

# Regulatory Information Resources

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## OBJECTIVES

- ❑ Become familiar with print and electronic information resources relevant to the regulatory healthcare industry
- ❑ Understand how to access and retrieve publicly available, Internet-based government agency and association resources to support the regulatory intelligence process
- ❑ Recognize the value of industry associations to expand professional knowledge and develop regulatory core competencies
- ❑ Learn how to access selected Web 2.0 tools (blogs and social networks) to increase professional effectiveness

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## LAWS, REGULATIONS AND GUIDELINES COVERED IN THIS CHAPTER

- ❑ *Federal Register (FR) and Code of Federal Regulations (CFR)*

## Introduction

Regulatory professionals have significantly improved their productivity, effectiveness and expertise in the workplace through access to the ever-increasing array of Internet-based regulatory information resources. The ease with which regulatory information may now be obtained is profound compared to the days when the only way to acquire this documentation was via telephone, fax or mail. This chapter provides a detailed review of a broad range of electronic industry, government and association resources available to regulatory professionals. The value of each of these tools in

supporting product substantiation, regulatory review analysis, strategic planning and increasing professional knowledge will be assessed.

## Print and Electronic Publications

Print and electronic information resources play an essential role in a regulatory professional's ability to gain, maintain and advance knowledge and understanding of various healthcare industry product sectors. The regulatory profession is characterized by repeated job changes among professionals as well as by frequent mergers among the pharmaceutical, device and biologics companies themselves. For example, it is not uncommon for a regulatory professional's career to begin in the pharmaceutical industry and transition into the devices area due to a job change, a lateral move into another division within a company or perhaps to a work assignment in an area that requires an understanding of combination products. There are many and varied reasons why a professional may require additional regulatory information. Fortunately, available print and electronic tools to fulfill this requirement are increasingly abundant.

## Book Publishers

A number of publishers specialize in print and electronic publications focused on healthcare regulatory topics. This section reviews industry, government, association and standards publishers that target the regulatory healthcare profession and explains how regulatory professionals can retrieve the most relevant resources using the publisher's online catalogs. Because regulatory affairs is an interdisciplinary profession, publishers that primarily concentrate on scientific research and development (R&D), law, medicine, business or government, or possibly all of the above, may also feature publications focused specifically on the regulatory aspects of these subjects.

**Table 36-1. Publisher Resources**

<b>Publisher</b>	<b>Website</b>	<b>Resources</b>
AdvaMed	<a href="http://www.advamed.org/MemberPortal/">www.advamed.org/MemberPortal/</a>	News Alerts (Fee-based)
American Society for Quality (ASQ Press)	<a href="http://www.asq.org/quality-press/index.html">www.asq.org/quality-press/index.html</a>	Books, Standard, Training Materials & Journals
American Society of Testing and Materials (ASQM)	<a href="http://www.astm.org/Standard/books_journals.shtml">www.astm.org/Standard/books_journals.shtml</a>	Books, Standards, Technical Publications, Manuals, Handbooks, Journals
Aspen Publishers	<a href="http://www.aspenpublishers.com">www.aspenpublishers.com</a>	Books, Journals & Newsletters (Fee-based)
Association of Clinical Research Professionals ACRP)	<a href="http://www.acrpnet.org/">www.acrpnet.org/</a>	Newsletters (Free)
Barnett International	<a href="http://www.barnettinternational.com/EducationalServices/Publications.aspx">www.barnettinternational.com/EducationalServices/Publications.aspx</a>	Books, Reference Manuals & Compendiums
Bureau of National Affairs (BNA)	<a href="http://storefront.bnabooks.com/epages/bnastore.sf/">http://storefront.bnabooks.com/epages/bnastore.sf/</a>	Books, Directories & Handbooks
Canon Communications	<a href="http://www.devicelink.com/">www.devicelink.com/</a>	Newsletters (Free)
Canon Communications Pharmaceutical Media Group	<a href="http://www.pharmalive.com/">www.pharmalive.com/</a>	Newsletters (Free & Fee-based)
CRC Online Press	<a href="http://www.crcpress.com">www.crcpress.com</a>	Books & Journals
Donawa Consulting	<a href="http://www.donawa.com/">www.donawa.com/</a>	Newsletters (Free)
Drug Information Association (DIA)	<a href="http://www.diahome.org/DIAHome/">www.diahome.org/DIAHome/</a>	Directories, Compilations, Journals & Newsletters (Fee-based)
DRW Research & Information Services	<a href="http://www.drw-research.com/index.htm">www.drw-research.com/index.htm</a>	Newsletters (Free)
FDANews	<a href="http://www.fdanews.com/">www.fdanews.com/</a>	Books, White Papers & Newsletters (Free & Fee-based)
F-D-C Reports	<a href="http://www.fdcreports.com">www.fdcreports.com</a>	Newsletters (Free & Fee-based)
FDC-Windhover	<a href="http://www.biopharmtoday.com/">www.biopharmtoday.com/</a>	Newsletters (Free)
Ferdic, Inc.	<a href="http://www.fhareview.com/">www.fhareview.com/</a>	Newsletters (Fee-based)
FierceMarkets	<a href="http://www.fiercemarkets.com/advertise/publications">www.fiercemarkets.com/advertise/publications</a>	Newsletters (Free)
Food and Drug Law Institute (FDLI)	<a href="http://www.fдли.org/">www.fдли.org/</a>	Books, Directories, White Papers, CDs & Journals & Newsletters (Free & Fee-based)
Global Regulatory Press	<a href="http://www.globalregulatorypress.com/">www.globalregulatorypress.com/</a>	Newsletters (Fee-based)
GMP Publications	<a href="http://www.gmppublications.com/">www.gmppublications.com/</a>	Books, Handbooks & Manuals
Government Printing Office (GPO)	<a href="http://bookstore.gpo.gov/">http://bookstore.gpo.gov/</a>	Books, Handbooks, Manuals, Guides, Journals & Newsletters (Fee-based)
Infinata	<a href="http://www.biopharminsight.com/clinical_trials_network.html">www.biopharminsight.com/clinical_trials_network.html</a>	Newsletter (Free)
Informa Healthcare	<a href="http://www.pjbpubs.com/home.htm">www.pjbpubs.com/home.htm</a>	Newsletters (Fee-based)
Institute for Electrical and Electronics Engineers (IEEE)	<a href="http://www.ieee.org/portal/site/iportals/">www.ieee.org/portal/site/iportals/</a>	Books, Standards, Conference Proceedings & Journals
International Organization for Standardization (ISO)	<a href="http://www.iso.org/iso/home.htm">www.iso.org/iso/home.htm</a>	Standards, Handbooks, CDs & Journals

## Regulatory Information Resources

Publisher	Website	Resources
John Wiley & Sons	<a href="http://www.wiley.com/WileyCDA/">www.wiley.com/WileyCDA/</a>	Books & Journals
Lippincott Williams & Wilkins	<a href="http://www.lww.com/">www.lww.com/</a>	Books, Journals & Newsletters (Fee-based)
Majors.com	<a href="http://www.majors.com">www.majors.com</a>	Books
Medical Device Manufacturers Association (MDMA)	<a href="http://www.medicaldevices.org/public/">www.medicaldevices.org/public/</a>	Newsletters (Fee-based)
Medtech Insight	<a href="http://www.medtechinsight.com">www.medtechinsight.com</a>	Newsletters (Fee-based)
Parenteral Drug Association (PDA)	<a href="http://www.pda.org">www.pda.org</a>	Books, Handbooks, Technical Bulletins, CDs & Journals
Piribo	<a href="http://www.urchpublishing.com/publications/regulatory/index.html">www.urchpublishing.com/publications/regulatory/index.html</a>	Market Reports
Regulatory Affairs Professionals Society (RAPS)	<a href="http://www.raps.org/personifyebusiness/">www.raps.org/personifyebusiness/</a>	Books, Journals, CDs & Newsletters (Fee-based)
SmartBrief	<a href="http://www.smartbrief.com/index.jsp">www.smartbrief.com/index.jsp</a>	Newsletters (Free)
Society of Clinical Research Associates (SoCRA)	<a href="http://www.socra.org/">www.socra.org/</a>	Journals
SPG Media	<a href="http://www.pharmaceutical-technology.com/">www.pharmaceutical-technology.com/</a>	Newsletters (Free)
Springer	<a href="http://www.springer.com">www.springer.com</a>	Books, Handbooks & Journals
Thompson Publishers	<a href="http://www.thompson.com/public/library.jsp?cat=FOODDRUG">www.thompson.com/public/library.jsp?cat=FOODDRUG</a>	Books, Reports, CDs & Newsletters (Fee-based)
The Organisation for Professionals in Regulatory Affairs (TOPRA)	<a href="http://www.topra.org/">www.topra.org/</a>	Newsletters (Fee-based)
United States Pharmacopeia (USP)	<a href="http://www.usp.org">www.usp.org</a>	Books, Compendiums, & Standards
VertMarkets	<a href="http://www.vertmarkets.com">www.vertmarkets.com</a>	Newsletters (Free)
VirSci Corporation	<a href="http://www.virsci.com/pharmamarketing.html">www.virsci.com/pharmamarketing.html</a>	Newsletters (Free)

Note: Website URLs are current at time of publication.

CRC Online Press, John Wiley & Sons, Lippincott Williams & Wilkins/Wolter Kluwer Health, Majors.com and Springer are major publishing firms that provide broad subject coverage while also featuring a significant number of publications directed at the regulatory profession.

The CRC Online Press website contains numerous regulatory books within the general category of pharmaceutical science. Users can locate these publications within the following subcategories: biotechnology/biopharmaceutical, cleaning and sterilization, clinical trials, computer software, drug delivery and development, drug discovery, laboratory, manufacturing and engineering, medical devices, quality assurance, regulations and standards, training and validation. Similarly, John Wiley & Sons produces regulatory publications on drug submissions, clinical trials, drug safety evaluation, pharmaceutical manufacturing regulations, quality and preclinical development.

Lippincott Williams & Wilkins, a division of Wolters Kluwer Health, also produces several publications on drug development, clinical trials and pharmaceuticals. Majors.com's publications focus on regulatory compliance, quality assurance, risk management, HIPAA, coding and reimbursement, administrative law and regulatory practice, pharmaceutical research, medical devices, biotechnology, chemistry, manufacturing and controls compliance, laboratory auditing, validation and clinical research. Springer, by comparison, covers regulatory and toxicology issues such as pharmaceutical safety evaluation in its pharmaceutical science area.

The following keywords are effective for searching these online catalogs:

- regulatory
- regulatory affairs
- regulatory healthcare
- pharmaceutical
- biotechnology

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- medical device
- pharmacology

Other industry publishers concentrate on specific regulatory areas such as quality assurance and standards. For example, the American Society for Quality (ASQ Press) publishes books, standards and training materials relating to quality issues, and the Bureau of National Affairs (BNA) concentrates on the legal aspects of regulatory affairs. Selected topics covered by BNA publications include pharmaceutical, biotechnology and health law, intellectual property and patent law.

In the same manner, the United States Pharmacopeia (USP), an official public standards-setting authority for prescription, over-the-counter medicines and US manufactured healthcare products, develops documentary and quality reference standards. Its key publications include the *US Pharmacopeia–National Formulary (USP–NF)*, the *Food Chemical Codex* and the USP Reference Standards. USP Reference Standards are based directly on official monographs in the *USP–NF*, whose standards and procedures are enforceable by the US Food and Drug Administration (FDA). The *USP–NF* contains public pharmacopeial standards for medicines, dosage forms, drug substances, excipients, medical devices and dietary supplements. USP Reference Standards are used to conduct identification tests, limit tests, drug substance assays, system suitability tests and calibrations.<sup>1</sup>

Another valuable standards resource for regulatory professionals is IEEE, formerly the Institute of Electrical and Electronics Engineers, which develops and publishes conference proceedings, training materials, standards and publications central to regulatory research. It is the leading global professional association for the advancement of technology and the authority on biomedical engineering and medical devices.

The International Organization for Standardization (ISO), similarly, is a key nongovernmental standards-producing organization, consisting of a network of national standards institutes for 159 countries and a coordinating Central Secretariat in Geneva, Switzerland. ISO's catalog comprises more than 175,000 published international standards.

The American Society of Testing and Materials (ASTM) is additional example of a standards organization that produces Special Technical Publications, compilations, manuals, monographs, journals and handbooks on regulatory topics.

Standards publications focused on healthcare regulatory issues may be located by searching with the following terms:

- biological
- biotechnology
- clinical
- pharmaceutical
- medical device
- medical instrumentation

- quality management
- regulatory

Several industry publishers specialize in publications that focus entirely or largely on regulatory and compliance issues. Barnett International is one such company; it publishes regularly updated reference manuals, industry compendiums and job aids to assist regulatory professionals in complying with federal regulations. It also prepares regulatory industry executive analyses, question and answer guides on regulatory topics and a study site training series for regulatory professionals. FDANews is another publisher that prepares reference tools specifically aimed at the pharmaceutical, biologic and medical device regulatory industry. Its products include the CFR compilations, an adverse event compliance series and publications dealing with biologics, biosimilars and combination drug products. Similarly, GMP Publications targets the regulatory industry through its CFR pocket guides and good clinical practice and good manufacturing practice handbooks.

The Government Printing Office (GPO), serves as the country's official online bookstore for US government publications. GPO serves as the primary resource for gathering, cataloging, producing, providing, authenticating and preserving published information in all its forms for the executive, legislative and judicial branches of the federal government.<sup>2</sup> Publications pertaining to regulatory healthcare topics may be accessed by searching with the keywords "FDA" or the "Food and Drug Administration" and "DHHS" or "Department of Health & Human Services" combined with more specific terms such as "pharmaceutical," "clinical" or "drug industry." GPO Access operates within the GPO to provide free electronic access to legislative resources including Congressional bills, the *Congressional Record*, public and private law, the US Code; executive sources such as the CFR, the *FR* and presidential materials; and judicial sources including the Supreme Court, trial and appellate court cases, opinions, oral arguments and decisions.

Another type of publication of particular value to regulatory professionals is the market research report. Piribo, which brands itself as "online business intelligence for the BioPharma Industry,"<sup>3</sup> specializes in this type of resource. The UK-based publisher prepares detailed and costly global market research reports, handbooks, strategic analysis profiles and regulatory overviews. Report subject categories range from biotechnology, drug delivery and medical devices to prescription drugs, regulatory policy, and pricing and reimbursement. Urch Publishing, like Piribo, is a publisher of market intelligence reports covering the global pharmaceutical and healthcare industry. Also UK-based, Urch covers topics including chemicals, drug discovery/R&D, generics, pharmaceutical industry trends, pricing and reimbursement, regulatory, sales, and marketing and therapeutics.

Thompson Publishing, by comparison, dedicates an

entire product line to food and drug regulatory materials. Thompson's products are primarily subscription-based and are available in print or electronically. These products generally consist of two-volume manuals containing regularly updated newsletters, an archive and special reports in conjunction with access to additional online resources. Topics covered include good clinical practice, FDA advertising and promotion, FDA enforcement and medical device regulation. Aspen Publishers, another division of the aforementioned Wolters/Kluwer, also publishes a complete line of food, drug and medical device publications. It provides detailed coverage of the FDA approval process and expert guidance on generic drugs. The majority of Aspen's manuals are loose-leaf formatted and subscribers automatically receive documentation updates, supplements and/or new editions.

Many associations, such as the Regulatory Affairs Professionals Society (RAPS) and the Food and Drug Law Institute (FDLI), publish materials intended for regulatory professionals that are available in their online bookstores. This book is a key example of one such product produced by RAPS. In addition, RAPS publishes regulatory affairs certification (RAC) exam preparatory materials for the US, Canada, the European Union (EU) and the new General Scope exam, as well as a self-assessment exam for each certification. Also included in RAPS' bookstore are third-party publications of interest to regulatory professionals. FDLI, similarly, markets publications the organization has prepared as well as third-party products addressing regulatory topics.

### Free Industry Resources (Electronic Newsletters (e-Newsletters))

In addition to books, reports and standards, a number of industry resources are available to regulatory professionals to monitor current events and advance their knowledge of healthcare product regulation. This section reviews both free and fee-based sources. However, the free publications will be discussed in greater detail as there are several valuable free sources of which regulatory professionals may not be aware. The fee-based resources, by comparison, tend to encompass the more widely recognized monthly journals and association publications made available as a membership benefit. The sources reviewed in this section cover a range of drug, device and biologic regulatory publications. Although not comprehensive, they may give regulatory professionals a solid basis for further independent research.

Many publishers produce multiple newsletters aimed at different healthcare product sectors. For example, FDAnews publishes the following free e-newsletters: *FDAnews Device Daily Bulletin*, *FDAnews Drug Daily Bulletin* and *The QMN Weekly Bulletin*. *FDAnews Device Daily Bulletin* monitors FDA regulatory, legislative and business news developments as well as selected international news affecting the medical device industry. *FDAnews Drug Daily Bulletin* provides parallel coverage

for the pharmaceutical industry. *The QMN Weekly Bulletin* covers current quality management news, regulatory developments and inspection trends. The summaries provided by these publications offer brief but valuable perspectives on current regulatory management issues for drugs, devices and quality. A link to the full-text article is listed below each summary; some of the cited sources require subscriptions to fee-based publications. These links afford regulatory professionals an opportunity to obtain further information on a particular subject as well as learn about new resources.

SmartBrief, an independent e-newsletter publisher, produces 20 industry-specific daily newsletters that are available free of charge by subscription. This company partners with trade associations and professional societies to publish its newsletters. *AdvaMed SmartBrief* is issued in conjunction with the Advanced Medical Technology Association (AdvaMed) and targets medical device, diagnostic product and health information system professionals. *BIO SmartBrief*, produced in cooperation with the Biotechnology Industry Organization (BIO), focuses on biotechnology industry professionals, and *FDLI SmartBrief* works with FDLI to reach food and drug industry professionals. The summaries in all three publications are based on original information from news organizations and repackaged by SmartBrief's editorial staff. Each newsletter typically covers top stories, healthcare in transition, hot topics, business and market trends, science and health or science and health policy, emerging technologies, and product-specific and association-specific news. Regulatory professionals can use these publications to track current regulatory developments in time-saving compilations and obtain valuable competitive intelligence.

In a similar manner, VertMarkets has established 68 online community marketplaces for eight industry groups to connect buyers and suppliers. For each of its online industry communities, VertMarkets produces free biweekly email bulletins that provide not only product offerings, but also industry updates and the latest news to its members. The newsletters directed to regulatory professionals fall into the life sciences category and include the *Bioresearch Online Newsletter*, *Drug Discovery Online Newsletter*, *Laboratory Network Community Newsletter*, *Medical Device Online Community Newsletter* and *Pharmaceutical Online Newsletter*. Typical content includes top news stories, featured articles, featured downloads and a product showcase.

FierceMarkets is a digital media company that also specializes in supporting business-to-business marketing in the life sciences, healthcare, IT, telecom and finance industries through its e-newsletters, websites, webinars and live events. *FiercePharma* is a daily e-newsletter focused on pharmaceutical company news and market development of FDA-approved products. Regulatory professionals can stay informed and save time by reviewing these types of industry-specific publications. Categories

included in *FiercePharma* are pharmaceutical company news and reports, FDA rulings, regulations, recalls and warnings, drug launches and safety, pharmaceutical sales, and marketing news and activities of key industry professionals. *FierceBiotech* is another daily e-newsletter in the FierceMarkets' digital product family. It concentrates on drug discovery and clinical trials news as well as the latest biotechnology trends, breakthroughs and FDA approval updates. *FierceBioResearcher* reports on biotechnology research news, information and tools, with a special focus on the science of drug discovery. *FierceVaccines*, *FierceHealthcare* and *FierceSarbox* are the company's other three e-newsletters within the healthcare division.

F-D-C Reports, an Elsevier subsidiary, is a newsletter publisher that has been serving the healthcare product industry since 1939. Although the majority of its publications are fee-based, it does offer a complimentary subscription to a few of its weekly e-newsletters. The first of these is *Biopharma Today*, formerly *FDA Legislative Watch*. This e-newsletter covers current FDA reform initiatives specifically pertaining to the biomedical industry. The second is *Medical Devices Today*, which provides strategy, regulation, innovation and investment coverage from *The Gray Sheet*, *Medtech Insight*, *IN VIVO*, *Start-Up*, *The Silver Sheet* and *Strategic Transactions*. The articles cover drug and business development, finance, strategy, regulation and reimbursement. Summaries and reprints are excerpted from recognized publications including FDC Reports' *The Pink Sheet*, *The Gold Sheet*, *Pharmaceuticals Approval Monthly* and *PharmAsia News* and Elsevier Business Intelligence's *Start-Up* and *The RPM Report*.

A few other free electronic resources worth briefly mentioning are *Pharma Marketing News*, the *Pharmaceutical Technology Newsletter* and *PharmaFocus*. VirSci Corporation's *Pharma Marketing News* is a monthly newsletter for pharmaceutical and marketing professionals designed to keep subscribers informed about industry trends and innovations. It also offers a professional network for career advancement. Frequently covered topics include physician marketing, sales and education, regulatory compliance, patient education, and direct-to-consumer advertising and marketing.

*Pharma Technology Newsletter* is produced by a UK-based company, SPG Media. The newsletter is dedicated to pharmaceutical professionals working with technology. Subscribers have access to the latest developments in global industry projects, company profiles, industry events and a recruitment section that provides career information and the latest job vacancies. *PharmaFocus* is also published in the UK, but unlike *Pharma Technology Newsletter*, its primary focus is on news affecting the pharmaceutical industry and the UK's National Health Service. This publication is a bit more exclusive in that it is only sent free of charge to selected permanent employees of companies that manufacture ethical and OTC pharmaceuticals and biotechnology companies. The

complete version of the latest issue, however, is accessible on the website.

Three additional pharmaceutical industry-oriented e-newsletters published by Canon Communications Pharmaceutical Media Group are *PharmaLive*, *Therapeutics Daily* and *Daily Advantage*. The subscriptions to all three are free of charge if users register with the *Pharmalive.com* website. These newsletters are another great source of industry intelligence, providing summaries of industry events and trends affecting pharmaceutical and clinical professionals accompanied by a link to the full text and related articles. Information is categorized by business and therapeutic area, and the news and information focuses on clinical research, product marketing and pharmaceutical business. The therapeutic product areas covered in *Therapeutics Daily* include cardiovascular, oncology, pain and inflammation, central nervous system and infectious disease.

Several regulatory consulting firms also produce free newsletters to support their clients and the professional regulatory community. DRW Research & Information Services, LLC, an independent regulatory research consulting firm, produces a free monthly e-newsletter, *DRW Monthly*, which covers a broad range of global healthcare regulatory topics. Each month is dedicated to reviewing medical device, biologic or pharmaceutical global regulatory developments. Donawa Consulting, a regulatory consultant based in Italy, also produces a quarterly publication. The *Donawa Consulting Newsletter* provides an overview of international medical device, quality system and clinical regulatory developments.

Clinical monitoring news is another area covered in a free weekly e-newsletter entitled *BioPharm Insight Clinical Newsletter*. Infinata, the publisher, is also the developer of *BioPharm Insight*, a commercial, fee-based database discussed later in this chapter. The newsletter covers the latest information on clinical enrollments, clinical results, drug approvals, drug licensing and medical devices. An additional free electronic resource providing current news for the clinical research community is the Association for Clinical Research Professionals' (ACRP) biweekly e-newsletter, *ACRP Wire*.

The medical device industry also receives excellent web coverage through a number of free publications. *Medical Device & Diagnostic Industry (MD&DI)* is one of 11 magazines published by Canon Communications that focus on the medical technology industry. *MD&DI* is a monthly magazine written exclusively for original equipment manufacturers of medical devices and *in vitro* diagnostic products. For more than 25 years, it has supported the industry's efforts to comply with regulations, keep up-to-date on current events, improve manufacturing and design processes and understand market demand. *Medical Device Link* is a Canon publication available free of charge by becoming a member of *MedicalDeviceLink.com*. Once a member, the user can sign up for all of Canon Communications' publications.

*Medical Device Link* is a biweekly email newsletter that reports on top industry headlines and important FDA announcements and features articles from several of the publisher's medical device trade publications.

### Fee-Based Industry Resources

The list of fee-based regulatory publications is long and varied, ranging from industry newsletters and peer-reviewed journals to association magazines. Key publishers in the regulatory sphere include Canon Communications, Dickinson, F-D-C Reports, PJB Publishers and Thompson Publishing.

The previously mentioned Canon Communications Pharmaceutical Media Group also publishes two fee-based magazines: *Med Ad News* and *R&D Directions*. *Med Ad News* is an established resource for competitive business intelligence and marketing strategies information. *R&D Directions* provides extensive coverage of pharmaceutical product development and insight into successful R&D strategies. Canon also publishes special reports on biotechnology, company analysis, drug delivery and development, healthcare sales and marketing, pipeline data, strategic issues and therapeutic areas.

*Dickinson's FDAReview* is a monthly newsletter published by Ferdic Inc. that provides in-depth analyses of the medical device and drug industries as well as FDA inspection and enforcement activities including *Freedom of Information Act (FOIA)* daily logs and Warning Letter summaries. *FDAUpdate* is a weekly fax document containing *FR* updates pertaining to FDA rules and regulations, newly released Warning Letters, weekly filed citizen petitions, advisory committee proceedings and calendar, and late-breaking FDA and pharmaceutical product news. Free items also available on Dickinson's interactive website, *FDAWebview*, include FDA Warning Letters, *FR* notices and an FDA calendar.

In addition to the free e-newsletters published by FDAnews, this company distributes 10 fee-based subscription newsletters. The publications are: *Clinical Trials Advisor*, *Devices & Diagnostics Letter*, *Drug GMP Report*, *Drug Industry Daily*, *Generic Line*, *International Medical Device Regulatory Monitor*, *International Pharmaceutical Regulatory Monitor*, *The Food & Drug Letter*, *The GMP Letter* and *Washington Drug Letter*. As mentioned above, F-D-C Reports publishes newsletters designed to clarify developments affecting US healthcare product and services marketing and regulation for industry executives, policymakers and analysts. Newsletters published by F-D-C Reports include: *The Pink Sheet/The Pink Sheet DAILY*, *Pharmaceutical Approvals Monthly*, *The Gold Sheet* and *PharmAsia News* in the pharmaceuticals and biotechnology category; *The Silver Sheet* and *The Gray Sheet* in the medical devices and diagnostics category; *The Tan Sheet* and *The Rose Sheet* in the consumer products category; and, *Health News Daily* in the health policy and biomedical research category.

Another well-recognized, fee-based publisher is

Informa Healthcare, which is one of the largest publishers of business information for the pharmaceutical, biotechnology, medical devices and diagnostics industries. Its two key regulatory publications are *Regulatory Affairs Journal (RAJ) Pharma* and *Regulatory Affairs Journal (RAJ) Devices*. *RAJ Pharma* has served as a key source of global news, commentaries and analyses of regulation in the pharmaceutical and biotechnology industries since 1990. Pharmaceutical regulatory intelligence on worldwide rules governing the development, launch and postmarket surveillance of medicines and combination products is provided. Areas of coverage include regulatory agencies and legislation, application requirements and guidelines, R&D, patents and intellectual property, international harmonization, pediatric legislation, pharmacovigilance, pharmacoeconomics and drug safety. Since 1995, *RAJ Devices* has also reported on current worldwide news and provided analyses of worldwide medical device regulatory affairs. Some unique areas of focus include trade and environmental issues, healthcare systems and their impact on regulation and marketing, vigilance, and approval requirements and guidelines. Informa Healthcare also produces a broad range of fee-based industry news sources (e.g., *Scrip World Pharmaceutical News*), business and market research reports, R&D analytical tools and databases (e.g., *Pharmaprojects* and *TrialTrove*), contact directories (e.g., *Scrip Directory*) and research journals (e.g., *Clinical Research & Regulatory Affairs*, *Drug Development and Industrial Pharmacy*).

Elsevier Business Intelligence distributes several e-newsletters that monitor business information and intelligence trends, technologies and companies in the medical device, diagnostics and biotech industry. The company's fee-based newsletters include *Medtech Insight*, *IN VIVO: The Business and Medicine Report*, *START-UP: Emerging Medical Ventures* and *The RPM Report*. *Medtech Insight* is particularly useful to regulatory professionals for its clinical and industry perspectives on products, procedures and technologies shaping the global medical technology market. *IN VIVO* provides in-depth analyses of marketing, R&D, regulatory and finance strategies in the biopharmaceutical, medical technology and diagnostics industries. *START-UP* examines new product and leading-edge company and investment trends in the pharmaceutical, biotechnology, medical device and *in vitro* diagnostics industries. *The RPM Report* is a useful business resource for the biopharmaceutical regulatory professional. Its primary focus is on FDA, the Centers for Medicare and Medicaid Services (CMS) and public sector issues. Global Regulatory Press' *Journal of Medical Device Regulation* is yet another important resource for medical device regulatory professionals. This is a quarterly publication currently only available in electronic format. Regulatory professionals can monitor global regulatory developments through legislative changes summarized in each issue and obtain guidance from review articles

analyzing current medical device regulatory and compliance issues.

### Fee-Based Association Resources

The majority of association publications are free with membership but require non-members to pay an annual subscription fee. RAPS is one example of an association that publishes a monthly magazine, *Regulatory Focus*, that is only available to its members. This magazine focuses on current regulatory issues affecting the drug, medical device and biological healthcare product sectors. Another member-based resource that RAPS offers is a weekly email newsletter, *RAPS Weekly Update*. Similarly, The Organization for Professionals in Regulatory Affairs (TOPRA) publishes an international journal, *Regulatory Rapporteur*, for its members that provides current news and analyses on regulatory and legislative topics. In addition, TOPRA issues a quarterly member newsletter, *In Touch*, which serves as an association news digest covering member and organizational activities. FDLI publishes a quarterly magazine, the *Food and Drug Law Journal*, which is also available free to members and by subscription to the public. The journal features articles on food, drug, cosmetic, medical device and healthcare technology industry regulation and legislation, implications of proposed regulations, policy trends and analyses of court decisions in food and drug law. Its member-only resource, *Update*, is issued bimonthly and contains the latest association and industry news, viewpoints on industry-specific trends, FDA agency developments and articles on various regulatory topics.

In a similar manner, the Drug Information Association (DIA) publishes *DIA Today*, a member newsletter covering current industry activities, as well as the *Drug Information Journal*, a monthly scholarly, international, multidisciplinary, peer-reviewed publication. The Parenteral Drug Association (PDA) has a membership publication entitled *PDA Letter* that is comparable to the ones produced by the other organizations. It reports on science, technology, quality, regulatory affairs, association news and updates relevant to the PDA community. The *PDA Journal of Pharmaceutical Science and Technology* is a bimonthly publication that contains peer-reviewed scientific and technical papers covering the pharmaceutical and biotech industries. The journal is distributed to the PDA membership as a member benefit and is also available by subscription. *PDA Technical Reports* are global consensus documents addressing a range of topics relating to pharmaceutical production, validation and quality assurance. Expert task forces prepare the reports, which are then reviewed by technical forums and ultimately evaluated and approved by an advisory board and the PDA board of directors. *PDA Technical Bulletins* are short, scientific position papers responding to issues raised during worldwide regulatory inspections. These board-reviewed and approved papers address a single

issue in one or two pages and can be used to support an industry response to a regulatory concern.

Within the biologics/biotechnology sphere, BIO supports professionals engaged in R&D of new healthcare technology, biotechnology and others through its advocacy, business development and communications services. Its member-only publication, *BIO News*, is published six times a year and reports on organizational activities, professional perspectives on industry issues and member activities. The Society for Biomaterials is another biologics-focused organization that promotes progress in biomedical materials R&D. The society also publishes member-only resources to foster an understanding of current industry and regulatory developments among regulatory professionals. Members are afforded free access to its official news magazine, *Biomaterials Forum*, which is available by subscription to nonmembers as well. The forum reports on current biomaterials community activities and includes book reviews, technical briefs and professional services information. The *Journal for Biomedical Materials Research* is the official journal of the society and is a peer-reviewed publication provided free to members. It features clinical studies and research reports on a range of topics including the preparation, performance and development of new biomaterials. *Applied Materials* is published as Part B of the journal. It contains peer-reviewed articles on device development, implant retrieval and analysis, manufacturing, regulation of devices, liability and legal issues, standards, reviews of devices and clinical applications. Nonmembers may subscribe directly by contacting John Wiley & Sons.

In the medical device and technology field, AdvaMed is a lobbying/advocacy organization that supports the industry's goals of advancing global healthcare and increasing patient access to medical technology. AdvaMed also promotes policies that encourage high ethical standards, rapid product approvals, appropriate reimbursement and international market access. Its members-only publications include three alerts: the *Member Advisory Program (MAP) Alerts* to follow the latest payment policy changes; the *Technology and Regulatory News Alert* to stay informed about key FDA regulatory developments; and the *International News Alert* to monitor global medical technology sales and operations developments. By comparison, the Medical Device Manufacturers Association (MDMA) represents the interests of smaller, innovative medical technology companies through its advocacy and educational services. Its member-only publications include the *Weekly MDMA Update*, the *Monthly Member Services Newsletter* and the *MDMA Q Review*. The latter is a quarterly e-newsletter for the entrepreneurial medical device community that covers updates on legislative and regulatory developments, association news and members-only programs and events.

Two key associations in the clinical research area are the aforementioned ACRP and the Society of Clinical Research Associates (SoCRA). In addition to its free

biweekly e-newsletter, ACRP publishes a bimonthly journal, *The Monitor*, featuring peer-reviewed articles, association news and a guide to certification preparation courses and exams available only to members. SoCRA, like ACRP, is dedicated to the continuing education and development of its members and publishes the *SoCRA Research Journal*, a members-only quarterly publication that contains scientific and professional articles, society news and events, and professional opportunities and services. Selected articles from past issues of the journal are available to the public on SoCRA's website.

### Online Commercial and Government Databases

#### Commercial Databases— Regulatory Intelligence

A number of commercial, fee-based databases are available to support the regulatory professional's legislative tracking and regulatory analysis responsibilities. These tools are extremely valuable when used in conjunction with other sources of regulatory expertise, from networking with colleagues to contacting consultants and/or directly communicating with government agency authorities.

Tarius Regulatory Database, a fee-based subscription database service owned by the Danish publishing company, The Schultz Group, is included among these database providers. The Tarius database enables regulatory and quality professionals to stay informed about the latest legislative developments worldwide and to interpret regulations and guidelines applicable to global healthcare products. Tarius offers two types of products: customized regulatory and quality databases and predefined base modules on drugs and devices. The customized database solution prescreens data from multiple global government and legislative websites according to searches defined by a particular company or individual. The predefined drug and device modules, by comparison, contain continuously updated reference documents compiled from US and EU regulatory authorities and key international regulatory bodies. As part of its database subscription service, Tarius offers users a complimentary daily electronic summary of published *FR* proposed rules, notices and regulations pertaining to CFR Titles 9, 21 and 40 relevant to drugs, biologics and devices. Tarius also produces a weekly newsletter, Tarius Standard Solutions, which provides regulatory intelligence documents based on user-tailored profiles. Other users may pay a nominal fee to subscribe.

Liquent's IDRAC is another fee-based global regulatory intelligence database of regulatory, legal and scientific information accessed by professionals who develop and register human drug and biologic products. As is true of Tarius, IDRAC frequently updates its documents and provides expert analyses on key regulatory topics for more than 60 countries. The database also provides excellent

coverage of FDA advisory committee activities through its AdComm Bulletins, summaries of new pharmaceutical legislation and summary bases of approvals (SBAs). In addition, subscribers can choose to receive the *IDRAC Weekly Alert*, covering current global regulatory developments, or customize an email alert with saved queries structured to meet their own information preferences.

Wolters Kluwer's MediRegs is also a provider of healthcare research products and software solutions for regulatory professionals. Its healthcare compliance software and risk management solutions product, ComplyTrack Suite, enables risk and compliance professionals to restructure their compliance programs and risk management initiatives to achieve greater efficiency. Revenue Cycle Solutions software targets coding and reimbursement healthcare professionals while the Life Science Regulatory Solutions online portal supports regulatory compliance professionals in the pharmaceutical, device and food industries. US and European database resources include regulatory publications, policy manuals, guidance documents, commission reports and automatic updates from domestic and international regulatory bodies.

MediRegs' US-focused regulatory resources include the Pharmaceutical Regulation Suite and the Device Regulation Library. The Pharmaceutical Regulation Suite provides access to enforcement materials, Establishment Inspection Reports (EIRs), 483s and Warning Letters dating back to the 1970s, SBAs dating back to 1964, US Code and public law legislation, the CFR, the *FR* back to 1991, FDA/NIH manuals and guidelines and *FOIA* logs. The Device Regulation Library also affords regulatory professionals access to enforcement materials and EIRs, 483s and Warning Letters, as well as establishment registration and product listings, premarket approval (PMA) summaries back to 1945 and FDA product safety information.

Founded in 1975, FOI Services, Inc., is an additional source for *FOIA* documents. The FOI online library contains more than 150,000 FDA-related documents including new drug application and abbreviated new drug application approval letters, drug reviews, drug and biologics SBAs, dissolution reviews, device and biologics premarket notifications 510(k)s, PMAs, device Summaries of Safety and Effectiveness, EIRs, 483s, company/FDA inspection correspondence, Warning Letters, advisory committee minutes, guidance manuals, internal FDA meetings, color and food additive petitions and veterinary FOI summaries. *FOIA* documents may also be identified using the online commercial database, DIOGENES—FDA Regulatory Information Online. Available through the database vendor, The DIALOG Corporation, this resource provides data from FDA's Enforcement Reports, 510(k)s, PMAs, medical device reports (MDRs) and the new drug list. Clients can request documents not already available in FOI's library. This fee-based FDA document service offers an excellent path for professionals seeking essential

**Table 36-2. Commercial and Government Databases**

Databases	Website	Subject Coverage
<b>Commercial</b>		
BioPharm Insight	<a href="http://www.biopharminsight.com/">www.biopharminsight.com/</a>	Drug/Biotech & Device Business & Regulatory Intelligence
e-Knowledgebase	<a href="http://www.pharmalive.com/content/neweKB/">www.pharmalive.com/content/neweKB/</a>	Drug/Biotech Business & Regulatory Intelligence
FOI Services	<a href="http://www.foiservices.com">www.foiservices.com</a>	Regulatory Intelligence
IDRAC	<a href="http://www.idrac.com/FrontPage.aspx">www.idrac.com/FrontPage.aspx</a>	Drug/Biotech Regulatory Intelligence
MediRegs	<a href="http://www.mediregs.com">www.mediregs.com</a>	Regulatory Intelligence
MedTRACK	<a href="http://www.medtrack.com/research/default.asp">www.medtrack.com/research/default.asp</a>	Drug/Biotech Business Intelligence
Pharmaprojects	<a href="http://www.pjbpubs.com/pharmaprojects/index.htm">www.pjbpubs.com/pharmaprojects/index.htm</a>	Business & Regulatory Intelligence
Pipeline	<a href="http://sites.informahealthcare.com/pipeline/">sites.informahealthcare.com/pipeline/</a>	Drug/Biotech Business Intelligence
Tarius	<a href="http://www.tarius.com">www.tarius.com</a>	Drug/Biotech & Device Regulatory Intelligence
TrialTrove	<a href="http://www.citeline.com/trialtrove.html">www.citeline.com/trialtrove.html</a>	Drug/Biotech Clinical Trial Intelligence
<b>Government</b>		
Business.gov	<a href="http://www.business.gov/">www.business.gov/</a>	Federal agency information portal for small businesses
Code of Federal Regulations (CFR)	<a href="http://www.gpoaccess.gov/cfr/index.html">www.gpoaccess.gov/cfr/index.html</a>	Drug/Biotech & Device Regulatory & Legislative Intelligence
Forms Catalog	<a href="http://www.forms.gov/bgfPortal/main.do">www.forms.gov/bgfPortal/main.do</a>	Federal agency form resource
Federal Register (FR)	<a href="http://www.gpoaccess.gov/fr/index.html">www.gpoaccess.gov/fr/index.html</a>	Drug/Biotech & Device Regulatory & Legislative Intelligence
FDA Warning Letter Database	<a href="http://www.fda.gov/foi/warning.htm">www.fda.gov/foi/warning.htm</a>	Drug/Biologics & Device Regulatory Intelligence
FDA/CBER On-Line: Establishment Registration & Biological Product Deviation Reporting	<a href="https://www.accessdata.fda.gov/scripts/cber/CFApps/Login/Index.cfm?CFID=19739204&amp;CFTOKEN=4b5801a44b35d755-36EF1D27-1372-5AE1-6AA44EA2CBE290EA">https://www.accessdata.fda.gov/scripts/cber/CFApps/Login/Index.cfm?CFID=19739204&amp;CFTOKEN=4b5801a44b35d755-36EF1D27-1372-5AE1-6AA44EA2CBE290EA</a>	Biologics/Biotech Regulatory Intelligence
FDA/CBER Vaccine Adverse Event Reporting System (VAERS)	<a href="http://vaers.hhs.gov/">http://vaers.hhs.gov/</a>	Biologics/Biotech Regulatory Intelligence
FDA/CDER Adverse Event Reporting System (AERS)	<a href="http://www.fda.gov/cder/aers/default.htm">www.fda.gov/cder/aers/default.htm</a>	Drug/Biologics Regulatory Intelligence
FDA/CDER Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) Database	<a href="http://www.fda.gov/cder/ob/default.htm">www.fda.gov/cder/ob/default.htm</a>	Drug/Biologics Regulatory Intelligence

competitive regulatory intelligence while wishing to be discreet about their research.

#### **Commercial Databases—Business Intelligence**

In addition to the regulatory intelligence tools available to support a regulatory professional's surveillance,

## Regulatory Information Resources

Databases	Website	Subject Coverage
FDA/CDER Bioresearch Monitoring Information System (BMIS)	<a href="http://www.accessdata.fda.gov/scripts/cder/bmis/">www.accessdata.fda.gov/scripts/cder/bmis/</a>	Drug/Biologics Regulatory Intelligence
FDA/CDER Clinical Investigator Inspection List	<a href="http://www.accessdata.fda.gov/scripts/cder/cliil/">www.accessdata.fda.gov/scripts/cder/cliil/</a>	Drug Regulatory Intelligence
FDA/CDER Drug Firm Annual Registration Status Database	<a href="http://www.accessdata.fda.gov/scripts/cder/drls/default.cfm">www.accessdata.fda.gov/scripts/cder/drls/default.cfm</a>	Drug/Biologics Regulatory Intelligence
FDA/CDER Drugs@FDA Database	<a href="http://www.fda.gov/Drugs/InformationOnDrugs/ucm135821.htm">www.fda.gov/Drugs/InformationOnDrugs/ucm135821.htm</a>	Drugs/Biologics Regulatory Intelligence
FDA/CDER National Drug Code Directory	<a href="http://www.fda.gov/cder/ndc/database/">www.fda.gov/cder/ndc/database/</a>	Drugs Regulatory Intelligence
FDA/CDRH Advisory Meeting Materials Archive	<a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfAdvisory/search.cfm">www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfAdvisory/search.cfm</a>	Device Regulatory Intelligence
FDA/CDRH Clinical Laboratory Improvement Amendments (CLIA) Database	<a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/clia.cfm">www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/clia.cfm</a>	Device Regulatory Intelligence
FDA/CDRH MAUDE (Manufacturer and User Facility Device Experience) Database	<a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM">www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM</a>	Device Regulatory Intelligence
FDA/CDRH Medical Device Reporting (MDR) Database	<a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmdr/search.CFM">www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmdr/search.CFM</a>	Device Regulatory Intelligence
FDA/CDRH Premarket Approval (PMA) Database	<a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm">www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm</a>	Device Regulatory Intelligence
FDA/CVM Animal Drugs@FDA Database	<a href="http://www.accessdata.fda.gov/scripts/animaldrugsatfda/">www.accessdata.fda.gov/scripts/animaldrugsatfda/</a>	Drug Regulatory Intelligence
GovTrack.us	<a href="http://www.govtrack.us/">www.govtrack.us/</a>	Drug/Biotech & Device Regulatory & Legislative Intelligence
GPO Access	<a href="http://www.gpoaccess.gov">www.gpoaccess.gov</a>	Drug/Biotech & Device Regulatory & Legislative Intelligence
NIH ClinicalTrials.gov	<a href="http://clinicaltrials.gov/">http://clinicaltrials.gov/</a>	Clinical Research
NLM - PubMed	<a href="http://www.ncbi.nlm.nih.gov/pubmed">www.ncbi.nlm.nih.gov/pubmed</a>	Biomedical research
NLM – TOXNET	<a href="http://toxnet.nlm.nih.gov/">http://toxnet.nlm.nih.gov/</a> ,	Biomedical/ Toxicological research
OMB/GSA RegInfo.gov	<a href="http://www.reginfo.gov/public/">www.reginfo.gov/public/</a>	OMB Regulatory Reviews/GSA Regulatory & Deregulatory Actions
Regulations.gov	<a href="http://www.regulations.gov/search/index.jsp">www.regulations.gov/search/index.jsp</a>	Federal agency published regulations & public comments
Thomas	<a href="http://thomas.loc.gov/">http://thomas.loc.gov/</a>	Drug/Biotech & Device Regulatory & Legislative Intelligence
USA.gov	<a href="http://www.usa.gov/">www.usa.gov/</a>	Federal agency information portal

Note: Website URLs are current at time of publication.

analysis and strategic planning responsibilities, numerous commercial business intelligence databases are now available to increase understanding of industry competition.

Originally, these resources were only accessible to professional information searchers, but now the databases are specifically designed for users without prior search

experience. It is currently possible to independently access these invaluable resources through company database subscriptions.

Infinata's BioPharm Insight, briefly mentioned earlier in the chapter, is a fee-based online database that provides global biotechnology and pharmaceutical industry competitive intelligence. This resource covers the entire drug product lifecycle from discovery and development through the drug approval stages, as well as licensing deals, pharmaceutical sales/projections, management contacts and medical devices. BioPharm Insight partners with Pharmawire journalists, a part of the Financial Times Group, to report on key events including drug pipelines, patent expirations and litigation issues, licensing pipelines, and merger and acquisition pipelines. The BioPharm Insight database consists of Pharmawire Intelligence, the Clinical Trials Network, Drug Profiles, Drug Forecasts and Drug Licensing Deals. The BioPharm Devices database, in turn, affords users detailed coverage of the medical device pipeline. Each company profile contains a review about of the organization and its markets, product forecasts and launches, manufacturing facilities and key management contacts. Profiles of devices currently in distribution are also included in the database, as well as clinical trial and investigational device exemption daily updates. And lastly, BioPharm Outsource is a database containing detailed profiles of contract service providers for the pharmaceutical and biotechnology industry.

Another pharmaceutical industry competitive intelligence resource is eKnowledgebase, an interactive online pharmaceutical database. eKnowledgebase is produced by Canon Communications Pharmaceutical Media Group, the publisher of the publications *MedAdNews*, *R&D Directions* and *Trend Reports*. This fee-based database provides extensive company coverage as well as pipeline information for each stage of a drug's development. eKnowledgebase is updated daily and contains more than 26,000 compounds in development and drugs currently on the market. A user can choose to subscribe to the entire eKnowledgebase database, or purchase either the Pipeline portion to search drugs in development or the Brands portion to search drugs on the market.

Informa Healthcare's Pharmaprojects database also serves as a valuable source of pharmaceutical intelligence. This tool tracks more than 36,500 drugs in active development with a drug, company and therapy profile for each. The drug profile contains product data including therapies and indications by phase, originator and licensees, chemical data and structure, clinical trials, pharmacologies, country information, licensing opportunities and more. The company profile consists of addresses, subsidiaries, overview of operations, financial results, joint ventures and agreements, a licensing contact and a direct link to the corporate website. The therapy profile is comprised of incidence, prevalence and market data, trends and forthcoming events, pharmacological strategies in progress

and links to related websites. Pharmaprojects enables drug regulatory professionals to analyze competitor performance, review R&D pipeline data to assess trends and evaluate potential business partnerships. Data sources include the companies themselves, Pharmaprojects' sister publication, *Scrip World Pharmaceutical News* and interviews with company personnel who attend global conferences.

Another Informa Healthcare product that contributes to the wealth of available pharmaceutical intelligence database resources is Pipeline. This database consists of all the novel drugs and formulations developed since 1980. These drugs are tracked throughout their product lifecycle and are kept in the database even if they fail at any stage. What makes Pipeline unique is that it not only affords web-based access to an unlimited number of employees under one site license, but also includes free, unlimited research support from expert analysts and free training. Regulatory professionals can use this global drug resource to monitor competitors' R&D programs, discover new competitors, evaluate the competitive landscape for a specific drug, benchmark product performance and identify potential collaborators.

Elsevier's PharmaPendium database, by comparison, provides drug safety data on US approved drugs. This online resource affords researchers searchable access using the *Medical Dictionary for Regulatory Activities* (MedDRA) search terminology. It also incorporates animal and human study data from FDA's Adverse Events Reporting System (AERS); drug monographs from *Mosby's Drug Consult*; *Meyler's Side Effect of Drugs*; preclinical, clinical and postmarket data from FDA approval packages/SBAs; Registry for Toxic Effects of Chemical Substances toxicity data; and metabolite data for approved drugs. Regulatory professionals can use this database to obtain pharmacovigilance data to evaluate the full scope of projected risks early in the drug development process.

While the pharmaceutical intelligence databases discussed earlier focus on drug pipelines and R&D data, Life Science Analytics' MedTRACK concentrates on worldwide private and public biomedical company intelligence data. MedTRACK's key areas of focus are company profiles and financials, product data, R&D spending, patents, corporate deals, venture financing, industry statistics and epidemiology.

Clinical trial surveillance information is also accessible through Citeline's TrialTrove. This database contains a comprehensive repository of global ongoing clinical trials information. Clinical and regulatory professionals have access to competitive trial information organized by 90 disease groups through analyst monitoring of more than 12,000 data sources. As is true of the Pipeline database product, TrialTrove offers users a research support service with direct access to Citeline analysts for no extra charge.

### Government Databases—Legislative and Regulatory Tracking

An integral component of a regulatory professional's work is to stay informed about the latest regulatory and legislative developments. The resources reviewed in this section highlight noteworthy governmental and nongovernmental database tools to support these monitoring and surveillance responsibilities. GPO Access, discussed at the beginning of this chapter, operates within the GPO to provide electronic access to legislative reference tools. The *FR*, published by the Office of the Federal Register, National Archives and Records Administration, serves as the official daily publication for rules, proposed rules, executive orders, presidential documents, and federal agency and organization notices. The *FR* volume for 2009 is Volume 74 and it may be searched separately or in conjunction with prior years dating back to 1994, Volume 59. Users may also sign up for a free daily email containing the *FR* table of contents. The CFR codifies the general and permanent rules published in the *FR*. The CFR is divided into 50 titles representing broad areas subject to federal regulation. Each CFR volume is updated once a year and issued quarterly. Titles are divided into chapters, usually bearing the issuing agency's name. Chapters, in turn, are subdivided into parts covering specific regulatory areas (e.g., 21 CFR 316.24 = Title 21—Food and Drugs; Part 316—Orphan Drugs; Chapter—Granting orphan-drug designation.) Some CFR records on GPO Access date back to 1996; all titles are available from 1997 to the current year. Documents are available as ASCII text and PDF files.<sup>4</sup> In addition to the *FR* and CFR, GPO Access contains links to numerous searchable databases including Congressional bills, the Congressional Record, the US Code, statutes at large and public and private laws.

Unveiled in 1995, the Library of Congress' THOMAS Database was created at the direction of the 104<sup>th</sup> Congress to make federal legislation publicly available. THOMAS offers a vast range of government resources including databases to search bill resolutions, bill and amendment summaries, bills across multiple Congresses, public laws searchable by number, House and Senate roll call votes, legislation by sponsor, Congressional activity databases, the *Congressional Record*, days-in-session calendars, committee reports and treaties. GovTrack.us, an independent, nonpartisan, noncommercial and open-source website launched in September 2004, provides access to some of the same tools available on THOMAS and GPO Access. This website is extremely useful if a regulatory professional needs to monitor the status of federal legislation or Congressional events. Users can subscribe to RSS feeds (commonly referred to as really simple syndication) throughout the site or use trackers to create customized feeds and receive email updates. RSS feeds are a family of Internet feed formats used to publish frequently updated works—such as blog entries, news headlines, audio and video—in a standardized format.<sup>5</sup>

### Government Databases—Federal Agency Resources

In addition to the legislative and regulatory tracking databases discussed previously, many federal agencies have built their own specialized databases to monitor specific regulatory issues and provide public access to biomedical, clinical and other useful government resources. This section focuses primarily on the databases created within FDA's centers. The Center for Drug Evaluation and Research (CDER) and the Center for Devices and Radiological Health (CDRH) have developed the largest number of database systems, with some overlap between CDER and the Center for Biologics Evaluation and Research (CBER). The Center for Veterinary Medicine (CVM) and the Center for Food Safety and Applied Nutrition (CFSAN) have also developed some unique databases. Due to chapter length constraints, however, this summary will review only selected center databases. A comprehensive list of all the agency's databases and corresponding website addresses is provided in **Table 36-2**.

CDER and CBER share the responsibility of reviewing postmarket safety reports submitted to the Adverse Event Reporting System (AERS), a database containing voluntarily submitted reports on approved drugs or therapeutic biologic products. CBER's other database systems include one for storing incoming Biological Product Deviation Reports and a Vaccine Adverse Event Reporting System (VAERS). Like the AERS database, VAERS is based on a cooperative agency program between CBER and the Centers for Disease Control (CDC) to address vaccine safety.

Two of CDER's most heavily searched databases focus on drug product approvals: the Approved Drug Products with Therapeutic Equivalence Evaluations (*Orange Book*) database, which lists drugs approved on the basis of safety and effectiveness; and the Drugs @FDA database, a searchable/browsable catalog of brand-name and generic prescription and over-the-counter human drugs and biological therapeutic products approved since 1939. Drug manufacturing firms are required to register their sites with Drugs@FDA within five days of commercial distribution and re-register annually at the Drug Firm Annual Registration Status database. The National Drug Code Directory is a database of marketed prescription drugs listed by universal product identifiers. CDER's two clinically oriented databases are the Biosearch Monitoring Information System, which identifies personnel engaged in Investigational New Drug (IND) studies; and the Clinical Investigator Inspection List, which contains data relevant to IND studies gathered by clinical investigator inspections.

CDRH has built and maintains more than 15 databases to monitor medical device and radiological products. Its 510(k)s—Premarket Notifications (PMN) database, which contains releasable 510(k)s, and its Premarket Approval (PMA) database, which provides manufacturer premarket approval status, are critical to device regulatory professionals. CDRH has also developed two adverse

event reporting systems similar to CDER's AERS database: the MAUDE (Manufacturer and User Facility Device Experience) database and the Medical Device Reporting (MDR) (formerly CDRH's Device Experience Network) database. MAUDE presents voluntarily submitted user facility, distributor and manufacturer medical device adverse event reports between 1991 and 1996; and MDR data consist of reports on devices that may have malfunctioned or caused a death or serious injury from 1992 through 1996. Other noteworthy CDRH databases include the Advisory Committee/Panel Meetings database containing both information about upcoming meetings and historical information with links to summaries and/or transcripts of recent past meetings; the Clinical Laboratory Improvement Amendments (CLIA) database, which represents commercially marketed FDA and CDC categorized *in vitro* diagnostic test systems; and the Establishment Registration database, which comprises domestic establishments engaged in the manufacture, preparation, propagation, compounding, assembly or processing of medical devices intended for human use and commercial distribution. CVM's Animal Drugs@FDA is comparable to CDER's Drugs@FDA and CDRH's 510(k) and PMA databases. This database allows users to search for approved animal drug products, suitability petitions, sponsors, the *Green Book*, CFR, FR, patents and exclusivity. In addition, FDA maintains its own Warning Letter database through its FOI office. The Warning Letter collection covers documents issued from November 1996 to the present. The database can be searched by company, subject, issuing office or date.

In addition to the regulatory information available through FDA's databases, regulatory professionals requiring biomedical research can access PubMed, the National Library of Medicine's (NLM) biomedical database, which includes more than 18 million citations from MEDLINE and other life science journals dating back to 1948.<sup>6</sup> NLM also produces TOXNET, the toxicology data network, which consists of databases on toxicology, hazardous chemicals, environmental health and toxic releases. For molecular biology information, NLM's National Center for Biotechnology Information (NCBI) offers a comprehensive resource. Established in 1988, NCBI has created numerous public databases covering genetic sequencing and molecular processes affecting human health and disease, as well as developed software tools for analyzing genome data. And lastly, the National Institute of Health's (NIH) ClinicalTrials.gov site contains current information to identify federally and privately supported clinical trials for a range of diseases and conditions. The database includes 71,340 trials sponsored by NIH, other federal agencies and private industry conducted in all 50 states and 165 countries.<sup>7</sup>

A few additional recommended federal databases are the Forms Catalog and RegInfo.gov. Branded as "the US government's official hub for federal forms," the Forms Catalog contains many, though not all, of the citizen and

business forms issued by federal agencies. Forms may be searched by agency, agency list or form number, and alphabetically listed by form name or keyword. A direct link to forms published on specific agency websites is also available if the form being searched is not available through the Forms Catalog. The Office of Management and Budget (OMB) and the General Services Administration (GSA), in turn, jointly produce RegInfo.gov. This website contains a catalog searchable by government agency to locate all the regulatory reviews conducted by OMB's Office of Information and Regulatory Affairs (OIRA). It also has a catalog of the GSA's Regulatory Information Service Center's (RISC) semiannually published *Unified Agenda of Federal Regulatory and Deregulatory Actions* dating back to fall 1995. The *Regulatory Plan* is part of the fall edition of the *Unified Agenda*. The *Regulatory Plan* serves as a defining statement of the administration's regulatory and deregulatory policies and priorities, while the *Unified Agenda* provides information about regulations that the government is considering or reviewing. RISC is responsible for gathering and publishing information on federal regulations through the semiannual *Unified Agenda of Federal Regulatory and Deregulatory Actions* and the annual *Regulatory Plan*, both required by Executive Order 12866, "Regulatory Planning and Review." The same executive order gives OIRA the mandate to review federal regulations and information collections. OIRA also develops and oversees the implementation of government-wide policies on information technology, information quality, privacy and statistics.<sup>8</sup>

Reginfo.gov also provides links to several other government resources that will be briefly mentioned in this section. The first is USA.gov, the government's official portal to federal agency websites and information. This website is the product of an interagency initiative administered by the GAO's Office of Citizen Services and Communications. It provides a centralized database to locate information on US local, state and federal government agency websites. Regulations.gov is another resource that is linkable from Reginfo.gov's website. It is an extremely valuable tool to locate government agency regulations, rulemakings or notices, and is also useful for finding, submitting and obtaining public comments on proposed FR regulations. In addition, a comment can be directly submitted through the website by accessing documents that are still open for public comment. Business.gov, the US government's official website for small businesses, is the final website to be reviewed as a link from Reginfo.gov. This resource provides information on regulatory compliance and other information for small business owners. Managed as a partnership by 22 government agencies, Business.gov offers a wealth of information on regulatory compliance, legal issues surrounding running a business and registration, license and permit requirements. For example, a pharmaceutical or biotech small business can click on the industry link and find a page dedicated to complying with laws and regulations applicable to producers, distributors and marketers of

human and veterinary drugs, medicines, biologics, medical devices and equipment and controlled substances.

### Government Resources Related to Healthcare Product Regulation

The previous section reviewed federal agency databases useful for legislative tracking and healthcare product approval review and reporting. This section features government agency websites that offer additional healthcare product regulatory information.

#### US Government Agencies

In addition to FDA's wealth of databases, the agency, to its credit, provides users with many handy navigational tools to obtain information from its website. Upon launching the agency's homepage, users are introduced to numerous ways to access information, from using the search box highlighted in blue at the top of the page to browsing the A–Z Index listed directly below. Moreover, users can select one of the broad subject categories (food, drugs, medical devices, biologics/blood/vaccines, animal/veterinary, cosmetics, radiation-emitting products and combination products) listed on the left-hand side of the page to be directed to an agency center or office. Within each of these links, additional navigational tools are provided to locate information. CDER's homepage offers the latest news, featured links, quick links to frequently searched topics and seven browsable, tabbed categories at the top. The CDER Site Info link can be used to browse an alphabetical topic index. CBER offers similar choices through its links to current news, key center categories, hot topics, general CBER information, useful government sites, a search box and the CBER alphabetical topic index. CDRH provides links to industry assistance topics, health topics, information about the center, news and events, device program areas, radiological health, key topics, a featured site, information resources and a search box as well as an alphabetical CDRH topic index. CFSAN supplies links to its center overview and activities, FDA documents, instructions for interacting with the center, recent news, program areas, national food safety programs, special interest areas, other sources of information, prior notice, food facility registration, CFSAN search/subject index, and food, nutrition and cosmetics questions and answers. CVM presents key topics related to the center, news and events, hot topics listed horizontally and vertically on the website, a veterinarian newsletter, a search box and an alphabetical topic index. The Office of Combination Products (OCP), which is the last main category listed on FDA's homepage, plays a role in all of the centers in which combination products are reviewed. Its links are designed to assist users in defining their own products. Consequently, the links include product jurisdiction/assignment of combination products, requests for comment, guidance documents and procedures, reports, workshops and presentations and what's new.

A few other particularly helpful pages within the FDA website are the Information for FDA-Regulated Industry within the Office of Compliance and FOIA. The Information for FDA-Regulated Industry page organizes industry information by clearly defined categories: industry information by subject, small business, adverse event reporting, compliance and enforcement, contact FDA, what's new, food industry and meetings/workshops. The FOIA page contains links to frequently asked questions, how to make an FOIA request, FOIA fees, online payments, an electronic reading room, Annual Reports, the *Privacy Act*, reference materials, contacts and links to other FOIA requester centers within the US Department of Health and Human Services (DHHS).

DHHS is the US federal agency whose mission is to protect the health of all US citizens and provide essential human services. The office of the secretary and its subdivisions carry out DHHS' initiatives while 11 operating agencies perform a broad range of tasks and services, from conducting research and ensuring food and drug safety to funding grants and programs and managing health insurance. The specific operating agencies are: the Administration for Children and Families, the Administration on Aging, the Agency for Healthcare Research and Quality (AHRQ), the Agency for Toxic Substances and Disease Registry, the Center for Medicare & Medicaid Services, CDC, FDA, the Health Resources and Services Administration, the Indian Health Service, NIH, and the Substance Abuse and Mental Health Services Administration. Due to chapter length limits, the DHHS operating agencies other than FDA are not discussed in detail. However, they are listed with their corresponding website addresses in **Table 36-3** for readers to review.

An especially valuable feature of the DHHS website is the ability to subscribe to multiple DHHS and partnering agency publications with a single email address. Once a user selects the Email Updates envelope icon at the top of the page and enters the appropriate email address, he or she can check the boxes next to all preferred publications. These preferences will then be forwarded to the appropriate agencies within DHHS. The partnering agencies that list publications are the National Institute of Allergy and Infectious Diseases, AHRQ, CDC, FDA, Disabilityinfo.gov, the Department of Defense Military Health System, the President's Malaria Initiative and USAID Health.

It is also worth mentioning a few other government agency websites that are helpful to professionals conducting healthcare product regulatory reviews and designing strategic product development plans. The first is the US Environmental Protection Agency, which examines the potential environmental, chemical and medical waste regulatory concerns related to developing various healthcare products. The second is the US Federal Trade Commission (FTC), which addresses issues related to enforcing appropriate business competition and monitoring anticompetitive practices. The FTC's Bureau of

**Table 36-3. Agencies Associated With Healthcare Product Regulation**

Agency	Website	Subject Coverage
Consumer Product Safety Commission	<a href="http://www.cpsc.gov/">www.cpsc.gov/</a>	Poisoning, Packaging, Labeling, Prescription/OTC Drug Products
Environmental Protection Agency	<a href="http://www.epa.gov/">www.epa.gov/</a>	Environment & Public Health, Chemicals, Air Pollutants, Medical Waste
Federal Trade Commission	<a href="http://www.ftc.gov/">www.ftc.gov/</a>	Business Competition & Consumer Protection
Food & Drug Administration (FDA)	<a href="http://www.fda.gov">www.fda.gov</a>	Food, Drugs, Medical Devices, Biologics/ Blood & Vaccines, , Animal & Veterinary, Cosmetics, Radiation-Emitting Products, Combination Products
CBER	<a href="http://www.fda.gov/BiologicsBloodVaccines/default.htm">www.fda.gov/BiologicsBloodVaccines/default.htm</a>	
CDER	<a href="http://www.fda.gov/Drugs/default.htm">www.fda.gov/Drugs/default.htm</a>	
CDRH	<a href="http://www.fda.gov/MedicalDevices/default.htm">www.fda.gov/MedicalDevices/default.htm</a>	
CFSAN	<a href="http://www.cfsan.fda.gov/Food/default.htm">www.cfsan.fda.gov/Food/default.htm</a>	
CVM	<a href="http://www.fda.gov/AnimalVeterinary/default.htm">www.fda.gov/AnimalVeterinary/default.htm</a>	
OCP	<a href="http://www.fda.gov/CombinationProducts/default.htm">www.fda.gov/CombinationProducts/default.htm</a>	
FOIA Reading Room	<a href="http://www.fda.gov/RegulatoryInformation/foi/default.htm">www.fda.gov/RegulatoryInformation/foi/default.htm</a>	
Information for the FDA-Regulated Industry	<a href="http://www.fda.gov/ForIndustry/default.htm">www.fda.gov/ForIndustry/default.htm</a>	
Department of Health & Human Services (DHHS)	<a href="http://www.hhs.gov">www.hhs.gov</a>	Public Health, Food & Drug Safety, Grants & Funding, Research, Health Insurance
Administration for Children & Families	<a href="http://www.acf.hhs.gov/">www.acf.hhs.gov/</a>	
Administration on Aging	<a href="http://www.aoa.gov/">www.aoa.gov/</a>	
Agency for Healthcare Research & Quality	<a href="http://www.ahrq.gov/">www.ahrq.gov/</a>	
Agency for Toxic Substances & Disease Registry	<a href="http://www.atsdr.cdc.gov/">www.atsdr.cdc.gov/</a>	
Centers for Disease Control & Prevention	<a href="http://www.cdc.gov/">www.cdc.gov/</a>	
Centers for Medicare & Medicaid Services	<a href="http://www.cms.hhs.gov/">www.cms.hhs.gov/</a>	
Health Resources & Services Administration	<a href="http://www.hrsa.gov/">www.hrsa.gov/</a>	
Indian Health Service	<a href="http://www.ihs.gov/">www.ihs.gov/</a>	
National Institutes of Health	<a href="http://www.nih.gov/">www.nih.gov/</a>	
Substance Abuse & Mental Health Services Administration	<a href="http://www.samhsa.gov/">www.samhsa.gov/</a>	
Global Harmonization Task Force (GHTF)	<a href="http://www.ghtf.org/">www.ghtf.org/</a>	Medical Devices

Consumer Protection is specifically responsible for handling fraudulent and dishonest consumer protection activities, which encompass advertising and e-commerce oversight. Advertising and consumer safety are also key priorities to healthcare product regulatory professionals. The US Consumer Product Safety Commission (CPSC) is another agency that deeply impacts a regulatory professional's product development decisions. CPSC's primary

mission is to protect the public from unreasonable risks of injury or death from a broad range of consumer products. For example, its poison prevention packaging standards and testing procedures, as well as its child-resistant and senior-friendly packaging guidelines, determine how over-the-counter and prescription drugs and physician samples must be packaged. Although a regulatory professional's decision making process is shaped by several

Agency	Website	Subject Coverage
International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use	<a href="http://www.ich.org">www.ich.org</a>	Drugs & Biologics
World Health Organization (WHO)	<a href="http://www.who.int">www.who.int</a>	Public Health, Drugs & Biologics
WHO Biologicals Program	<a href="http://www.who.int/biologicals/en">www.who.int/biologicals/en</a>	
WHO Essential Medicines & Pharmaceutical Policies	<a href="http://www.who.int/medicines/about/en/index.html">www.who.int/medicines/about/en/index.html</a>	

Note: Website URLs are current at time of publication.

other federal agency regulations and guidelines, this chapter will not go into detail about these governmental bodies. However, an in-depth and instructive discussion on this subject appears in a 2007 *Regulatory Affairs Focus* article by Novales-Li and Temple.<sup>9</sup>

### Global Organizations

Although this chapter centers on US regulatory information resources, a few global organizations are too important to overlook given the critical role the US plays within each of these groups. The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is one of these global bodies. ICH brings together the regulatory bodies of Europe, the US and Japan and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration.<sup>10</sup> The organization's safety, efficacy, quality and multidisciplinary guidelines are indispensable to pharmaceutical regulatory professionals as they evaluate proposed products to ensure regulatory compliance. The Global Harmonization Task Force (GHTF) is another international organization in which US regulatory representatives actively participate. GHTF is a partnership between national medical device regulatory authorities and the regulated industry and is composed of five founding members: the EU, the US, Canada, Australia and Japan. Established in 1992, the organization aims to harmonize regulatory practices that will ensure the safety, effectiveness, performance and quality of medical devices, promote technological innovation and facilitate international trade.<sup>11</sup> These harmonized practices are incorporated and disseminated through documents developed by five GHTF study groups. Medical device regulatory professionals review these documents as they evaluate device conformity assessment, quality management systems and postmarket surveillance issues surrounding their device products. The World Health Organization (WHO) is the final intergovernmental body to be considered in this section. WHO provides leadership on health matters, shapes the health research agenda, and sets norms and standards within the United Nations. The US actively participates in WHO activities, particularly within its Essential Medicines and Pharmaceutical

Policies Department, which is involved in developing, implementing and monitoring national medicines policies and guidelines. Another WHO program in which the US participates is the Biologicals Program. The goal of this program is to ensure that national regulatory authorities implement effective systems to ensure the quality and safety of blood products and *in vitro* diagnostic devices. **Table 36-3** lists websites for these global organizations.

### Industry Associations

Print and electronic publications, online commercial and government databases and other Internet-based government agency resources unquestionably have an integral place in a regulatory professional's work. These resources enable him or her to monitor the latest news, track the status and development of laws, regulations and guidelines and engage in effective strategic product development. It is, however, industry associations that function as indispensable educational resources for regulatory professionals themselves. The organizations mentioned earlier in the chapter, including RAPS, DIA, TOPRA, BIO, AdvaMed, FDLI and ACRP, offer a broad variety of learning opportunities to their members. Regulatory professionals can initiate or update their knowledge of the regulatory healthcare industry and fulfill core competency requirements by participating in classroom and online courses, self-paced home study, audio and web-based training and certificate programs and attend workshops and conferences. In addition to offering formal learning options, associations enable professionals to engage in networking and exchange information with their colleagues through forums and online communities.

### Web 2.0 Tools

The second generation of Internet-based services, commonly referred to as Web 2.0, has enabled Internet users to participate in more dynamic and interactive information sharing. To complement the networking benefits of industry association memberships, regulatory professionals can now connect with colleagues through blogs and social networking websites. The rapidly growing number of blogs, or weblogs, which are regularly updated journal entries designed to be read by a professional audience

and representing the unique personality of the author or website,<sup>12</sup> is remarkable. Some of the more popular blogs worth reviewing within the regulatory healthcare sector are: FDA Law Blog (Hyman, Phelps & McNamara PC); Biotech Blog; Eye on FDA (RX for Pharma Industry Communications and Planning); Medical Device and Diagnostic Industry (MDDI) blogs including Device Talk, Biomaterials Talk and Transforming FDA; HTA Blog (Health Technology Assessment); and Pharmed Blogs including PharmaBlogReview, MedAdNewsInsider and R&D Directions Insider. This list does not begin to scratch the surface of what is truly available for this profession; however, it is a good starting point.

Social networking sites are another widely used Web 2.0 Internet service. Regulatory professionals can participate in sites such as LinkedIn and RegulatoryWorld.com to establish a public professional profile, search for jobs, interact with colleagues, search for other regulatory professionals, review uploaded presentations and read member interviews. LinkedIn is an interconnected network of experienced professionals from around the world, representing 170 industries and 200 countries.<sup>13</sup> Joining the network is free and simply requires the user to create a profile summarizing his or her professional experience and accomplishments. The information a user chooses to make publicly available can then be searched by other professionals within the LinkedIn network to meet and collaborate with other members. RegulatoryWorld.com is another social networking website designed exclusively for regulatory professionals. Launched in 2007, RegulatoryWorld.com is still in the early stages of defining itself. Currently, the site has 4,047 members from 75 countries, with the majority from the US and the UK. As is true of LinkedIn, RegulatoryWorld.com membership and its user services are free of charge.<sup>14</sup>

### Summary

This chapter has reviewed a wide range of print and electronic information resources and selected social networking tools available to regulatory professionals. From this review, it is clear that the wealth of publications, databases and government, association and industry web-based tools, as well as social networking opportunities that have sprouted up in just the past few decades is truly staggering. The new challenge for regulatory professionals is to distill the essential knowledge they require from the vast storehouse of information available to perform their jobs as effectively as possible. This will call for carefully managing electronic and print subscriptions, becoming skilled in using relevant government and industry databases, making use of association educational resources to advance professional knowledge and, finally, using social networking tools with discipline and discrimination. In this way, regulatory professionals will be certain to reap

the greatest benefit from the abundant resources available, thereby increasing their productivity, effectiveness and overall expertise.

### References

1. "About USP – An Overview." US Pharmacopeia. Available at: [www.usp.org/aboutUSP/](http://www.usp.org/aboutUSP/). Accessed 7 April 2009.
2. "About GPO Access." GPO Access. Available at: [www.gpoaccess.gov/about/index.html](http://www.gpoaccess.gov/about/index.html). Accessed 7 April 2009.
3. "About Us." Piribo. Available at: [www.piribo.com/](http://www.piribo.com/). Accessed 7 April 2009.
4. "Code of Federal Regulations (CFR) Main Page." GPO Access. Available at: [www.gpoaccess.gov/cfr/index.html](http://www.gpoaccess.gov/cfr/index.html). Accessed 7 April 2009.
5. "RSS." Wikipedia. Available at: [http://en.wikipedia.org/wiki/RSS\\_\(file\\_format\)](http://en.wikipedia.org/wiki/RSS_(file_format)). Accessed 7 April 2009.
6. "PubMed." NCBI. Available at: [www.ncbi.nlm.nih.gov/pubmed/](http://www.ncbi.nlm.nih.gov/pubmed/). Accessed 7 April 2009.
7. "About ClinTrials.gov." ClinTrials.gov. Available at: <http://clinicaltrials.gov/ct2/info/about>. Accessed 7 April 2009.
8. "RegInfo.gov:Where to Federal Regulatory Information." RegInfo.gov. Available at: [www.reginfo.gov/public/](http://www.reginfo.gov/public/). Accessed 7 April 2009.
9. Novales-Li P, Temple L. "Non-FDA Agencies Involved in US Healthcare Regulation." *Regulatory Affairs Focus*. Vol 12. No 8, pp 8-15 (August 2007).
10. "Welcome to the official website for ICH." ICH. Available at: [www.ich.org](http://www.ich.org). Accessed 7 April 2009.
11. "About GHTF." Global Harmonization Task Force. Available from: [www.ghtf.org/about/](http://www.ghtf.org/about/). Accessed 7 April 2009.
12. "Glossary." bytown Internet. Available at: [www.bytowninternet.com/glossary](http://www.bytowninternet.com/glossary). Accessed 7 April 2009.
13. "About Us." LinkedIn. Available at <http://press.linkedin.com/about>. Accessed 7 April 2009.
14. "About Us." RegulatoryWorld.com. Available at: [www.regulatoryworld.com/php/faqpub.php?PHPSESSID=bf3df0c9ecfbc53d5996da4c30370849](http://www.regulatoryworld.com/php/faqpub.php?PHPSESSID=bf3df0c9ecfbc53d5996da4c30370849). Accessed 7 April 2009.

**Review Questions**

1. What is the best source to track pharmaceutical legislation?
  - a. MediRegs
  - b. GovTrack.us
  - c. THOMAS
  - d. GPO Access
  - e. All of the above
  
2. True or false: USP is an official public standards-setting authority for prescription and, over-the-counter medicines and US manufactured healthcare products.
  
3. CDRH's medical device adverse event reports from 1992 through 1996 are stored in which database?
  - a. Adverse Event Reporting System (AERS)
  - b. Medical Device Reporting (MDR)
  - c. TOXNET
  - d. MAUDE

**Answers:**

1. e
2. True
3. b

**Chapter 36**