for Human Research Protections (OHRP) released a final guidance on reviewing and reporting unanticipated problems including adverse events and risks to subjects or others. The new guidance reiterates the agency's draft guidance, issued in October 2005, which stated that "the vast majority of adverse events occurring in human subjects are not unanticipated problems" that must be reported under 45 C.F.R. Part 46. The new guidance defines "unanticipated problems" and provides examples of unanticipated problems that are not adverse events but that must still be reported under 45 C.F.R. Sec. 46.103(a) and Sec. 46.103(b)(5). The new guidance does not impact other federal guidance and requirements (e.g., FDA, NIH) for reporting adverse events. OHRP also posted revised versions of its guidances on continuing review and written IRB procedures that conform to the new guidance on unanticipated problems. The written procedures guidance also has a revised discussion of when an IRB must defer approval of research.
    - The OHRP guidance on reporting unanticipated problems is available at http://www.hhs.gov/ohrp/policy/AdvEvntGuid.pdf
    - The OHRP revised guidance on continuing review is available at http://www.hhs.gov/ohrp/humansubjects/guidance/contrev0107.pdf

  - The revised guidance on written IRB procedures is available at http://www.hhs.gov/ohrp/humansubjects/guidance/irbgd107.pdf

- According to an article in the *Economic Times India Times*, the Indian government is contemplating the creation of a single pharmaceutical regulatory authority modeled on India's Telecom Regulatory Authority or the U.S. FDA to create standards for drugs, pharmaceuticals, and cosmetics. India's current pharmaceutical standards under the Drugs and Cosmetics Act are only enforced in certain parts of the county. The drug industry in India also wants one single authority and standard-maker. A copy of the article is available at: http://economictimes.indiatimes.com/Unified_pharma_regulatory_body_soon/articleshow/1697054.cms.

Meetings of Interest

Information from Recent Meetings

- ***Inhalation and Nasal Drugs: The Regulatory Landscape*** sponsored by the International Pharmaceutical Aerosol Consortium on Regulation and Science (IPAC-RS), was held on 6-8 November 2006 in North Bethesda, MD. Presentations are posted at http://www.ipacrs.com/conf2006.html.

- FDA held a public workshop on issues related to the application process for seeking approval for marketed unapproved drugs. Presentations from the 9 January 2007 are available at http://www.fda.gov/cder/drug/unapproved%5Fdrugs/

- On 7 February 2007 FDA held a public meeting to solicit comments on issues that FDA should consider when developing revisions to its regulations regarding chemistry, manufacturing, and controls (CMC) supplements and other changes to approved marketing applications for human drugs. Meeting materials can be found at http://www.fda.gov/cder/meeting/CMC.htm.

- The IPAC-RS Supplier Quality Control Working Group held its Second ***OINDP Component Supplier GMP Workshop*** on Wednesday, 14 February 2007 in Chicago, Illinois to introduce the Guideline and discuss its use with OINDP manufacturers and component suppliers. The Workshop was held in conjunction with the 13 February 2007 ***IPAC-RS Symposium on Extractables in Materials for OINDP***, at which control of extractables in the OINDP supply chain was discussed. Presentations are available at http://www.ipacrs.com/supplier.html.

- On 26 February 2007 FDA held a public meeting to discuss the FDA's proposed recommendations to Congress for the next reauthorization of the Prescription Drug User Fee program which, if adopted, would significantly broaden and upgrade the agency's drug safety program, increase resources for review of television drug advertising, and facilitate more efficient development of safe and effective new medications for the American public. The following background materials are available: Press Release: http://www.fda.gov/bbs/topics/NEWS/2007/NEW01544.html; Federal Register notice regarding the meeting: http://www.fda.gov/OHRMS/DOCKETS/98fr/07-122.pdf; Agenda: http://www.fda.gov/ohrms/dockets/dockets/07n0005/07n-0005-lst0001.htm; and Presentations: http://www.fda.gov/ohrms/dockets/dockets/07n0005/07n0005.htm.

- On 28 February – 2 March the AAPS/FDA/IPSE co-sponsored a workshop entitled "***U.S. Food and Drug Administration's Pharmaceutical Quality Initiatives: Implementation of a Modern Risk-Based Approach***" held in North Bethesda, MD. An agenda and copies of presentations are available at http://www.aaps-ispe.org/.

Upcoming Meetings

- **FDA and Society of Clinical Research Associates (SoCRA)** will hold a two-day workshop on FDA clinical trial statutory and regulatory requirements. The workshop for the clinical research community targets sponsors, monitors, clinical investigators, institutional review boards, and those who interact with them for the purpose of conducting FDA-regulated clinical research. The workshop will include both industry and FDA perspectives on proper conduct of clinical trials regulated by FDA. The Workshop will be held on 7-8 February 2007 in San Diego, California; 16-17 May 2007 in Oakbrook, Illinois and 14-15 November 2007 in Honolulu, Hawaii (http://www.socra.org/html/FDA_Conference.htm)

- **FDA's Center for Devices and Radiological Health and Office of Regulatory Affairs**, in cooperation with **AdvaMed's Medical Technology Learning Institute**, is announcing a series of three seminars on FDA medical device regulations. These 2-day seminars, which are designed to address the training needs of start up and small device manufacturers and their suppliers, will include both industry and FDA perspectives and a question and answer period. 15-16 March 2007 in Irvine, California (http://www.advamedmtli.org/mtli/mtg07-13.cfm); 22-23 May 2007 in Lakewood, Colorado http://www.advamedmtli.org/mtli/denver.cfm); and 6-7 June 2007 in Pittsburgh, Pennsylvania (http://www.advamedmtli.org/mtli/pittsburgh.cfm).

- **International Symposium on Innovations and Advancements in Monitoring Oxygenation and Ventilation** (ISIAMOV 2007) sponsored by Duke University, FDA CDRH, Society for Technology in Anesthesia, and the University of Lübeck, on 15-17 March 2007 in Durham, North Carolina, USA (www.isiamov2007.org)

- **17th Annual AAMI/FDA International Conference on Medical Device Standards and Regulation** on 21-22 March 2007 in Herndon, Virginia. (http://www.aami.org/isc/)

- **19th Annual EuroMeeting Vienna 2007** sponsored by DIA to be held on 26-28 March 2007 in Vienna, Austria. (http://www.diahome.org/diahome/flagshipmeetings/home.aspx?meetingid=10610).

- **PQRI Training Course: Leachables and Extractables Best Practices** on 12-13 April 2007 in Chicago, IL. (www.pqri.org)

- **Respiratory Drug Delivery – Europe 2007** will be held on 17-20 April 2007 in Paris, France (http://www.rddonline.com/conferences/rddeurope2007.asp).

- **Smi's 3rd Annual Asthma & COPD Conference on** 25-26 April 2007 in London, United Kingdom. (http://www.smi-online.co.uk/events/overview.asp?is=4&ref=2508)

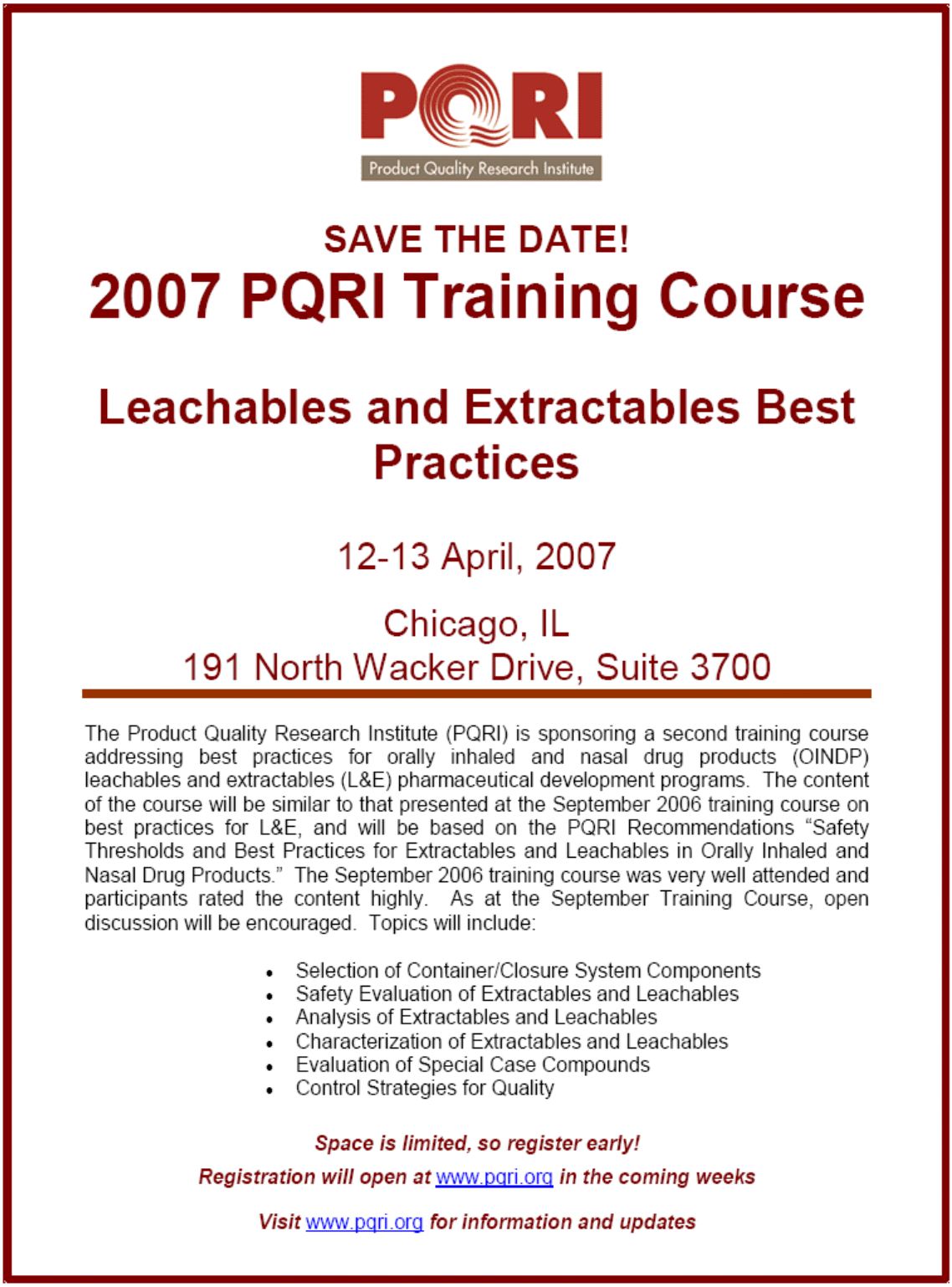
- **FDA Manufacturing Subcommittee of the Advisory Committee for Pharmaceutical Science and Clinical Pharmacology** (formerly Advisory Committee for Pharmaceutical Science) on 30 April 2007 in Rockville, MD. (http://www.fda.gov/OHRMS/DOCKETS/98fr/E7-3717.pdf)

- **The 2nd Congress on Global Approaches to Risk Management throughout Product Life Cycles** sponsored by FDA, Virginia Tech and AdvaMed, on 15-17 May 2007 in North Bethesda, MD. (http://www.advamedmtli.org/mtli/mtg07-08.cfm)

- **Workshop on BE, BCS and Beyond**, co-sponsored by FDA and APPS on 21-23 May 2007 in North Bethesda, Maryland (www.aapspharmaceutica.com/bebcs)

- **2nd Annual Drug Delivery 2007** on 6-8 June 2007 in San Diego, California. (http://www.pharmedassociates.com/conference.aspx?ccode=p666)

- **16th International ISAM Congress** sponsored by the International Society for Aerosols in Medicine (ISAM) on 16-20 June 2007 in Tours, France. (http://www.isam2007.com).
- **43rd Annual DIA Meeting** on 17-21 June 2007 in Atlanta, Georgia. (http://www.diahome.org/DIAHome/FlagshipMeetings/home.aspx?meetingid=11362)
- Save the Date: **RDD 2008 Meeting** 11-15 May 2008 in Scottsdale Arizona.



Reference Library

Guidances

- 2006 Annual Comprehensive List of Guidance Documents at the FDA (CBER, CDER, CDRH, CFSAN, CVM, OC/OP, ICH, ORA) http://www.fda.gov/OHRMS/DOCKETS/98fr/06-2941.pdf.
- Comprehensive List of CDER Guidance Documents: http://www.fda.gov/cder/guidance/CompList032007.pdf
- New/Revised/Withdrawn List of CDER Guidance for 2007: http://www.fda.gov/cder/guidance/newrevwithdrawn200702.pdf
- New/Revised/Withdrawn List of CDER Guidances for 2006: http://www.fda.gov/cder/guidance/newrevisedwithdrawn200612.pdf
- Guidance Agenda: Guidances CDER is Planning to Develop During Calendar Year 2006 http://www.fda.gov/cder/guidance/CY06.pdf
- Drug interactions http://www.fda.gov/cder/drug/drugInteractions/default.htm
- Guidance for Industry: M2: eCTD Specification Questions and Answers and Change Requests. Companion Document: Current Q & As and Change Requests

Approvals and Related Information

- CDRH list of approved premarket approval applications (PMAs): http://www.fda.gov/cdrh/pmapage.html
- PMA Safety and Effectiveness Summaries: http://www.fda.gov/OHRMS/DOCKETS/98fr/E6-59.pdf
- Drug Master Files: http://www.fda.gov/cder/dmf/index.htm
- Standard Costs for Components of the Process for the Review of Human Drug Applications (updated 6.1.06) http://www.fda.gov/cder/pdufa/pdufa_costs.htm
- Inspection of Medical Device Manufacturers http://www.fda.gov/cdrh/comp/guidance/7382.845.pdfversion.html
- CDRH Annual Report for Fiscal Year 2005: http://www.fda.gov/cdrh/annual/fy2005/fy2005.pdf.

People

- CDER Key Officials: http://www.fda.gov/cder/directories/keyoffic.pdf
- Office of Pharmaceutical Science (OPS): http://www.fda.gov/cder/OPS/default.htm
- Office of Pharmaceutical Sciences Coordinating Committee (OPS CC) http://www.fda.gov/cder/mapp/5000.6.pdf
- OPS Informatics and Computational Safety Analysis Staff (ICSAS): http://www.fda.gov/cder/Offices/OPS_IO/default.htm
- Center for Drug Evaluation Research Organizational Chart (http://www.fda.gov/cder/cderorg/cder-all.pdf)
- Office of Center Director (http://www.fda.gov/cder/cderorg/ocd.pdf)
- Office of Management (http://www.fda.gov/cder/cderorg/OM.pdf)
- Office of Pharmaceutical Sciences (http://www.fda.gov/cder/cderorg/ops.pdf)
- Office of Pharmacoepidemiology and Statistical Science (http://www.fda.gov/cder/cderorg/OPaSS.PDF)

- Office of New Drugs (http://www.fda.gov/cder/cderorg/OND.PDF)
- Division of Drug Marketing, Advertising, and Communications (DDMAC) (http://www.fda.gov/cder/ddmac/organizationlist.htm)
- Center for Devices and Radiological Health (http://www.fda.gov/cdrh/organiz.html)
- Pharmaceutical Science Advisory Committee Roster (http://www.fda.gov/cder/audiences/acspage/pharmaceuticalroster.htm)

Outside of FDA

- PAT in Europe: http://www.emea.eu.int/Inspections/PAThome.html
- Summaries of the USP Expert Committees meetings: http://www.usp.org/USPNF/meetingSummaries.

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- Representing companies and associations in rulemaking proceedings before medicines agencies, including the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMEA).

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- FDA's Regulation of Promotion of Medical Products
- FDA Prescription Drug Marketing Act (PDMA)
- Consumer/Prescriber Privacy Laws
- State Consumer Protection and Pharmaceutical Sales and Marketing Laws
- Evaluation of Chemistry, Manufacturing and Controls and Bioavailability/Bioequivalence Requirements

If you would like more information about DBR's services in these areas, please contact Dede Godstrey at dede.godstrey@dbr.com.

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