Chapter 39

Regulatory Information Resources in Review

By Elizabeth Goldstein, RAC and Dinar Suleman, RAC

OBJECTIVES

- ❑ Become familiar with information resources relevant to the regulatory healthcare industry
- ❑ Learn where to access and retrieve publicly available government, industry and association resources to build regulatory intelligence
- ❑ Recognize the value of regulatory intelligence for use in business strategy development and compliance for the healthcare industry

Introduction

Regulatory professionals in the healthcare industry are faced with the challenge of navigating an ever-changing landscape in the form of new and modified regulations, standards and industry practices. Compounding this variability are company structure and focus changes, such as mergers, acquisitions and new product development. Therefore, regulatory professionals must develop a proactive and vigilant approach to stay abreast of current healthcare industry information. As such, information resource identification and management are necessary objectives for maintaining regulatory compliance. Within the regulatory field, the transition to digital transactions and electronic data has resulted in increased reliability, trustworthiness, usability and portability of online information technology tools.

Given the fluidity of the global regulatory environment, regulatory professionals are expected to develop regulatory strategy based on a variety of data streams: print (e.g., books and magazines), static electronic (e.g., e-newsletters and government websites) and interactive electronic resources (i.e., social medial and webinars). This chapter discusses the value of each data stream and provides a comprehensive review of resources available to build US regulatory intelligence and support product substantiation.

Regulatory Intelligence

US Governing Law

The US Government Publishing Office (GPO) is the official source for US government publications and information products. GPO is the primary resource for gathering, cataloging, producing, providing, authenticating and preserving published information in all its forms for the federal government's executive, legislative and judicial branches.[1] Publications pertaining to regulatory healthcare topics may be accessed online via the GPO's Federal Digital System (FDsys), using keywords such as "FDA" or "Food and Drug Administration" and "HHS" or "Department of Health & Human Services," combined with more-specific terms such as "pharmaceutical," "medical devices" or "clinical." FDsys provides free electronic access to legislative resources, including Congressional bills, the Congressional Record, public and private law and the US Code; executive sources, such as the Code of Federal Regulations (CFR), the *Federal Register* (*FR*) and presidential materials; and judicial sources, including the Supreme Court, trial and appellate court cases, opinions, oral arguments and decisions.

The *FR*, published daily (except on weekends and federal holidays), is the official daily publication for rules, proposed rules, executive orders, presidential documents and federal agency and organization notices. The *FR* is administered by the National Archives and Records Administration's (NARA) Office of the Federal Register

(OFR) and GPO. The 2018 *FR* is Volume 83 and may be searched online. Volumes 59 (1994) to present may be searched online in summary, PDF, text or HTML format. Volumes 59 (1994) and earlier have been digitized and may be accessed online as full issue PDF files only.[2] Individuals also may subscribe to the electronic *FR* or the daily table of contents.[3] The CFR codifies general and permanent rules published in the *FR* and is divided into 50 titles representing broad areas subject to federal regulation. Titles are divided into chapters, usually bearing the issuing agency's name, which are subdivided into parts covering specific regulatory areas (e.g., 21 CFR 316.24 = Title 21—Food and Drugs, Chapter I—Food and Drug Administration, Department of Health and Human Services, Subchapter D—Drugs for Human Use, Part 316—Orphan Drugs, Subpart C—Designation of an Orphan Drug, Section 316.24—Granting orphan-drug designation). Each CFR volume is updated yearly and issued quarterly. CFR records on FDsys span 1996 to the current year. Documents are available as ASCII text, HTML and PDF files.[4]

In addition to the *FR* and CFR, FDsys serves as the official source of legislation and regulations; however, reference information for FDA legislation, rules, regulations, guidance documents, administrative FDA proceedings and rule-making documents and standards reside on FDA's website.[5] The Electronic Reading Room provides a collection of publicly releasable FDA agency records categorized under the Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), Center for Devices and Radiological Health (CDRH), Center for Food Safety and Applied Nutrition (CFSAN), Center for Veterinary Medicine (CVM), Division of Dockets Management Branch (DMB), Office of Regulatory Affairs (ORA), Center for Tobacco Products, Agency Manuals and frequently requested regulatory records. The FDA's Dockets Management, administered by the Federal Dockets Management System (FDMS), is the FDA's repository for documents including *FR*s and petitions. FDMS allows public access to these administrative FDA proceedings and rule-making documents and gives consumers an opportunity to submit electronic comments. Separate from the FDA website, Congress.gov, the official website for US federal legislative information, offers a vast range of government resources, including databases to search bill resolutions; bill and amendment summaries; public laws; legislation by sponsor; and committee reports.[6]

Importers and exporters of FDA-regulated products must be familiar with applicable US trade laws. US Customs and Border Protection (CBP) regulates and enforces US regulations on trade and customs. CBP resources, such as the Intellectual Property Rights Search (IPRS) database and the Customs Rulings Online Search System (CROSS), support a company's efforts to enforce its intellectual property rights on trademarks, copyrights and patents. CBP maintains the Intellectual Property Rights Search (IPRS), a searchable database of trademarks registered with the US Patent and Trademark Office (PTO).[7] The CBP website also provides a searchable repository of *FR* notices related to product importation into the US. The Customs Rulings Online Search System (CROSS) is a database allowing the retrieval of CBP trade-related rulings and legal decisions from 1989 to present.[8] CBP resources support a company's efforts to enforce its intellectual property rights on trademarks, copyrights and patents.

In 2016, CBP introduced the Automated Commercial Environment (ACE), replacing the Automated Commercial System (ACS).[9] ACE is the primary system used by industry to electronically submit all data required by various US government agencies to manage imports and exports.

Along with CBP, the US Department of Commerce's Bureau of Industry and Security (BIS) monitors and regulates the import and export of goods across US borders. BIS manages and enforces export control and treaty compliance, including items related to anti-boycott laws under *Export Administration Act* provisions. BIS makes unofficial electronic Export Administration Regulations (EAR) files accessible on its website, while the *FR* provides the official text. BIS makes boycott guidelines (43 FR 3454, 44 FR 66272, 49 FR 18061 and 52 FR 2511) accessible on its website. In addition, foreign boycott requests are reportable on the BIS website.[10]

US Government Agencies

A regulatory professional's decision-making process is shaped by federal regulations and guidelines. This section features government agency websites providing additional healthcare product regulatory information. This chapter will not go into detail about all these governmental bodies, but **Table 39-1** provides the websites where further information about these agencies can be accessed.

The US Department of Health and Human Services (HHS) is the US federal agency whose mission is to protect the health of all US citizens and provide essential human services. HHS has 11 agencies and offices that 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. Eight of the 11 HHS agencies are in the US Public Health Service (PHS), including the Food and Drug Administration (FDA), which is the primary focus of the following discussion.

FDA is managed by the Office of the Commissioner, which presides over four offices: Medical Products and

Tobacco; Foods; Global Regulatory Operations and Policy; and Operations. The functions pertaining to this publication are managed by the Office of Medical Products and Tobacco and include the Center for Drug Evaluation and Research (CDER), the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER). This office also oversees the Oncology Center of Excellence and the Office of Special Medical Programs (OSMP), which is comprised of the Office of Combination Products (OCP), the Office of Good Clinical Practice (GCP), the Office of Orphan Products and the Office of Pediatric Therapeutics.

FDA's website features center links; recalls and alerts; approvals and clearances; news and announcements; resources targeting industry, consumers and healthcare professionals; links to program area coverage; a search box and contact information.[11] It also provides several convenient listings, which include but are not limited to, the Humanitarian Device Exemptions Listing, FDA Debarment List (Drug Product Applications) and Clinical Investigators—Disqualification Proceedings. FDA also offers a free email alert for updates on topics related to FDA-regulated products.[12]

Another helpful resource found on FDA's website is the Office of Regulatory Affairs (ORA). ORA includes resources such as recalls, market withdrawals and safety alerts; enforcement reports; and a link to the ORA *Freedom of Information Act* (*FOIA*) electronic reading room, which contains publicly available copies of ORA domestic inspection and associated records. The records are available online for a period of five years prior to being archived. FDA's *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; and contact details. Additionally, FDA maintains its own Warning Letter database through the FOI office. The Warning Letter collection covers documents issued from November 1996 to present. This database can be searched by company, subject, issuing office or date.

As an added resource, FDA's website hosts training and continuing education resources, including videos and podcasts. The training modules educate users; foster transparency between FDA and academia, industry and clinical investigators; and promote public health. A subset of these learning tools is offered in French and Spanish for the international audience. In addition, FDA periodically hosts online webinars with senior agency officials speaking on specific topics. Webinar attendees are given the opportunity to engage with FDA staff by asking questions.

The US Consumer Product Safety Commission (CPSC) is another agency deeply impacting industry decisions. CPSC's primary mission is to protect the public from unreasonable risks of injury or death associated with the use of 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 OTC and prescription drugs and physician samples must be packaged.

Last, the US Federal Trade Commission (FTC) addresses issues related to enforcing appropriate business competition and monitoring anticompetitive practices. FTC's Bureau of Consumer Protection is responsible for handling fraudulent and dishonest consumer protection activities, which encompass advertising and e-commerce oversight. Advertising and consumer safety also are key priorities for healthcare product regulatory professionals.

Online Commercial and Government Databases

An integral component of a regulatory professional's job is staying informed about the latest regulatory and legislative developments. Numerous commercial, fee-based, web-based databases and free, federal, web-based databases are available to support the regulatory professional's legislative tracking and regulatory analysis responsibilities. The resources reviewed in this section highlight noteworthy governmental database tools to support these monitoring and surveillance responsibilities.

Federal Government Databases—Agency Resources

Many federal agencies have built their own databases to monitor specific regulatory issues and provide public access to government resources. The beginning of this chapter discusses databases housing US Governing Law (e.g., Congress.gov, CROSS and FDsys). Further review will highlight repositories useful for manufacturer and device registrations, submission preparation and post-market surveillance. This section focuses primarily on the databases created by FDA's centers.

CDER and CDRH have developed the largest number of databases, with some overlap between CDER and CBER. Due to chapter length constraints, this summary will review only selected center databases. A comprehensive list of all agency databases and corresponding website addresses is provided in **Table 39-2**.

Domestic and foreign manufacturers, re-packers and re-labelers for drug products in the US are required to register their establishments and commercially marketed drug products online with FDA. As a self-identification and Drug Establishment Registration and Drug Listing requirement, FDA requires human generic drug facilities or sites and registrant owners (if in a different location than the facility or site) to obtain Data Universal Numbering System (D-U-N-S) numbers. Since 1963, D-U-N-S numbers, established by Dun & Bradstreet

Table 39-1. Agencies, Organizations, Institutes, Centers and Offices Associated with Healthcare Product Regulation

Organization	Website	Subject Coverage
US Consumer Product Safety Commission (CPSC)	www.cpsc.gov	Safety Education, Recalls, Poisoning, Packaging, Labeling, Drugs, Children's Products
	www.cpsc.gov/Regulations-Laws–Standards	Regulations, Laws, Bans, Guidances, Standards, Federal Register Notices
US Environmental Protection Agency (EPA)	www.epa.gov	Environment Health, Public Health, Chemicals, Air Pollutants, Medical Waste
US Department of Health and Human Services (DHHS)	www.hhs.gov	Public Health, Food Safety, Drugs, Medical Devices, Biologics, Blood and Vaccines, Cosmetics, Radiation-Emitting Products, Combination Products, Grants and Funding, Research, Health Insurance
Assistant Secretary for Preparedness and Response (ASPR)	www.phe.gov	Public Health and Medical Disasters and Emergencies
Administration for Community Living (ACL)	www.acl.gov	Aging and Disability Population
Agency for Healthcare Research and Quality (AHRQ)	www.ahrq.gov	Research and Resources on Outcomes, Cost, Safety, Access and Quality of Healthcare
Centers for Disease Control and Prevention (CDC)	www.cdc.gov	Disease Control and Prevention
National Institute for Occupational Safety and Health (NIOSH)	www.cdc.gov/niosh	Prevention of Workplace Illness and Injury
Agency for Toxic Substances and Disease Registry (ATSDR)	www.atsdr.cdc.gov	Harmful Exposures and Diseases Related to Toxic Substances
Centers for Medicare & Medicaid Services (CMS)	www.cms.gov	Medicare, Medicaid and Children's Health Insurance Program (CHIP) coverage
US Food and Drug Administration (FDA)	www.fda.gov	Public Health, Regulations, Food, Drugs, Medical Devices, Biologics, Vaccines, Tissue and Tissue Products, Blood and Blood Components, Cosmetics, Animal and Veterinary Products
Center for Biologics Evaluation and Research (CBER)	www.fda.gov/BiologicsBloodVaccines/	Vaccines, Blood and Biologics
Center for Drug Evaluation and Research (CDER)	www.fda.gov/Drugs/	Drugs
Center for Devices and Radiological Health (CDRH)	www.fda.gov/MedicalDevices	Medical Devices
Center for Food Safety and Applied Nutrition (CFSAN)	www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CFSAN/	Food and Cosmetics Safety; Including Dietary Supplements, Infant Formulas, and Medical Foods
Office of Special Medical Programs	www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/OfficeofScienceandHealthCoordination/	Combination and Orphan Products; GCP; Pediatric Therapeutics
Freedom of Information (FOI) Electronic Reading Room	www.fda.gov/aboutfda/centersoffices/officeofglobalregulatoryoperationsandpolicy/ora/oraelectronicreadingroom	Frequently Requested FDA Documents
FDA Information—For Industry	www.fda.gov/ForIndustry	Information for Companies
Health Resources and Services Administration (HRSA)	www.hrsa.gov	Healthcare Access
Indian Health Service (IHS)	www.ihs.gov	Public Health of Federally Recognized American Indians and Alaska Natives
National Institutes of Health (NIH)	www.nih.gov	Biomedical and Clinical Research Resources

Table 39-1. Agencies, Organizations, Institutes, Centers and Offices Associated with Healthcare Product Regulation (cont'd.)

Organization	Website	Subject Coverage
Substance Abuse and Mental Health Services Administration (SAMHSA)	www.samhsa.gov	Behavioral Health: Substance Abuse and Mental Illness
US Small Business Association (SBA)	www.sba.gov	Congressional Advocacy, Federal Procurement, Training and Financing
International Council on Harmonisation (ICH)	www.ich.org	Drugs and Biologics
International Medical Device Regulators Forum (IMDRF) (formerly Global Harmonization Task Force (GHTF))	www.imdrf.org	Medical Devices
	www.imdrf.org/documents/documents.asp	Current and Archived Final Documents
World Health Organization (WHO)	www.who.int/en	Public Health, Drugs, Medical Devices, Biologics, Vaccines
	www.who.int/library/databases	
Medical Dictionary for Regulatory Activities (MedDRA)	www.meddra.org	Standardization of Medical Terminology for Adverse Events and Medication Errors Coding
Occupational Safety and Health Administration (OSHA)	www.osha.gov	Workplace Safety and Health
Federal Trade Commission (FTC)	www.ftc.gov	Prevention of Fraud, Deception and Unfair/ Anticompetitive Business Practices
US Nuclear Regulatory Commission (NRC)	www.nrc.gov	Radioactive Materials
US Patent and Trademark Office (PTO)	www.uspto.gov	Granting Patents, Registering Trademarks, Intellectual Property Law and Policy

Note: Website URLs are current at time of publication.

(D&B), have been used as identifiers for a broad range of global businesses.[13] In the case of generic drugs, the D-U-N-S number uniquely identifies the registrant and the physical location of each facility or site to FDA. Requests are made online and typically are processed in 20 business days. D&B hosts a public database for searching D-U-N-S numbers.[14]

CDER's two clinically-oriented databases are the Bioresearch Monitoring Information System, which identifies personnel engaged in Investigational New Drug (IND) studies; and the Clinical Investigator Inspection List Database, which contains data relevant to IND studies gathered by clinical investigator inspections. Information on registered drug products can be found on some of CDER's most heavily searched databases: the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) database, which lists drugs approved by the FDA on the basis of safety and effectiveness; the National Drug Code Directory, a database of marketed prescription drugs listed by universal product identifiers; and the Drugs@FDA database, a searchable catalog of brand-name and generic prescription and OTC human drugs and biological therapeutic products approved since 1939. Elsevier's PharmaPendium database, by comparison, provides drug safety data on FDA-approved drugs. This online resource affords researchers searchable access using the Medical Dictionary for Regulatory Activities (MEDRA) search terminology. It also incorporates animal and human study data from FDA's Adverse Event Reporting System (FAERS), preclinical and clinical studies and postmarket data. Regulatory professionals can use PharmaPendium's FDA database to obtain pharmacovigilance data to evaluate projected risks.[15]

CDER's two clinically oriented databases are the Bioresearch Monitoring Information System, which identifies personnel engaged in Investigational New Drug (IND) studies; and the Clinical Investigator Inspection List Database, which contains data relevant to IND studies gathered by clinical investigator inspections.

CDER and CBER share the responsibility for reviewing postmarket safety reports submitted to FAERS, a database containing voluntarily submitted adverse event reports, medication error reports and product quality complaints for approved drugs or therapeutic biologics products. FAERS data can be accessed by the public through the FAERS dashboard, FAERS data files and *FOIA* requests. CBER's other database systems include one that stores incoming Biological Product Deviation Reports and a Vaccine Adverse Event Reporting System

Table 39-2. Databases for Healthcare Product Regulatory-Related Intelligence

Database	Website	Subject Coverage
Government		
CPSC/Consumer Product Safety Information Database	www.saferproducts.gov	Searchable reports and recalls related to consumer products
CPSC/National Electronic Injury Surveillance System (NEISS)	https://cpsc.gov/research–statistics	US sample of technical reports available for different consumer products, injuries
Federal Recalls	www.recalls.gov	Compilation of federal recalls: environmental, food, medicinal, cosmetic and consumer products
CMS/National and Local Coverage Determinations (NCD/LCD)	www.cms.gov/medicare-coverage-database/	Medicare coverage
CMS/Open Payments	www.cms.gov/openpayments	Financial relationships between manufacturers/group purchasing organizations (GPOs) and hospitals/ physicians
USA.gov	www.usa.gov	Federal information and services portal
NIH/NLM PubMed	www.pubmed.gov	Bibliographic database of biomedical and life science journal articles at NIH/NLM
Regulations.gov	www.regulations.gov	Public comments, agency regulatory agendas, federal regulations, federal notices and federal adjudications
	resources.regulations.gov/public/component/ main	
GSA/OIRA/OMB Reginfo.gov	www.reginfo.gov/public/jsp/Utilities/index.jsp	Federal regulatory agendas/plans and regulatory/deregulatory actions
GPO Access: Federal Register and Code of Federal Regulations (CFR)	www.gpo.gov/fdsys	Legislative intelligence
Congress.gov	www.congress.gov	Federal legislative information: bills, records and reports
FDA Acronyms and Abbreviations	www.accessdata.fda.gov/scripts/cder/acronyms	General information
FDA Guidance Documents	www.fda.gov/RegulatoryInformation/Guidances	FDA guidance documents
FDA/Inspections Database	www.accessdata.fda.gov/scripts/inspsearch	Compliance status of firms marketing FDA-regulated products
FDA/Warning Letter Archive	www.fda.gov/ICECI/EnforcementActions/ WarningLetters	Warning Letters
FDA/Medical Product Safety Network (MedSun)	www.accessdata.fda.gov/scripts/cdrh/cfdocs/ Medsun/searchReport.cfm	Device regulatory intelligence: adverse event reporting
NIH - ClinicalTrials.gov	clinicaltrials.gov	Publicly and privately supported global clinical studies
National Cancer Institute (NCI) Clinical Trials	www.cancer.gov/clinicaltrials	NCI-sponsored clinical trial studies
NIH/ClinRegs	clinregs.niaid.nih.gov	Country-specific clinical research regulatory information
FDA/Global Unique Device Identification Database (GUDID)	gudid.fda.gov/gudid	FDA-regulated devices with unique identifier (not yet searchable)
	accessgudid.nlm.nih.gov	Public-access to GUDID
FDA/Label Repository	labels.fda.gov	Drug regulatory intelligence: drug labels and other drug-specific information
FDA/Pediatric Labeling Information Database	www.accessdata.fda.gov/scripts/sda/ sdNavigation.cfm?sd=labelingdatabase	Pediatric labeling information
FDA/Import Trade Auxiliary Communications System (ITACS)	itacs.fda.gov/app/welcomeToITACS.jsf	Import tracking
USPTO/Patent Database	appft.uspto.gov/netahtml/PTO	Patent databases
USPTO/Patent Application Information Retrieval	portal.uspto.gov/pair/PublicPair	Issued patents and status of published patent applications

Table 39-2. Databases for Healthcare Product Regulatory-Related Intelligence (cont'd.)

Database	Website	Subject Coverage
CBP/Intellectual Property Rights Search	www.dhs.gov/intellectual-property-rights-search	Intellectual property rights
FDA Establishment Registration & Listing Module	www.access.fda.gov	FDA Industry System (FIS)
FDA/CVM Approved Animal Drug Products	https://animaldrugsatfda.fda.gov/adafda/views/#/search	Drug regulatory intelligence: approved animal products
	www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/	Green Book: approved animal drug products
FDA/CVM Veterinary Recalls	www.fda.gov/AnimalVeterinary/SafetyHealth/RecallsWithdrawals	Drug regulatory intelligence: recalls
NIH and US Department of Agriculture (USDA)/Dietary Supplement Ingredient Database	www.dietarysupplementdatabase.usda.nih.gov	Dietary Supplement Ingredient Database (DSID)
NIH and NLM/Dietary Supplement Label Database	www.dsld.nlm.nih.gov/dsld	Sample dietary supplement product labels
FDA/CDRH Product Classification	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm	Device regulatory intelligence: product codes and device classification
	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm	Device regulatory intelligence: de novo classification orders
	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm	Device regulatory intelligence: radiation-emitting electronic product codes
FDA/CDRH Premarket Clearances and Approvals	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm	Device regulatory intelligence: PMA
	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pmamemos.cfm	Device regulatory intelligence: PMA summary review memos
	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm	Device regulatory intelligence: 510(k)
	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfHDE/hde.cfm	Device regulatory intelligence: approved Humanitarian Device Exemptions (HDEs)
	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfIVD/Search.cfm	Device regulatory intelligence: cleared or approved OTC in vitro diagnostic products
FDA/CDRH Establishment Registration & Listing	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfrl/textsearch.cfm	Device regulatory intelligence: medical devices and establishments registered with FDA
FDA/CDRH Establishment Inspections	https://www.accessdata.fda.gov/scripts/inspsearch/	Device regulatory intelligence: establishment inspections
FDA/CDRH Recognized Consensus Standards	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/search.cfm	Device regulatory intelligence: federally recognized national and international medical device standards
FDA/CDER Postmarket Requirements and Commitments	www.accessdata.fda.gov/scripts/cder/pmc	Drug/Biologic regulatory intelligence: postmarket requirements, studies and clinical trials for approved products
FDA/CDRH 522 Postmarket Surveillance Studies	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pss.cfm	Device regulatory intelligence: studies mandated under Section 522 of the *FD&C Act*
FDA/CDRH Corrective Actions and Recalls	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD_RH/rh_res.cfm	Device regulatory intelligence: radiation-emitting electronic products corrective actions
FDA/Medical Device Recalls	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm	Device regulatory intelligence: medical device recalls
FDA/CDRH Medical Device Reporting (MDR)	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmdr/search.CFM	Device regulatory intelligence: information on medical devices that may have malfunctioned or caused a death or serious injury 1984–1996

Table 39-2. Databases for Healthcare Product Regulatory-Related Intelligence (cont'd.)

Database	Website	Subject Coverage
FDA/MedWatch	www.fda.gov/Safety/MedWatch	Safety Information and Adverse Event Reporting Program
FDA/CDRH Manufacturer and User Facility Device Experience (MAUDE)	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm	Device regulatory intelligence: monitoring for device-associated deaths, serious injuries and/or malfunctions
FDA/CDRH Clinical Laboratory Improvement Amendments (CLIA)	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm	Device regulatory intelligence: certified clinical laboratory diagnostic test
FDA/CDRH CLIA-Waived Analytes	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm	Device regulatory intelligence: waived clinical laboratory diagnostic test
FDA/CDRH Meetings/Panels	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfAdvisory/search.cfm	Device regulatory intelligence: Advisory Committee Meeting materials
FDA Meetings, Workshops and Conferences	www.fda.gov/NewsEvents/MeetingsConferencesWorkshops	Calendar of events and meeting materials
FDA/CDRH Total Product Life Cycle (TPLC)	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTPLC/tplc.cfm	Device regulatory intelligence: PMA, 510(k), adverse events and recalls
FDA/CDER FDA-Recommended Dissolution Methods	www.accessdata.fda.gov/scripts/cder/dissolution	Drug regulatory intelligence: methods recommended by the Division of Bioequivalence, Office of Generic Drugs
FDA/CDER Drugs@FDA Database	www.accessdata.fda.gov/scripts/cder/drugsatfda	Drug regulatory intelligence: approved products
FDA/CDER National Drug Code Directory	www.accessdata.fda.gov/scripts/cder/ndc	Drug regulatory intelligence: all drugs available for commercial distribution
FDA/CDER Drug Establishments Current Registration Site (DECRS) Database	www.accessdata.fda.gov/scripts/cder/drls	Drug regulatory intelligence: establishments registered with FDA
FDA/CDER Bioresearch Monitoring Information System (BMIS)	www.accessdata.fda.gov/scripts/cder/bmis	Biologics/drug regulatory intelligence: responsible parties involved in Investigational New Drug (IND) studies
FDA/CDER Clinical Investigator Inspection List (CLIIL)	www.accessdata.fda.gov/scripts/cder/cliil/index.cfm	Device regulatory intelligence: clinical investigators involved with IND studies
FDA/CDER Adverse Event Reporting System (FAERS)	www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm082193.htm	Biologics/device regulatory intelligence: adverse event and medication error reports
NIH/NLM Toxicology Data Network (TOXNET)	www.toxnet.nlm.nih.gov	Scientific and regulatory intelligence on hazardous drugs and other chemicals
FDA/CDER Inactive Ingredients Database	www.accessdata.fda.gov/scripts/cder/iig/index.cfm	Drug regulatory intelligence: inactive ingredients for approved products
FDA/Substance Registration System	fdasis.nlm.nih.gov/srs/srs.jsp	Unique Ingredient Identifier (UNII) repository for FDA-regulated products
FDA/CDER Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) Database	www.accessdata.fda.gov/scripts/cder/ob	Drug regulatory intelligence: approved products
FDA/Orphan Drug Designations and Approvals	www.accessdata.fda.gov/scripts/opdlisting/oopd	Drug regulatory intelligence: designations and approvals
FDA/Reported Drug Shortages and Discontinuations	www.accessdata.fda.gov/scripts/drugshortages	Drug regulatory intelligence: current and resolved drug shortages and discontinuations reported to FDA
FDA/Product-Specific Recommendations for Generic Drugs	www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075207.htm	Bioequivalence recommendations for specific products arranged by active ingredient

Table 39-2. Databases for Healthcare Product Regulatory-Related Intelligence (cont'd.)

Database	Website	Subject Coverage
FDA/CBER Vaccine Adverse Event Reporting System (VAERS)	vaers.hhs.gov/index wonder.cdc.gov/vaers.html medalerts.org/	Drug regulatory intelligence: reports (unverified) of adverse events with US-licensed vaccines
FDA/Human Cell and Tissue Establishment Registration-Query	www.accessdata.fda.gov/scripts/cber/CFAppsPub/tiss	Registered Human Cell and Tissue Establishments
FDA/Blood Establishment Registration- Query	https://www.accessdata.fda.gov/scripts/cber/cfappspub/	Registered Blood Establishments
FDA/ Electronic Biological Product Deviation Reporting (eBPDR) System	www.accessdata.fda.gov/scripts/cber/CFApps	Events for biologics, blood (or components), human cell, tissue and cellular and tissue-based products (HCT/P)
Non-Governmental		
WHO/ISRCTN Registry	www.isrctn.com/search?q=	Clinical trial registry (proposed, ongoing or completed studies)
GovTrack.us	www.govtrack.us	Legislative intelligence on bills and congressional voting
Global Medical Device Nomenclature (GMDN) Agency	www.gmdnagency.com	Medical device identifiers

Note: Website URLs are current at time of publication.

(VAERS). Like the FAERS database, VAERS is based on a cooperative agency program between CBER and CDC to address vaccine safety.

CDRH has built and maintains more than 20 databases to monitor medical devices and radiological products. Its 510(k) Premarket Notification (PMN) database and its Premarket Approval (PMA) database are searchable and contain information on cleared and approved devices. CDRH also has developed two adverse event reporting systems similar to the FAERS database: the Medical Device Reporting (MDR) database (formerly CDRH's Device Experience Network) and the Manufacturer and User Facility Device Experience (MAUDE) database. The MDR database is a combination of mandatory reports on devices that may have malfunctioned or caused a death or serious injury, submitted under the MDR program from 1984–1996, and voluntary reports submitted up to June 1993, when it was replaced by MAUDE. MAUDE contains medical device adverse events reports; voluntary adverse event reports since 1993, user facility reports since 1991, distributor reports since 1993 and manufacturer reports since 1996, with searchable data for the last 10 years.

CDRH provides an integrated database offering a total lifecycle summary of selected medical devices. The Total Product Life Cycle (TPLC) database includes premarket and postmarket information pulled from various CDRH databases, such as product clearances and approvals, adverse events and recalls. TPLC can be searched using the common device name, product code, regulation and/or number.

Other noteworthy CDRH databases include those based on: *Clinical Laboratory Improvement Amendments* (*CLIA*), which contains information on commercially marketed *in vitro* test systems and tests categorized by FDA and CDC; Advisory Committee/Panel Meetings, which contains both information about upcoming meetings and historic information; and Establishment Registration & Device Listing, which comprises establishments engaged in the production and distribution of medical devices intended for human use and commercially distributed within the US. FDA, in collaboration with the National Library of Medicine (NLM), released the AccessGUDID web-based database, which makes information on medical devices with Unique Device Identifiers (UDI) publicly available. With the transition to UDI by device labelers, the database will continue to develop.

In addition to the regulatory information available through FDA's databases, regulatory professionals requiring biomedical research can access PubMed, NLM's biomedical database that includes more than 24 million citations from MEDLINE and other life science journals dating back to 1948. 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 and has developed software tools for analyzing genome data. Finally, NIH's ClinicalTrials.gov site contains current information identifying federally and privately supported clinical trials for a range of diseases and conditions. The database includes nearly 300,000 research studies conducted in all 50 states and more than 200 other countries.[16]

Additional recommended federal databases are RegInfo.gov, USA.gov and Regulations.gov. The Office of Management and Budget (OMB) and the General Services Administration (GSA), jointly produce RegInfo.gov, which contains a searchable catalog of regulatory reviews conducted by OMB's Office of Information and Regulatory Affairs (OIRA), and a catalog of GSA's Regulatory Information Service Center's (RISC) semiannual Unified Agenda of Federal Regulatory and Deregulatory Actions and the annual Regulatory Plan. USA.gov is the government's official portal to federal agency websites and information. This website is the product of an interagency initiative administered by the Government Accountability Office's (GAO) 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 valuable tool for locating government agency regulations, rulemakings or notices, and is useful for finding, submitting and obtaining public comments on proposed *FR* regulations. A comment can be submitted directly via the website by accessing documents still open for public comment.

Table 39-2 provides websites for federal databases useful in reviewing the following topics:

- Warning Letters and recalls
- adverse event reporting
- consumer product injury surveillance
- product and substance registration
- site registration and inspections
- guidance documents, consensus standards and drug recommendations
- product classification
- orphan drug designations
- postmarket requirements and studies
- nonclinical study recommendations
- clinical trials
- export certificates and import communications
- labeling: supplements, pediatrics and drugs
- Medicare coverage database and drug shortages
- supplement and inactive ingredients
- patents

Databases With Global Regulatory Coverage

Databases providing global coverage of country-specific regulations and guidelines also play an essential role in the regulatory professional's capability to monitor the overall regulatory landscape, including legislative developments, conduct regulatory analyses and understand compliance requirements for all drug, biologic and device product lifecycle development phases. These are invaluable tools when used in conjunction with other sources of regulatory expertise, including colleagues, consultants and/or government agency authorities. This section discusses several databases offering international regulatory information.

Publicly launched in September 2014, the National Institute of Allergy and Infection Diseases' (NIAID) ClinRegs database is designed to help clinical researchers navigate country-specific clinical research regulatory information. Organized by country and topic area, the site also allows users to make side-by-side comparisons of country-specific requirements. The website includes information on regulatory authorities, Ethics Committees, clinical trial lifecycle, sponsorship, informed consent, investigational products and specimens. ClinRegs currently includes summaries of clinical research regulatory information for Australia, Brazil, Canada, China, Guinea, India, Kenya, Liberia, Malawi, Mali, Mexico, Peru, Sierra Leone, South Africa, Tanzania, Thailand, Uganda, United Kingdom, Vietnam and the US.[17]

Clinical trial surveillance information also is accessible through Informa PLC's TrialTrove. This database contains a comprehensive repository of global, ongoing clinical trial information. In addition, Informa PLC's Pharmaprojects database serves as a valuable source of pharmaceutical intelligence. This tool tracks drugs in active development, with a drug, company and therapy profile for each.[18] 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 Tarius Regulatory Database, a fee-based subscription database service, enables regulatory professionals to stay informed about global legislative developments and to interpret regulations and guidelines applicable to global healthcare products.[19] Thomson Reuters Cortellis' Intelligent Regulatory Database (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 biologics products.[20] As is true of Tarius, IDRAC frequently updates its documents and provides expert analyses on key regulatory topics for a variety of global markets.

Industry and International Standards

The International Organization for Standardization (ISO) is a key nongovernmental standards-producing organization, comprising a network of national standards institutes representing 162 countries and 785 technical committees and subcommittees. ISO's catalog lists more than 22,000 published international standards covering general topics, such as quality management, as well as standards specific to individual product types across a range of industries, including drugs and medical devices.[21] The International Electrotechnical Commission (IEC) and ASTM Internationally (formerly known as the American Society for Testing and Materials) are examples of similar standards organizations that produce special technical publications, compilations, manuals, monographs, journals and handbooks on regulatory topics. Standards' publications focusing on healthcare may be found by searching terms such as biological, biotechnology, clinical, pharmaceutical, medical device, medical instrumentation or quality management.

Another valuable standards resource for regulatory professionals is the Institute of Electrical and Electronics Engineers (IEEE), 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.

In the same manner, the United States Pharmacopeia (USP), an official public standards-setting authority for prescription, OTC medicines and US-manufactured healthcare products, develops documentary and quality reference standards. Its key publications include the *US Pharnacopeia-National Formulary* (*USP-NF*), the *USP Dietary Supplements Compendium* (*DSC*) and the *Food Chemicals Codex* (*FCC*). The *USP–NF* contains public pharmacopeial standards for medicines, dosage forms, drug substances, excipients, medical devices and dietary supplements; the *DSC* offers standards and scientific information related to the development, manufacturing and testing of dietary supplements; and the *FCC* provides standards for the identification and purity of food ingredients.[22]

Historically, FDA and industry have joined forces with standards organizations, e.g., the Association for the Advancement of Medical Instrumentation (AAMI) and the National Institute of Standards and Technology (NIST). FDA's enforced performance standards are not limited to the aforementioned organizations; the agency relies on a growing list of organizations, including the American National Standards Institute (ANSI), the Clinical Laboratory Standards Institute and the Underwriters Laboratories Inc., among others, to ensure the safety and quality of regulated products.

Global Harmonized Guidelines

Although this chapter focuses on US regulatory resources, a few global organizations are too important to overlook, given the critical role of the US as a partner in the development of global guidelines. The International Council on Harmonisation (ICH) is one of these global bodies. ICH was founded by regulatory bodies and pharmaceutical industry partners from the US, EU and Japan, and has members and observers from additional international regulatory agencies and organizations. ICH safety, efficacy, quality and multidisciplinary guidelines are available online at the ICH website.

US regulatory representatives also participate actively in the International Medical Device Regulators Forum (IMDRF), successor to the Global Harmonization Task Force (GHTF). IMDRF is composed of medical device regulators from Australia, Brazil, Canada, China, Europe, Japan, Russia, Singapore, South Korea and the US, and is building on the GHTF foundation to achieve international medical device regulatory harmonization. The original GHTF documents embody harmonized regulatory practices for medical device safety, effectiveness, performance and quality and are being supplemented by new IMDRF documents, which are available online.

The World Health Organization (WHO) provides worldwide leadership on health matters, shapes the health research agenda and sets United Nations' norms and standards. In addition to monitoring and reporting on healthcare regulations, disease conditions and other global initiatives, the WHO website offers a variety of associated reports and resources. The US is an active WHO participant, particularly in the Essential Medicines and Pharmaceutical Policies Department, which develops, implements and monitors national medicines' policies and guidelines. The US also participates in WHO's biologicals program, the goal of which is to ensure national regulatory authorities implement effective systems to ensure blood product and in vitro diagnostic device quality and safety. WHO's International Clinical Trials Registry Platform (ICTRP) compiles registered clinical trial information into a single, global search portal. Trial sponsors must register and be issued a primary identifier by one of WHO's primary registries or its data set. Upon request, WHO issues a secondary identifier, a Universal Trial Number (UTN), to registered clinical trials.[23] **Table 39-1** lists websites for these respective guideline repositories.

Book Publishers

Several companies specialize in print and electronic publications focused on healthcare regulatory topics. This section reviews industry, government, association and standards publishers targeting the healthcare regulatory profession and explains how to retrieve the most relevant resources using online catalogs. Regulatory is an

interdisciplinary profession, therefore publishers concentrating on scientific research and development (R&D), law, medicine, business or government, may produce publications on regulatory topics.

CRC Online Press, John Wiley & Sons, Lippincott Williams & Wilkins/Wolters Kluwer Health, Majors.com and Springer are major publishing firms providing broad subject coverage and featuring numerous publications directed at the regulatory professional. The CRC Online Press website contains regulatory and related publications under the general category of pharmaceutical science, divided into subcategories including biotechnology/biopharmaceutical; cleaning and sterilization; clinical trials; drug development; quality assurance; regulations and standards; 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 has publications on drug development, clinical trials and pharmaceuticals. Majors.com's publications focus on regulatory compliance; quality assurance; risk management; the *Health Insurance Portability and Accountability Act* (*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
- medical device
- pharmacology

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

Several industry publishers, such as Barnett International, specialize in publications focusing entirely or largely on regulatory and compliance issues. Barnett International publishes reference manuals and industry compendia to assist in complying with federal regulations. It also publishes regulatory industry executive analyses, question and answer guides on regulatory topics and a training series for regulatory professionals. FDAnews prepares reference tools specifically aimed at pharmaceutical, biologics and medical device regulatory professionals. Its products include Code of Federal Regulations (CFR) compilations, an adverse event compliance series and publications on biologics, biosimilars and combination drug products. GMP Publications targets the regulatory industry, too, through its CFR pocket guides and Good Clinical Practice and Good Manufacturing Practice handbooks.

Thompson Publishing Group dedicates an entire product line to food and drug regulatory materials, with topics including Good Clinical Practice, FDA advertising and promotion, FDA enforcement and medical device regulation. These products generally consist of two-volume manuals. An annual subscription includes regularly updated newsletters, archived special reports, and access to other online resources.

Many associations, such as the Regulatory Affairs Professionals Society (RAPS) and the Food and Drug Law Institute (FDLI), publish materials intended for regulatory professionals, available in their online bookstores. In addition, RAPS publishes regulatory affairs certification (RAC) preparatory materials for the US, Canadian, EU, Global and sector-based exams; self-assessment exams for these certifications; and books on topics key to the development of regulatory professionals. FDLI, markets its own publications as well as third-party products addressing regulatory and legal topics. **Table 39-3** provides information on several additional book publishers.

Electronic Newsletters, Magazines and Journals

Industry Resources

In addition to books, reports and standards, several industry resources available to regulatory professionals monitor current events and advance their knowledge of healthcare product regulation. Regulatory professionals can stay informed and save time by reviewing these industry-specific publications, as the sources reviewed in this section cover a range of drug, device and biologic regulatory publications.

Many publishers produce multiple newsletters directed at different healthcare product sectors. For example, FDAnews publishes three 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 and selected international news affecting the medical device industry. Its *Drug Daily Bulletin* provides parallel coverage for the pharmaceutical industry. *The QMN Weekly Bulletin* covers current

quality management news, regulatory developments and inspection trends. Summaries in these publications offer brief but valuable perspectives on current regulatory management issues for drugs, devices and quality. Links to the full-text articles are listed below each summary. These links afford regulatory professionals an opportunity to obtain further information on a particular subject and learn about new resources. However, many of these publications require subscriptions. In addition to FDAnews' free e-newsletters, the company distributes 10 fee-based subscription newsletters. These include: *Clinical Trials Advisor*, *Drug GMP Report*, *Drug Industry Daily*, *Generic Line*, *International Medical Device Regulatory Monitor*, *International Pharmaceutical Regulatory Monitor* and *The GMP Letter*.

SmartBrief, an independent e-newsletter publisher, produces 25 industry-specific daily newsletters available free-of-charge with subscription. The company partners with trade associations and professional societies and publishes their newsletters. *FDLI SmartBrief* works with FDLI to reach food and drug industry professionals. Similarly, *AdvaMed SmartBrief* is issued in conjunction with the Advanced Medical Technology Association (AdvaMed) and targets medical device, diagnostic product and health information system professionals. AdvaMed is a lobbying/advocacy organization for the medical device and technology industry, advancing global healthcare and increasing patient access to medical technology. AdvaMed also promotes policies encouraging high ethical standards, rapid product approvals, appropriate reimbursement and international market access. SmartBrief publication summaries are based on original information from news organizations and repackaged by the firm's editorial staff. Each newsletter typically covers top stories: healthcare in transition, hot topics, business and market trends, 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.

VertMarkets has established online community marketplaces for eight industry groups to connect buyers and suppliers. For each of its online industry communities, VertMarkets produces free biweekly email newsletters providing not only product offerings, but also industry updates and the latest news to its subscribers. The newsletters directed to regulatory professionals fall into the life sciences category and include the *BioProcess Online Newsletter*, *Drug Discovery Leader Online Newsletter*, *Life Sciences Leader Online Newsletter*, *Clinical Leader 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 product showcases.

Questex is another digital media company specializing 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 the development of FDA-regulated products. In addition, the publication features FDA rulings, regulations, recalls, warnings, drug launches, drug safety information, pharmaceutical sales information and marketing news and activities of key industry professionals. *FierceBiotech* is another daily e-newsletter in the Questex digital product family. It concentrates on drug discovery and clinical trial news as well as the latest biotechnology trends, breakthroughs and FDA approval updates. *FierceBiotechResearch* reports on biotechnology research news, information and tools, with a special focus on the science of drug discovery. *FierceVaccines*, *FierceCRO*, *FiercePharmaManufacturing*, *FierceMedTech*, *FiercePharmaMarketing* and *FierceLifeSci Weekly Digest* are the company's six other e-newsletters published by its healthcare division.

Another well-recognized, fee-based publisher is Informa, one of the largest publishers of business information for the pharmaceutical, biotechnology, medical devices and diagnostics industries. Its subsidiary, Informa Business Intelligence, distributes several e-newsletters monitoring 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*, *Start-Up* 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 and regulatory and finance strategies in the biopharmaceutical, medical technology and diagnostics industries. *Start-Up* examines new products 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. It focuses primarily on FDA, the Centers for Medicare and Medicaid Services (CMS) and public-sector issues.

F-D-C Reports Inc., a subsidiary of the Informa Business Intelligence Unit (formerly Elsevier Business Intelligence), is another newsletter publisher serving the healthcare product industry. F-D-C Reports publishes fee-based newsletters designed to clarify developments affecting US healthcare products and services, including marketing and regulatory news, for industry executives, policymakers and analysts. Newsletters published by

Table 39-3. Publisher Resources

Publisher	Website	Resources
International Electrotechnical Commission (IEC)	www.iec.ch	Newsletters, News Alerts, Standards, CDs
AdvaMed	www.advamed.org	News Alerts**
American National Standards Institute (ANSI)	www.ansi.org	Standards, Newsletters, Articles*
American Society for Quality (ASQ Quality Press)	www.asq.org	Journals, Books, Standards
American Society for Testing and Materials (ASTM)	www.astm.org	Standards, Journals, Research Reports, Symposia Papers, Proceedings, Manuals
Association for the Advancement of Medical Instrumentation (AAMI)	www.aami.org	Newsletters, Journals, CDs, Standards
Association of Clinical Research Professionals (ACRP)	www.acrpnet.org	Newsletters, Journals, Reports, White Papers, Directories*
Barnett International	www.barnettinternational.com	Books, Reference Manuals, Compendiums
Bentham Science	www.benthamscience.com	Books, Journals
Bureau of National Affairs (BNA)	www.bna.com/books	News Alerts, Newsletters*
CenterWatch	www.centerwatch.com	Newsletters, Books, Reports, Guides, Data Libraries
Clarivate Analytics (Life Sciences)	https://clarivate.com/product-category/life-sciences/	Articles, Reports, Databases*
CRC Online Press (Taylor & Francis Group)	www.crcpress.com	Books, Journals
Drug Information Association (DIA)	www.diahome.org	Newsletters, Journals, White Papers, Directories*
FDAnews	www.fdanews.com	Newsletters, Books, Reports, White Papers, CDs*
Ferdic Inc.	www.fdareview.com	Newsletters
FierceMarkets	https://www.questex.com/	Newsletters
Food and Drug Law Institute (FDLI)	www.fdli.org	Newsletters, Books, Journals, White Papers, CDs*
Global Regulatory Press	globalregulatorypress.com	Journals
GMP Publications	www.gmppublications.com	Books, Handbooks, Manuals
Government Publishing Office (GPO)	bookstore.gpo.gov	Newsletters, Books, Journals, Handbooks, Manuals, Guides*
Infinata	www.infinata.com	Newsletters, White Papers, Reports**
Informa Business Intelligence	pharmamedtechbi.com	Newsletters
Institute for Electrical and Electronics Engineers (IEEE)	www.ieee.org	Standards, Books, Journals, Conference Publications
International Organization for Standardization (ISO)	www.iso.org	Journals, Standards, Handbooks, CDs
John Wiley & Sons	www.wiley.com/WileyCDA	Books, Journals
Majors Medical & Higher Education	www.majors.com	Books
Medical Device Manufacturers Association (MDMA)	www.medicaldevices.org	News Alerts, Newsletters, Reports, White Papers, Directories*

Table 39-3. Publisher Resources (cont'd.)

Publisher	Website	Resources
Medtech Insight	https://medtech.pharmaintelligence.informa.com/	Newsletters, Reports
OMICS International	https://www.omicsonline.org/	Journals**
PharmaLive	www.pharmalive.com/	Newsletters**
Parenteral Drug Association (PDA)	www.pda.org	Books, Journals, Directories*
Pharmaceutical-technology.com (Net Resources International)	www.pharmaceutical-technology. com	Newsletters, White Papers, Directories**
Regulatory Affairs Professionals Society (RAPS)	www.raps.org	Newsletters, Books, Guidances, Handbooks
SmartBrief	www.smartbrief.com	Newsletters**
Society of Clinical Research Associates (SOCRA)	www.socra.org	Newsletters, Journals, Manuals
Springer	www.springer.com	Books, Handbooks, Journals
The Organisation for Professionals in Regulatory Affairs (TOPRA)	www.topra.org	Newsletters
Thompson Publishers	www.thompson.com	Newsletters, Books, Reports, CDs
Tradepub.com	www.tradepub.com	Books, Newsletters, White Papers**
UBM Canon	ubmcanon.com	News Alerts, Newsletters, Directories**
United States Pharmacopeia (USP)	www.usp.org	Books, Compendiums, Standards*
Wolters Kluwer (Law & Business; Health)	www.wolterskluwerlb.com/health	White Papers, Databases*

**Resource may be fee-based or free.*
***Resource is free.*

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. Although the majority of its publications are fee-based, it does offer a complimentary subscription to a few of its weekly e-newsletters. One of these, *Medical Devices Today*, provides strategy, regulation, innovation and investment coverage from *The Gray Sheet*, *Medtech Insight*, *IN VIVO*, *Start-Up*, *The Silver Sheet*, *The Pink Sheet* and *Strategic Transactions*. The articles cover drug and business development, finance, strategy, regulation and reimbursement.

Another key regulatory publication by Informa is *SCRIP Regulatory Affairs* (*SRA*, formerly *Regulatory Affairs Journal Pharma/Devices*). *SRA* is a source of global news, commentaries and analyses of regulation in the pharmaceutical and biotechnology industries. The publication provides pharmaceutical regulatory intelligence on global regulations governing the development, launch and postmarket surveillance of medicines and combination products. 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. 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) and research journals (e.g., *Clinical Research & Regulatory Affairs*, *Drug Development* and *Industrial Pharmacy*).

The medical device industry also receives excellent web coverage through several free publications. *Medical Device & Diagnostic Industry* (*MD&DI*) is one of 13 magazines published by UBM Canon (formerly Canon Communications), focusing 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. The publication supports industry efforts to comply with regulations, keep

up-to-date on current events, improve manufacturing and design processes and understand market demand. *QMed Daily* is another UBM Canon publication available free of charge with membership to QMed, formerly *Medical Device Link*. *QMed Daily* is an e-newsletter reporting on top industry headlines and important FDA announcements and features articles on technology breakthroughs in the medical device industry worldwide. QMed also offers subscriptions to the *Consultants Corner* newsletter, which focuses on medical product development and commercialization, and the *MPMN Medtech Pulse* newsletter, which provides news on emerging medical technologies.

In addition, Dickinson's *FDAReview* is a monthly newsletter published by Ferdic Inc., providing 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 calendars; and late-breaking FDA and pharmaceutical product news. Also free on Dickinson's interactive website, FDAWebview includes FDA Warning Letters, *FR* notices and an FDA calendar.

A few other free electronic industry-specific resources worth mentioning briefly are *MedicalDeviceSummit*, *Today's Medical Developments Magazine*, *Marketing News*, in-PharmaTechnologist.com, *Pharmaceutical Technology Magazine*, PharmTech.com and Pharmafile.com. Clinical monitoring news is addressed in the free weekly e-newsletters, *BioPharm Insight* and *BioPharm Clinical*, published by Infinata. The newsletters cover the latest information on clinical enrollments, clinical results, drug approvals, drug licensing and medical devices.

VirSci Corporation's *Pharma Marketing News* is a monthly newsletter for pharmaceutical 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. Outcomes LLC (formerly UBM Canon and Canon Communications) is another publisher offering a free monthly magazine, *Med Ad News*, and the site, PharmaLive.com, which provides news updates for the pharmaceutical industry. The magazine is an established resource for competitive business intelligence and marketing strategy information. Last, TradePub.com is an excellent source for free healthcare and medical magazines, publications and newsletters covering the pharmaceutical and medical device industries and more.

Global Regulatory Press' *Journal of Medical Device Regulation* is yet another important resource for medical device regulatory professionals. This is a quarterly publication currently available only 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.

The list of free and fee-based regulatory publications is long and varied, ranging from industry newsletters and peer-reviewed journals to association magazines. This section provides a snapshot of some of these resources. These publications, although not an exhaustive list, provide regulatory professionals a solid basis for further independent research.

Association Resources

The majority of association publications are free with membership, but require nonmembers to pay an annual membership fee. RAPS is one such association, publishing a monthly electronic magazine, *Regulatory Focus*, which is available to its members, with limited online guest access to selected articles. The magazine focuses on current regulatory issues affecting the drug, medical device and biological healthcare product sectors. As an offshoot from the magazine, RAPS provides daily (weekdays only) news briefings via *RF Today*, featuring summaries of the top regulatory news stories from around the world relating to pharmaceuticals, medical devices, biotechnology and the agencies that regulate them. Another RAPS member-based resource is a weekly e-newsletter, RAPS Weekly Update. Similarly, The Organisation for Professionals in Regulatory Affairs (TOPRA) publishes a members-only international journal, *Regulatory Rapporteur*, which provides current news and analyses on regulatory and legislative topics. TOPRA also issues a quarterly member newsletter, *In Touch*, which serves as an association news digest covering member and organizational activities.

In addition, FDLI publishes a quarterly magazine, the *Food and Drug Law Journal*, which is 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 judicial decisions in food and drug law. Its members-only resource, *Update*, is bimonthly and contains the latest association and industry news, viewpoints on industry-specific trends, FDA agency developments and articles on various regulatory topics. FDLI also publishes the *Food and Drug Policy Forum* to discuss policy, and *Primers* to provide guidance on trending topics in food and drug law.

The Medical Device Manufacturers Association (MDMA) represents the interests of smaller, entrepreneurial medical technology companies through its advocacy and educational services. Its members-only publications include the *Weekly MDMA Update* and the *Monthly Member Services Newsletter*.

The Drug Information Association (DIA) publishes its official bimonthly journal, *Therapeutic Innovation & Regulatory Science* (formerly the *Drug Information Journal*). This newly launched journal encompasses drug, device and diagnostic innovations, global regulatory topics as well as pharmaceutical research and development issues. DIA produces *Global Forum*, a bimonthly magazine dedicated to global coverage of pharmaceutical and medical products, from discovery and development to regulation, marketing and surveillance. *Global Forum* also delivers up-to-date association and member news. In addition, DIA's e-newsletter, *DIA Daily*, provides news highlights and information about the pharmaceutical, biotechnology and medical device fields from thousands of global news sources.

The Parenteral Drug Association's (PDA) membership publication, *PDA Letter*, reports on science, technology, quality, regulatory affairs, association news and updates relevant to the PDA community. PDA's *Journal of Pharmaceutical Science and Technology* is a bimonthly publication containing peer-reviewed scientific and technical papers covering the pharmaceutical and biotech industries. The journal is distributed as a member benefit and also is 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 then are reviewed by technical forums and ultimately evaluated and approved by an advisory board and PDA's board of directors.

Within the biologics and biotechnology sphere, the Biotechnology Innovation Organization (BIO) supports professionals engaged in new healthcare technology, biotechnology and related R&D through its advocacy, business development and communications services. Its members-only publication, *BIO Newsletter,* is published weekly and disseminated via email. The newsletter reports on organizational activities, professional perspectives on industry issues and member activities. In cooperation with the SmartBrief publisher, BIO also produces *BIO SmartBrief*, which focuses on news updates within the biotechnology industry.

The Society of Biomaterials is one of many professional scientific organizations in which regulatory professionals can participate to keep abreast of the latest innovations and technology relevant to their products. The society promotes progress in biomedical materials research and development. Members are afforded free access to its news magazine, *Biomaterials Forum*, which is available by subscription to nonmembers. 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 society's official journal 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 and reviews of device and clinical applications.

Two key associations in the clinical research area are the Association of Clinical Research Professionals (ACRP) and the Society of Clinical Research Associates (SoCRA). In addition to its free biweekly email newsletter, *ACRP Wire*, ACRP also publishes a bimonthly journal, the *Clinical Researcher* (formerly *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 Source Journal*, a members-only quarterly publication containing 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.

A comprehensive list of all the fee-based and free publisher resources reviewed and their corresponding website addresses is provided in **Table 39-2**.

Regulatory Collaboration: Meetings and Education

It is vital for regulatory professionals to seek collaborative opportunities internally and externally across businesses, functional areas, product lines, customer-bases and/or geographies to facilitate delivery of safe, effective and high-quality healthcare products. Meetings and other resources offer opportunities for collaboration and innovation. This section discusses the benefits and roles of associations, FDA public meetings and consulting firms.

Associations and Continued Learning

Knowledge garnered from publications, government databases and other agency resources enable the regulatory professional to monitor the latest news, track the status and development of laws, regulations and guidelines and engage in effective strategic product development. Associations are additional educational resources for regulatory professionals. Through the active participation of their members, these associations embody the immediate

focus and future direction of the specific interest areas they serve. Organizations mentioned earlier in the chapter, including FDA, RAPS, DIA, TOPRA, BIO, AdvaMed, FDLI and ACRP, offer a broad variety of learning opportunities. **Table 39-4** provides a comprehensive, but not exhaustive, list of associations providing learning resources.

Many associations require a nominal membership fee, which grants individuals (or, in some cases, designated company representatives) access to member-only resources. These resources may include:

- discounts on the organization's resources, i.e., webinars and publications
- access to knowledge databases, reports, directories
- access to the latest news specific to the organization's focus via periodic newsletters, email updates and/or social media outlets
- access to education tools, i.e., e-learning and seminars
- access and/or discounts to partner associations' resources
- access to member directories and online forums
- participation in meetings, trade shows and/or conferences
- involvement in special partnerships and/or meetings with direct interaction with compliance bodies and regulatory agencies
- networking with other professionals with similar expertise or regulatory interests
- assistance with business and/or regulatory activities
- advocacy for the professional and/or an organization's professional interests
- participation on committees influencing the organization's vision and direction

Participation in these associations grants access and opportunities for learning through professional networking, committee involvement and educational tools. Regulatory professionals can maintain their knowledge of the regulatory healthcare industry and/or fulfill core competency requirements by participating in e-learning courses, web-based training, interactive webinars and/or online certificate programs.

Webinars may be open to members and nonmembers, depending on the organization. These webinars offer live, virtual group learning sessions, in which the presenter(s) and subject matter experts focus on a specific topic and open the floor to attendees for discussion and questions. Webinars also may provide attendees an opportunity to interact with representatives from regulatory bodies such as FDA.

Alternatively, e-learning resources provide archived learning sessions accessible at the regulatory professional's convenience, where the learner sets the pace of the online coursework. RAPS, DIA and the World Medical Device Organization (WMDO) provide e-learning curricula culminating in a certificate. A combined medical device and pharmaceutical regulatory affairs certificate is offered by RAPS, as well as individual certificates within each topic. DIA offers certificates in clinical research, regulatory affairs, clinical safety and pharmacovigilance, project management and medical communications. WMDO provides educational opportunities to regulatory professionals in the medical device arena, with certificates in clinical evaluation, Asia-Pacific and EU medical device regulatory affairs and medical device monitoring. Formal postgraduate degree programs in regulatory affairs (online and classroom settings) are offered by several universities. Uniquely, TOPRA offers a Master of Science degree in regulatory affairs, formally validated by the University of Hertfordshire. The program requires the completion of e-learning modules on regulations, regulatory strategy, clinical operations, regulatory submissions and product development, and submission of a research-based dissertation.

Organizations such as the American Association of Tissue Banks (AATB), ACRP, ASQ, RAPS and SOCRA provide industry-recognized certifications specific to their respective specialties: tissue banking, clinical research, quality, regulatory affairs and clinical investigations, respectively. Certification typically requires achieving a passing score on an association-administered standardized exam.

AATB, ACRP, ASQ, the Consumer Healthcare Products Association (CHPA), PDA and SOCRA provide face-to-face and/or virtual training sessions. For example, CHPA, which serves as a trade association for manufacturers and distributors of OTC medicines and dietary supplements, offers periodic face-to-face training sessions on compliance with current Good Manufacturing Practice (CGMP).

Typically, association members have access to periodic association meetings and conferences where in-person classroom workshops and training sessions may be offered to registrants. Less didactic learning occurs at annual meetings, conferences or seminars held or co-sponsored by the associations listed in **Table 39-4**. These meetings allow regulatory professionals and other industry-related professionals to become acquainted, learn about key topics and engage in discussions related to changes in the regulatory healthcare industry over the course of one to seven days, depending on the meeting topics and organization's size. Note: the American Herbal Products Association (AHPA), a scientific and regulatory advocate organization for herbs, botanicals and herbal products, and the Independent Cosmetic Manufacturers and Distributors (ICMAD) association, do not host meetings, but participate in industry exhibits, trade shows and expos. WMDO also does not host or participate in meetings, as it focuses on distance or online learning.

In addition to offering formal learning options, associations enable professionals to engage in networking

Table 39-4. Societies, Trade Associations, Advocacy Groups and Associations Providing Learning Resources

Organization	Website	Learning Resources
American Association of Blood Banks (AABB)	www.aabb.org	e-Learning, Meetings, Webinars
Advanced Medical Technology Association (AdvaMed)	www.advamed.org	e-Learning, Meetings, Webinars*
American Association of Homeopathic Pharmacists (AAHP)	www.aahp.info	Webinars
American Association of Pharmaceutical Scientists (AAPS)	www.aaps.org	e-Learning, Meetings, Webinars*
American Association of Tissue Banks (AATB)	www.aatb.org	Meetings, Webinars, Training, Certifications
American Herbal Products Association (AHPA)	www.ahpa.org	e-Learning
American Society for Quality (ASQ)	www.asq.org	e-Learning, Meetings, Webinars, Training, Certifications*
Association for Accessible Medicines (AAM)	www.accessiblemeds.org	Meetings
Association for the Advancement of Medical Instrumentation (AAMI)	www.aami.org	e-Learning, Meetings, Webinars Certifications*
Association of Clinical Research Professionals (ACRP)	www.acrpnet.org	e-Learning, Meetings, Webinars, Training, Certifications*
Association of Medical Diagnostics Manufacturers (AMDM)	www.amdm.org	Meetings
Association of Veterinary Biologics Companies (AVBC)	www.avbc.net	Meetings
Biotechnology Innovation Organization (BIO)	www.bio.org	Meetings
Consumer Healthcare Products Association (CHPA)	www.chpa.org	Meetings, Webinars, Training
Drug Information Association (DIA)	www.diahome.org	e-Learning, Meetings, Webinars, Training, Certificate Programs
Food and Drug Law Institute (FDLI)	www.fdli.org	Meetings
Healthcare Distribution Alliance (HDA)	healthcaredistribution.org	Meetings, Webinars*
Independent Cosmetic Manufacturers and Distributors (ICMAD)	www.icmad.org	Webinars*
Medical Device Manufacturers Association (MDMA)	www.medicaldevices.org	Meetings, Webinars*
Natural Products Association (NPA)	www.npainfo.org	Meetings, Webinars
Parenteral Drug Association (PDA)	www.pda.org	e-Learning, Meetings, Training
Personal Care Products Council (PCPC)	https://www.personalcarecouncil.org/	Meetings, Webinars
Plasma Protein Therapeutics Association (PPTA)	www.pptaglobal.org	Meetings
Regulatory Affairs Professionals Society (RAPS)	www.raps.org	e-Learning, Meetings, Webinars, Training, Certifications*
Society of Clinical Research Associates (SOCRA)	www.socra.org	e-Learning, Meetings, Training, Certifications
Society of Clinical Trials (SCT)	www.sctweb.org	Meetings, Webinars*
The Organisation for Professionals in Regulatory Affairs (TOPRA)	www.topra.org	e-Learning, Meetings, Degree Programs
World Medical Device Organization (WMDO)	www.wmdo.org	e-Learning, Certifications, Certificate Programs

**Resource may be fee-based or free.*
The absence of an asterisk indicates that the resource is fee-based. However, costs for members may differ.
Note: Website URLs are current at time of publication.

and information exchange with their colleagues through forums and online communities. Along with their periodic national meetings, numerous associations implement monthly or quarterly programs at the local chapter level to support ongoing networking and professional development activities. In concert, these association tools support the continued learning of the regulatory professional.

FDA Meetings

FDA accepts requests for formal meetings to discuss product development and regulatory submissions, and sponsors and co-sponsors meetings, workshops and other events open to the general public. (Chapters 4 and 5 provide detailed discussions of FDA formal meetings and Advisory Committee Meetings, respectively.) FDA announces upcoming sponsored and co-sponsored events, along with presentations by FDA representatives, on its website. The website organizes the meeting announcements by topic (Advisory Committee calendar, animal and veterinary, biologics, combination products, cosmetics, drugs, food, medical countermeasures, medical devices, science and research and tobacco products), typically a month or more in advance. Attendance at FDA-sponsored events, whether in-person or via webcast (Adobe Connect, web conference software), requires registration, which is accepted on a first-come, first-served basis due to limited seating. Registration and related fees may apply to co-sponsored events. FDA posts Advisory Committee Meeting announcements at least 15 calendar days before a meeting date in accordance with 41 CFR Section 102-3.150. In addition, FDA announces co-sponsored stakeholder meetings on its website a few days before the teleconference.[24]

Through these periodic stakeholder meetings, FDA aims to gain input from the public, particularly consumer organizations, researchers, scientists and industry representatives, on public health actions and initiatives. FDA posts text or PowerPoint versions of presentations, meeting materials (*FR* notice, agenda and panelists) and/or webcasts on its website.

Consulting Firms

Regardless of a healthcare company's size, knowledge gaps can arise that warrant the need for external expertise. Regulatory consultants execute a myriad of functions and offer knowledge in areas including, but not limited to, product regulations, trade compliance, customs regulation, clinical research/trials, testing (laboratory or animal), data management, quality management, auditing, reimbursement, medical writing and due diligence. Hundreds of consulting companies exist to support industry needs during all product lifecycle phases. Numerous associations and media portals offer listings and rankings of consulting services. For example, QMED offers a directory of vetted consultants, organized by service for the medical device and in vitro diagnostics industry.[25] These directories serve as a starting point for identifying a consulting firm. In some cases, the consulting firm's website may serve as an online knowledge tool, e.g., the medical device consulting firm Emergo by UL offers an open-access digital library of articles, charts, reports, regulations and archived webinars.[26] In addition, Centerwatch, a service provider of clinical trials information, offers access to white papers, clinical trial databases and a directory of consulting firms and services.[27] Given the healthcare field's complexity and dynamism, consultants can be a useful asset for a regulatory team.

Social Networking and Mobile Apps

Social networking and other forms of dynamic and interactive information-sharing by users have become pervasive in the healthcare industry, making on-demand access to current information the standard. Data users also expect regular opportunities for community-based input and content-sharing in their respective professional fields. To complement the networking benefits of industry association memberships, regulatory professionals now can connect with colleagues through blogs and social networking websites. The regulatory professional has several options through which to receive information:

- Tumblr, Blogs and Microblogs—regularly updated journal entries designed to be read by a professional audience and representing the unique personality of the author or website; multimedia postings with commenting features (more information provided below)
- LinkedIn—microblogging and networking tool for professionals, organizations and businesses
- Really Simple Syndication (RSS) feeds—automated tracking of updates to favorite websites
- Twitter—microblogging of videos, photos and status/activity updates, with commenting features (Example: FDA Recalls and FDA MedWatch provide safety and recall updates[28])
- YouTube—public video sharing with captioning and commenting features (Example: USPTO video series on applications[29])
- Facebook—microblogging and networking tool for sharing videos, photos and status and activity updates with commenting features (Example: NIH Research Matters provides a weekly review of NIH-funded research[30])
- Google Plus+—microblogging and networking tool for sharing videos, photos and status and activity updates with commenting features (Example: RAPS.org provides daily RAPS-specific and general regulatory news[31])

Government agencies and other industry associations have adopted numerous web-based information tools, particularly social media outlets and information feeds, as pathways to engage consumers, healthcare professionals and regulatory professionals. With the exception of the Academy of Veterinary Behavior Technicians (AVBT), all other trade associations, advocacy groups and associations listed in **Table 39-4**, and all of the US agencies, organizations, institutes, centers and offices listed in **Table 39-1**, utilize web tools such as social media. FDA provides web content devoted to staying informed via subscriptions,[32] RSS feeds and interactive media.[33]

Some of the more popular blogs within the regulatory healthcare sector include FDA Voice (official FDA blog); FDA Law Blog (Hyman, Phelps & McNamara PC); Biotech Blog (managed by Yali Friedman, PhD); Eye on FDA (RX for Pharma Industry Communications and Planning); and MDDI blogs.

RAPS members can connect on the Regulatory Exchange (RegEx) by joining communities, establishing connections with other members, contributing to the resource library and participating in discussions.[34] RegEx also provides information about upcoming RAPS events and publications, as well as volunteer opportunities. Elsmar Cove Discussion Forums, established in 1995, are popular for interacting with other industry professionals on topics including regulatory and quality basics, standards, quality systems, manufacturing, design and global regulations.[35] A free user account is required to post content and access shared files. Users also can subscribe to the RSS feed and subscribe to individual forums and threads.

Other social networking sites, such as Pinterest, Instagram, Flickr and Foursquare, are not covered in this discussion, as they have not yet been widely adopted as useful platforms for regulatory intelligence and/or information sharing. Notably, mobile application technology has emerged within the last decade as a tool for quick, user-friendly information retrieval on smartphones. The adoption of downloadable mobile applications ("apps") for regulatory content still is in its nascent stage, but growing. In March 2015, FDA released the agency's first free mobile app focused on relaying updates and the status of FDA drug shortages. Ultimately, the continued use of web-based technology and growing adoption of mobile apps will support increased interactions and collaboration across the regulatory field.

Summary

Regulatory professionals have been able to improve their productivity, effectiveness and expertise significantly by accessing ever-increasing, web-based regulatory resources. The ease with which regulatory information can be acquired is profound, compared to less than a decade ago when the only way to acquire similar information was through mail, fax and/or telephone. This chapter reviews a wide range of information resources available to regulatory professionals.

A new challenge for regulatory professionals is to distill the essential knowledge they require from the vast storehouse of information available as effectively as possible. This requires the careful management of subscriptions, effective use of government and industry databases, associations' educational resources, consulting firms, and the disciplined use of social networking tools. In this way, regulatory professionals will be certain to reap the greatest benefit from the resources available, for the purpose of ensuring the public receives safe, effective and quality healthcare products.

References

1. About GPO. GPO website. https://www.gpo.gov/about/. Accessed 14 March 2019.
2. About the Federal Register. National Archives website. https://www.archives.gov/federal-register/the-federal-register/about.html. Accessed 14 March 2019.
3. Subscription Options and Managing Your Subscriptions. https://www.federalregister.gov/reader-aids/using-federalregister-gov/subscription-options-and-managing-your-subscriptions. Accessed 14 March 2019.
4. Federal Register. National Archives website. https://www.archives.gov/federal-register/cfr/about.html. Accessed 14 March 2019.
5. Regulatory Information. FDA website. www.fda.gov/regulatoryinformation. Accessed 14 March 2019.
6. Congress.gov home page. https://www.congress.gov/. Accessed 14 March 2019.
7. Intellectual Property Rights Search. US Customs and Border Protection website. http://iprs.cbp.gov. Accessed 14 March 2019.
8. Customs Rulings Online Search System (CROSS) Data.gov website. https://catalog.data.gov/dataset/cbp-customs-rulings-online-search-system-cross. Accessed 14 March 2019.
9. ACE and Automated Systems website. https://www.cbp.gov/trade/automated. Accessed 14 March 2019.
10. Office of Antiboycott Compliance (OAC). https://www.bis.doc.gov/index.php/enforcement/oac. Accessed 14 March 2019.
11. US Food & Drug Administration website. https://www.fda.gov/default.htm. Accessed 14 March 2019.
12. FDA Email Updates. FDA website. https://www.fda.gov/AboutFDA/ContactFDA/ucm2005606.htm. Accessed 14 March 2019.
13. About Us and Dun & Bradstreet—FDA DUNS Request. Dun & Bradstreet website. www.dnb.com/government/duns-request.html. Accessed 14 March 2019.
14. D&B D-U-N-S® Number Lookup. Dun & Bradstreet website. https://www.dnb.com/duns-number/lookup.html. Accessed 14 March 2019.
15. PharmaPendium website. https://www.researchinformation.info/product/pharmapendium-0. Accessed 14 March 2019.
16. Trends, Charts, and Maps. ClinicalTrials.gov website. https://clinicaltrials.gov/ct2/resources/trends. Accessed 14 March 2019.
17. ClinRegs. NIAID website. https://clinregs.niaid.nih.gov/. Accessed 14 March 2019.
18. Pharma intelligence. Informa website. https://pharmaintelligence.informa.com/products-and-services/data-and-analysis/pharmaprojects. Accessed 14 March 2019.
19. Tarius Solutions website. www.tarius.com. Accessed 14 March 2019.

20. Cortellis Regulatory Intelligence Overview. Thomson Reuters website. thomsonreuters.com/en/products-services.html. Accessed 14 March2019.
21. International Organization for Standardization home page. https://www.iso.org/home.html. Accessed 14 March 2019.
22. US Pharmacopeia website. www.usp.org. Accessed 14 March 2019.
23. International Clinical Trials Registry Platform (ICTRP) home page. WHO website. http://www.who.int/ictrp/en/. Accessed 14 March 2019.
24. Stakeholder Meetings. FDA website. https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm. Accessed 14 March 2019.
25. Qualified Supplier Directory. Qmed website. https://directory.qmed.com/consultants-code005397.html. Accessed 14 March 2019.
26. Resource Library for Medical Device Professionals. Emergo website. http://www.emergogroup.com/resources. Accessed 14 March 2019.
27. Centerwatch News Resources. Centerwatch website. https://www.centerwatch.com/professional-resources/. Accessed 14 March 2019.
28. FDA recalls Twitter site. twitter.com/FDArecalls. Accessed 14 March 2019.
29. USPTO on youtube. https://www.youtube.com/user/USPTOvideo/. Accessed 14 March 2019.
30. NIH Research Matters. Facebook website. https://www.facebook.com/ResearchMatters. Accessed 14 March 2019.
31. Regulatory Affairs Professionals Society Google+ home page. https://plus.google.com/106321095709510076478/posts. Accessed 14 March 2019.
32. For Industry. FDA website. www.fda.gov/ForIndustry/FDABasicsforIndustry/ucm34630.htm. Accessed 14 March 2019.
33. Interactive Media. FDA website. https://www.fda.gov/newsevents/interactivemedia/default.htm. Accessed 14 March 2019.
34. RAPS Regulatory Exchange. RAPS website. https://connect.raps.org/home. Accessed 14 March 2019.
35. The Elsmar Cove Discussion Forums website. Elsmar website. https://elsmar.com/Forums/. Accessed 14 March 2019.