Regulatory Affairs: Resources

www.sciencemag.org/careers/2003/12/regulatory-affairs-resources

The field of regulatory affairs includes all aspects of drug development such as research and development, animal and human clinical trials, marketing, and approval. If you are interested in finding out more, check out the following regulatory affairs resources featuring organizations, societies, and institutes. The resource page is a great place to begin your search on careers in regulatory affairs.

U.S. Resources

Networks

The Regulatory Affairs Information Web site offers a diverse mix of Internet sites such as the latest worldwide RA news, listservs, Food and Drug Administration (FDA) forms, and online RA journals.

Agencies

The Center for Drug Evaluation and Research, a division of FDA, protects the public by assuring that the nation's pharmaceutical drugs are safe.

Organizations
The Regulatory Affairs Professionals Society (RAPS) provides its members with information on biotechnology, biologics, medical devices, and pharmaceuticals. This international organization holds workshops and annual meetings on regulatory affairs.

The National Association of Regulatory Utility Commissioners seeks to serve the public by improving the quality of public utility regulation by ensuring that the rates for these services are affordable and nondiscriminatory to customers.

The Center for Regulatory Effectiveness, established after the Congressional Review Act in 1996, ensures that the information used to develop federal regulations is accessible to the public. The site also maintains a listing of regulatory think tanks, which provide a variety of services such as data analysis and regulatory litigation reports.

The American National Standards Institute seeks to promote and facilitate voluntary standardization practices in the U.S. This private, nonprofit organization plays a vital role in regulatory affairs.

**Graduate Programs**

San Diego State University offers an M.S. in regulatory affairs through the Center for Bio/Pharmaceutical and Biodevice Development.

Temple University School of Pharmacy's Graduate Program offers an M.S. in Quality Assurance/Regulatory Affairs along with pre- and post-M.S. certificates.

Long Island University's Arnold and Marie Schwartz College of Pharmacy and Health Sciences offers an M.S. in drug regulatory affairs.

RAPS maintains a more exhaustive listing of degree programs, including those in Europe, Canada, and Australia.

**Canadian Resources**

The Canadian Association of Professional Regulatory Affairs, founded in 1982 as a means for pharmaceutical RA professionals in Canada to interact and discuss regulatory issues, continues to provide education and information on such topics as radiopharmaceuticals, veterinary medicines, herbals, and biologicals.

CanReg Inc., one of the largest regulatory affairs consulting firms in North America, provides strategic advice on regulations of the U.S. Food and Drug Administration (FDA), the Canadian Therapeutic Products Directorate (TPD), and the European Agency for the Evaluation of Medicinal Products (EMEA).

The Toronto Biotechnology Initiative brings together individuals in the Toronto area who are involved in biotechnology. Those interested in regulatory affairs in this region should find valuable contacts through this nonprofit organization.
The Pharmaceutical Sciences Group, started in Toronto in 1971, provides an international forum for those working in the pharmaceutical industry.

Barnett International, a division of PAREXEL International, advises clients on all aspects of the drug development process using integrated solutions.

European Resources

Organizations

The European Society of Regulatory Affairs (ESRA) is a society dedicated to enabling individual regulatory professionals in Europe to further their education, standing, and capability through the sharing of regulatory experience and knowledge. It is also a great gateway to other associations, national health agencies, and regulatory bodies across the world.

The UK's British Institute of Regulatory Affairs (BIRA), the Association Française des Affaires Réglementaires, and the Società Italiana Attività Regolatorie are a few of the national ESRA equivalents.

Regulatory Authorities

The Medicines and Healthcare Products Regulatory Agency in the UK (MHRA), L'Agence Française de Sécurité Sanitaire des Produits de Santé (Afssaps) in France, and the Instituto Nacional da Farmácia e do Medicamento (Infarmed) in Portugal are all examples of government agencies whose remit is to protect and promote public health and patient safety by ensuring that medicines, health care products, and medical equipment meet appropriate standards.

The European Agency for the Evaluation of Medicinal Products (EMEA) is doing a similar job at a European scale.

For a more complete list of drug regulatory agencies in Europe and across the world, click on the World Health Organization Web site. If you're especially interested in veterinary products, you'll find relevant information on HEVRA, the common Web site for the veterinary regulatory authorities in the European Union.

National Departments of Health

To see how national ministries of health get involved with regulatory affairs you may also click on their individual Web sites, such as the French Ministère de la Santé, de la Famille et des Personnes Handicappées and the Spanish Ministerio de Sanidad y consume.

Networks
EudraNet is a network in the field of European human and veterinary pharmaceuticals whose remit is partly to enable communication and the sharing of information and databases between the European Commission, EMEA, and the national Competent Authorities in pharmaceuticals.

Courses

The British Institute of Regulatory Affairs operate a diploma and M.Sc. in regulatory affairs, the qualifications being awarded by the University of Wales.

The Regulatory Affairs Professional Society gives a low-down of courses in regulatory affairs, from advanced degrees to refresher courses, in Europe and beyond.

Career Advice

A collaboration between BIRA/ESRA and the Regulatory Services Consultancy Unicus, is offering you Career Advice and Coaching services even if you're not a member.