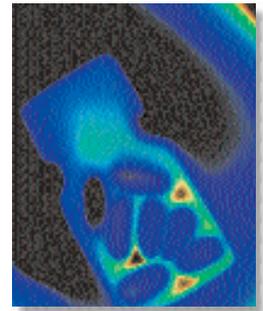


# Research Tips

## To Find Packaging Facts Fast

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Various sources, including Web sites, journals, and books can help ease the challenges many pharmaceutical makers face when looking for data related to packaging.

In an industry as complex and regulated as pharmaceutical, locating the right packaging information is sometimes a bigger challenge than designing, sourcing, filling, or labeling the package. The good news is that the maturing of the Internet has made it much easier to find up-to-date information on virtually any packaging-related topic.

The first place to start, particularly for matters relating to regulations, guidelines, and current good manufacturing practices (CGMPs) is FDA's Web site, [www.fda.gov](http://www.fda.gov). This Web site has a good search function as well as news, hot topics, and reference sections. The reference section is especially useful because it is divided into seven categories: laws that FDA enforces, the Code of Federal Regulations, the *Federal Register*, guidance documents, dockets, warning letters, and manuals and publications. The agency also offers a number of free e-mail newsletters, and documents can be downloaded from the Web site at no charge. Studying the original regulatory documents should be a standard practice for anyone involved in packaging pharmaceutical products because regulatory information from other sources might omit important details, contain inaccuracies, and offer interpretations that are not in line with the agency's thinking.

It also should be noted that the Center for Drug Evaluation and Research (CDER) has its own home page (which can be accessed from FDA's home page by clicking on "Drugs" under the heading, "Products FDA Regulates"). It lists a number

of "Quick Info" links to help find information fast.

The United States Pharmacopeial Convention Inc. (USP, Rockville, MD) provides standards for more than 3800 medicines, dietary supplements, and other healthcare products. This information is published in the *USP-National Formulary (USP-NF)*, the official drug standards compendia. USP also provides about 1300 premier chemical Reference Standards to conduct the tests specified in *USP-NF*. USP also works in the area of patient safety and maintains records related to medication errors through its Medmarx database. The USP Web site, [www.usp.org](http://www.usp.org), offers both a search function and an on-line store where reference standards and publications can be ordered. Fees are relatively low.

Another important source for regulatory information is the United States Consumer Product Safety Commission (CPSC, Washington, DC) Web site, [www.cpsc.gov](http://www.cpsc.gov), which oversees child-resistant packaging requirements. A library listing includes headings for official federal information (CPSC regulatory information) and CPSC publications. CPSC also maintains the National Electronic Injury Surveillance System, which collects data from hospital emergency rooms about consumer product-related injuries.

A wealth of domestic and global regulatory information can be found at [www.packaginglaw.com](http://www.packaginglaw.com), a Web site sponsored by the law firm Keller & Heckman LLP (Washington, DC). It features a different focus topic each month and archives back articles. Other sections include news headlines and an "ask an attorney" service. A search function makes it possible to check the Web site by section or in its entirety.

For topics related to parenteral products, volumes of information can be found at [www.pda.org](http://www.pda.org), the Web site of the Parenteral Drug Association (PDA, Bethesda, MD). The PDA Web site also has a good search function, which includes archived material. PDA is an excellent source for information about draft regulatory documents. Particularly valuable are the association's monthly

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newsletter, *PDA Letter*, and its bimonthly technical journal, *PDA Journal of Pharmaceutical Science and Technology*. The association also offers a *Pocket Code of Federal Regulations GMP Guide—2003 Edition* as well as technical reports about a variety of topics such as microbiological environmental monitoring and pharmaceutical package integrity. An on-line store simplifies ordering. Fees are nominal, especially for PDA members, who can receive a discount. Other PDA resources include a full calendar of technical meetings, courses, and audio conferences, and a well-developed network of special-interest groups, including isolation technology, packaging science, stability, sterilization/aseptic processing, and visual inspection of parenterals. Forums provide yet another method of interaction with other industry experts.

Of course, I'd be remiss not to mention *Pharmaceutical Technology's* Web site, [www.pharmtech.com](http://www.pharmtech.com). It archives back issues, and searches can be performed by key word, author name, or issue date. The Web site also includes a Buyers Guide to help locate suppliers as well as a list of industry links.

One of the links provided is [www.ispe.org](http://www.ispe.org), the Web site of ISPE, The Society for Life Science Professionals (Tampa, FL). This multilingual site provides a search function as well as discussion forums and technical publications that include seminar proceedings. A resources section contains regulatory and reference areas. The regulatory area provides links to regulatory news, worldwide regulatory agencies, and regulatory documents.

Whenever you're conducting research, don't forget to check the search engines because the results can point you in new, promising directions. My favorite search engine is Google, [www.google.com](http://www.google.com), but I often try more than one because the results sometimes are different. The key with Google or any other search engine is choosing the keyword or words that will generate the results you want. Usually search results are more targeted if multiple key words are used. A search for "seal integrity," for example, generates 363,000 hits with a number of pertinent references on the first page. Searching for "seal integrity stopper" or "seal integrity vial" results in a far shorter list of hits (in the

2000–4000 range) and also generates pertinent references on the first page. More importantly, the hits generated by the three-word searches are largely different from the hits listed on the first results page of the "seal integrity" search.

Of course, supplier Web sites can be essential to locating specific details about packaging materials, containers, machinery, and related items. If you don't already have a supplier list prepared, supplier directories can be helpful in locating contact information for firms you want to learn more about. Supplier directories can be found at [www.pharmtech.com](http://www.pharmtech.com) and on Packexpo.com's (Falls Church, VA) Web site, [www.packexpo.com](http://www.packexpo.com). The latter permits searches by either product or supplier and provides a searchable archive of news headlines and the weekly e-newsletter, *Ben Miyares' Packaging Management Update*. Supplier searches also can be conducted at an on-line marketplace such as [www.Alibaba.com](http://www.Alibaba.com) (Newark, CA), where both buyers and sellers congregate.

### Conventional references

A number of market research firms prepare periodic reports related to pharmaceutical packaging. Freedonia (Cleveland, OH), for example, published a pharmaceutical packaging study in March 2004 and a world pharmaceutical packaging study in December 2003. Report details and ordering information may be found at [www.freedoniagroup.com](http://www.freedoniagroup.com).

Another market research firm, Drug and Market Development Publications (Westborough, MA), [www.drugandmarket.com](http://www.drugandmarket.com), looks at trends and market opportunities in a March 2002 report, "Pharmaceutical Packaging—Trends Driving Innovations and Market Opportunities."

Standards organizations also provide essential information. Available in print or CD-ROM formats, *Consumer and Healthcare Packaging Standards* was published in May 2002 by ASTM International (West Conshohocken, PA). The 366-page book includes 85 of the latest standards on consumer and healthcare packaging, including water vapor transmission of flexible heat-sealed packages for dry products, minimum application torque of Type IA child-resistant closures, seal strength of flexible barrier materials, and detect-

**Supplier Web sites can help locate specific details about packaging materials, containers, machinery, and related items.**

ing gross leaks in porous medical packaging by internal pressurization bubble test.

Another book published in 2002 by Marcel and Dekker (New York, NY), *Parenteral Quality Control*, Third Edition, describes validation and execution of testing schemes for parenteral quality control and emphasizes testing methodologies for the evaluation of package integrity, finished product contamination, and sterility. A more-general book, the 664-page *Pharmaceutical Packaging Technology*, was published in 2001 by Taylor and Francis (London, UK).

### General packaging references

Although pharmaceutical packaging is highly specialized, general references about packaging shouldn't be overlooked. Highly detailed information about materials, containers, and machinery can be found in books such as *The Wiley Encyclopedia of Packaging Technology*, Second Edition, published by John Wiley & Sons, Inc. (New York, NY). Approximately 200 experts provided information for about 250 listings spanning all stages of the packaging process from raw materials through final package distribution. Entries cover all major segments, including materials, machinery, containers, components, quality assurance, recycling, and regulations.

Another general packaging reference, the *Fundamentals of Packaging Technology*, Third Edition, was published in 2002 by the Institute of Packaging Professionals (IoPP, Naperville, IL). Based on a popular four-week course given once or twice per year, the 20-chapter text includes detailed information on packaging materials and container formats, graphic design, package printing and decorating, closures, adhesives, distribution packaging, and the

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package development process.

IoPP also publishes a *Directory of Contract Packagers*, the *Shipper's Guide to Loading and Securement of Hazardous Materials/Dangerous Goods in Intermodal Equipment—Highway, Rail and Water*, and a *Glossary of Packaging Terminology*.

Standards-setting organizations also offer general packaging information. ASTM, for example, recently published

the fourth edition of its *ASTM Standards & Other Documents Related to Performance Testing of Shipping Containers* and a sixth edition of *Selected ASTM Standards on Packaging*. The latter defines 78 ASTM standards related to plastics, paper, glass, metals, rubber, and composites used in containers, cushioning, wrapping, barriers, closures, and aids for sealing, utilizing, reinforcing, and handling. The book

**Researching questions related to pharmaceutical packaging can take a shortcut with the dozens of Web sites that carry this type of information.**

also includes nine standards from TAPPI (Norcross, GA), a trade association for the pulp- and paper-converting industry. The TAPPI Web site, [www.tappi.org](http://www.tappi.org), offers a variety of resources, including bulletin boards and an "Ask the Experts" service. The group also archives conference proceedings.

Another group related to shipping standards, the International Safe Transit Association (ISTA, East Lansing, MI), publishes the *ISTA Resource Book*. It describes testing procedures and provides guidelines for testing to ensure a product will arrive intact at its destination. In addition to developing standards, the group certifies testing laboratories, test laboratory personnel, and packages. Its Web site, [www.ista.org](http://www.ista.org), includes discussion forums and a marketplace for procedures and publications as well as conference proceedings.

Another tack to take is packaging material/format oriented websites. These typically are maintained by trade associations such as the Glass Packaging Institute (Washington, DC), [www.gpi.org](http://www.gpi.org); the Can Manufacturers Institute (Washington, DC), [www.cancentral.com](http://www.cancentral.com); and the Corrugated Packaging Council (Rolling Meadows, IL), [www.cpc.corrugated.org](http://www.cpc.corrugated.org).

With dozens of additional Web sites carrying information, researching questions related to pharmaceutical packaging can take a shortcut. **PT**

