#### Ronald A. Rader

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#### **Education**:

B.S., Microbiology • University of Maryland (General Honors Program), 1973 M.L.S., Library Science • University of Maryland, 1979

## Summary:

World-class expertise in information retrieval, organization and analysis, competitive intelligence, technology and market assessments, information resources development, publishing and problem-solving concerning pharmaceutical and biotechnology products, R&D, commerce, technologies, patents and technology transfer, regulations and public affairs. Over 25 years experience managing, retrieving, integrating, assessing and publishing complex scientific, technological and commercial information. Successful independent information resources developer, publisher and entrepreneur since late 1990.

## **Professional Experience:** (all positions full-time)

## Biotechnology Information Institute, Rockville, MD

President (sole proprietor); December 1990 • Present

Develop and publish information resources and consult concerning biotechnology and pharmaceutical products, R&D technologies and commerce. Solely responsible for all aspects (conceptualizing, research, development and marketing) of databases, periodicals, books and Web sites used by biotech/pharma. companies worldwide including:

- a) BIOPHARMA: Biopharmaceutical Products in the U.S. and European Markets, the only biopharmaceuticals information resource/ reference (online database at www.biopharma.com; last printed edition, 2007, was 2 vol., 1602 pages,);
- b) Biopharmaceutical Expression Systems and Genetic Engineering Technologies: Current and Future Manufacturing Platforms, a directory of technologies available for licensing (365 pages);
- c) Antiviral Agents Bulletin, the only periodical specializing in antiviral drug and vaccine development (32 pages monthly, 15 years, 1987-2003; 5,700+ pages total) and;
- d) Federal Bio-Technology Transfer Directory, covering all federal, e.g., NIH, inventions (patents) and technology transfers (licenses and CRADAs) in biomedical/biotech areas (687-page book in 1994, online database to 2000).

Consulting (partial list): Many projects for BioPlan Associates including: creator/curator (currently) of *Top1000bio.com*, a Web site ranking >1,000 bioprocessing facilities worldwide by bioreactor capacity; in-depth market/technology assessment of animal-based toxicology/pharmacology testing services (269 pages); market research concerning microbial bioprocessing technologies (several projects); in-depth market/technology assessment concerning single-use/disposable bioprocessing systems (348 pages); in-depth market/ technology assessment of animal-derived biopharmaceuticals (350+ pages); a downstream bioprocessing/ purification study; and Director, *BioPipeline Project*, a biopharmaceutical R&D competitive intelligence service. Also influenza vaccine competitive intelligence for a major vaccine company; developed the Pandemic Influenza Digital Archive (PIDA) for the National Institute of Allergy and Infectious Diseases (NIAID), NIH; and various pharmaceutical market assessments for LifeTech Research, Inc.

Web sites: include biopharma.com; bioinfo.com; biosimilars.com; biopharmacopeia.com

**Porton International, Inc.** (and its OMEC International subsidiary), Washington, DC Manager of Information Services, Market Planning and Information Services Department October 1985 • December 1990

Provided information services and competitive intelligence and market and technology assessments for what was then the world's largest privately-held biotechnology company with subsidiaries for biopharmaceuticals and vaccines, diagnostics, culture media and reagents, fermentation equipment, protein sequencers, HIV clinical trials and publishing (OMEC Intl.). Provided information retrieval and assessment services supporting business development, product R&D, regulatory compliance, patents and technology transfer, marketing and strategic corporate decisions. Editor, *Porton Alert*, the monthly corporate current awareness bulletin; managed the corporate reference library/information center; and provided online database searching, reference, document delivery and other information retrieval services.

With OMEC International, Porton's information resources development/publishing subsidiary: Editor, *Antiviral Agents Bulletin* • conceived, developed and the sole author (April 1988-March 2003); Editor, *BioINVENTION*, monthly U.S. biotechnology patent abstracts and news periodical, 1985-1990; Project Leader/Editor, *Federal Biotechnology Programs Directory* and the *Federal Biotechnology Information Resources Directory*, the first studies/reference books surveying federal programs and information resources relevant to U.S. biotechnology R&D and industry.

[Note,  $\geq$ 80% of time in more recent years was devoted to Porton Intl. (corporate activities), while about 80% of time in the earliest 1-2 years was devoted to OMEC Intl. (publishing)].

#### **Technical Resources, Inc.**, Rockville, MD

Chemical Editor, Survey of Compounds Which Have Been Tested for Carcinogenic Activity (PHS-149), 1984/1985 (1 year).

Chemical identification, nomenclature assignment, cataloging and in-depth indexing of the world's published reports of animal carcinogenicity and chronic toxicology studies (NCI, NIH contract).

#### Biospherics, Inc., Rockville, MD

Information Scientist, Cancer Information Service; Manager, Cancer Information Clearinghouse, 1983/1984 (1 year)

Provided scientific/technical information services for the National Cancer Institute (NCI) public and health care professional information programs; information retrieval and assessment and online searching to support agency responses to public and technical queries and issues; managed NCI's health care professional cancer information clearinghouse (NCI, NIH, contract).

#### Computer Sciences Corp. (CSC), Falls Church, VA

User Support Coordinator, NIH/EPA Chemical Information System, 1982/1983 (1 year).

Managed user support, handling all inquiries and user and system problems, for the major federal chemical/toxicology/regulatory and chemical substructure search system (network of databases); wrote database users manuals; conducted marketing and user training (joint NIH/EPA contract).

#### MITRE Corp., McLean, VA

Information Scientist, Environment Division, 1978-1981 (2-2/3 years).

For various government agencies, developed toxicology, environmental and technology assessment information resources and authored related assessments and reports. Major projects included: the design and development of the *Chemical Information Resources Directory* component (a pioneer meta-index of information resources) of the Chemical Substances Information Network (CSIN); authored the first toxicology and environmental safety assessment of U.S. petroleum refining; developed an energy technology competitive intelligence system for a U.S. ally; authored the first assessment of information resources needed for the Dept. of Energy (DOE) Carbon Dioxide-Climate (global warming) research programs; provided database programming support and analyses for the first study of radiation exposure records/data systems at DOE nuclear facilities and their utility for epidemiological studies; and established a special library for the Environment Division, DOE.

#### Gillette Medical Evaluation Labs., Gillette Co., Rockville, MD

Information Specialist, Information Center, 1976-1978 (2 years)

Provided information retrieval and current awareness services supporting corporate toxicology and safety evaluations, regulatory affairs and research. Editor, *Medical Bulletin*, the company's internal safety and regulatory affairs current awareness bulletin; online database searching and document delivery services; document indexing and book cataloging; developed the company's first worldwide chemical (processing and ingredient) registry.

### **Publications** (for a list with links, see www.bioinfo.com/resume.html):

### Information Resources/References (books and databases):

- BIOPHARMA: Biopharmaceutical Products in the U.S. and European Markets (author/publisher), 10th edition, online database (www. biopharma.com), the only biopharmaceuticals information resource/reference [last printed Sept. 2007, 2 vol., 1602 dense pages; if printed now, likely >2,200 pages];
- Biopharmaceutical Expression Systems and Genetic Engineering Technologies, BioPlan Associates, 365 pages, Nov. 2008 (see http://www.bioplanassociates.com/es/expressionsystems.htm).
- Federal Bio-Technology Transfer Directory, (author/publisher), 687 page book, April 1994; then an online database (multiple vendors) until 2000 (see www.bioinfo.com/fbdhome.html).
- Federal Biotechnology Programs Directory, OMEC International, 162 pages, 1987.
- Federal Biotechnology Information Resources Directory, OMEC International, 151 pages, 1987
- Survey of Compounds Which Have Been Tested for Carcinogenic Activity (PHS-149; I was chemical editor), 1983-84, U.S. Government Printing Office (GPO), 1985.
- Structure and Nomenclature Search System; Chemical Evaluation Search & Retrieval System; Federal Register Search System; Thermodynamics NIH/EPA Chemical Information System user manuals, NTIS, 1984.
- Chemical Information Resources Directory: (vol. 1) Development and Uses, 79 pages, PB80-105190; and (vol. 2) Descriptive and Subject Indexes, PB80-105208, 673 pages; National Technical Information Service, 1980.

**Periodicals** (20+ years experience as author/publisher of monthly competitive intelligence periodicals):

- Antiviral Agents Bulletin (author/publisher), Biotechnology Information Institute, monthly, 32-pages; the only periodical specializing in antiviral drug and vaccine development, April 1988-March 2003 (15 years; 5,700+ pages). Also, Web site (www.bioinfo.com/antiviral.html) and its full-text online database.
- *BioINVENTION*, Editor, OMEC International, Oct. 1985-Dec. 1990, 28-32 page monthly periodical presenting abstracts of U.S. biotechnology patents plus patent/technology transfer news and analysis.

### Articles (industry periodicals, a sampling):

- "Upstream Single-Use Bioprocessing Systems: Future Market Trends and Growth Assessment," *Bio-Process International*, Feb. 2012 [in press].
- "Top 50 Biologics," Contract Pharma, July/Aug. 2011 [top 50 biopharmaceuticals by sales].
- "Nomenclature for Biosimilars Will Be Highly Controversial," *BioProcess International*, vol. 9, no, 6, June 2011, p. 26-33.
- "A History of Approved Recombinant Cell Culture Products, 1980-2010," *BioProcess International*, vol. 7, no. 11, Dec. 2009, large wallchart/poster insert.

- "Expression Systems for Process and Product Development: A Perspective on Opportunities for Innovator and Follow-on Product Developers," *BioProcess International*, vol. 6, issue 6, suppl. 4, *Success Stories in Protein Expression* (supplement lead article), p. 4-9, June 2008.
- "Biopharmaceuticals: Lack of Information Disclosure Confounds Public Trust, Particularly in the Context of Biosimilars," *BioWorld Perspectives*, vol. 2, issue 18, May 1, 2008.
- "Paucity of Biopharma Approvals Raises Alarm: Lower Numbers, Novelty and Economic Impact Indicate Problems," *Genetic Eng. & Biotechnology News (GEN)*, March 15, 2008.
- "What Is a Generic Biopharmaceutical? Biogeneric? Follow-On Protein? Biosimilar? Follow-On Biologic? "Part 1: Introduction and Basic Paradigms," *BioProcess International*, p. 28-38, March 2007; "Part II: Information, Nomenclature, Perceptions and the Market," p. 20-38, May 2007.
- "Biopharmaceutical Approvals Review." [2005-2006]. Genetic Eng. News, Aug. 1, 2006.
- "What is a Biopharmaceutical, Part 1: (Bio)Technology-Based Definitions," *BioExecutive*, March 2005, p. 60-65; and "Part 2: Company and Industry Definitions," May 2005, p. 42-49.

#### **Articles (peer-reviewed)**:

- "(Re)Defining Biopharmaceutical?," Nature Biotechnology, 26(7), 743-751, July 2008.
- "How Big is the World Market for Biopharmaceuticals?," in Friedman, Y., *Best Practices in Biotechnology Business Development*, Logo Press, p. 175-85, 2008.
- "An Overview of Biotechnology Information Resources," *Trends in Biotechnology*, Nov. 1990, 318-23.
- "Biotechnology Information: An Introduction" and "The Status of the Infrastructure of Information Resources Supporting U.S. Biotechnology," in *The Impact of Chemistry on Biotechnology*, American Chemical Society, 1988, p. 372-374 and 375-385, respectively.
- "Chemical Information Resources Directory: An Integrating Component of the Chemical Substances Information Network," *J. of Chem. Info. and Computer Sci.*, May, 1981, p. 78-82.
- "Information Retrieval for the Safety Evaluation of Cosmetic Products," *Special Libraries*, May/June, 1978, p. 206-14.

# Professional Activities (partial list):

# **Organizations:**

Primary affiliations:

Special Libraries Association • Pharmaceutical and Health Technology, Biology, Chemistry, and Competitive Intelligence Divisions

American Chemical Society • Chemical Information and Biochemical Technology uDivisions

American Society for Microbiology

Patent Information Users Group

Capital Area Biotechnology Information Network (CABIN), 1988-1990 • Founder and Program Chairman for this local biotechnology information users group; organized 3-4 meetings annually, each attended by 25-50 persons.

#### Awards:

Rittenhouse Award, Medical Library Association (MLA), 1978, Best Graduate Student Paper: "Bibliographic Analysis of the Literature of Government-Regulated Chemical Carcinogens: Patterns in the Literature Predict Future Regulation."

**Presentations** (I generally concentrate more on publications rather than presentations):

- "Analysis of the Biosimilars and Biobetters Pipeline." *Biosimilars and Biobetters*, March 19-20, 2012, Cambridge Healthtech Institute (CHI), Baltimore, MD.
- "Biosimilars and Biopharmaceuticals: Dealing with the Challenges," *Pharmaceutical and Health Technology (PHT) Division, Special Libraries Association (SLA), Spring Meeting*, March 18-20, 2012, Baltimore, MD.
- "Biosimilars Nomenclature and Implications for the U.S. Biopharmaceutical Industry," 6th Summit on Biosimilars and Follow-On Biologics, March 30-31, 2011, CBI, Falls Church, VA.
- "What Will Be the Market for FOB's [follow-on proteins/biosimilars]? What Forces Will Shape the Market? How Will New Entrants Compete and Innovators Adapt?," *Global Follow-On Biologics: Preparing for a Post-FOB Approval World*, IBC USA Conferences, Bethesda, MD, Nov. 17-18, 2008.
- "Information: The Next Battleground," *Biosimilars Conference 2008*, Visiongain, Philadelphia, PA, Nov. 11-13, 2008.
- "What Is a Generic Biopharmaceutical? Biogeneric? Follow-On Protein? Biosimilar? Follow-On Biologic?...," *Biosimlars and Follow-on Biologics*, Center for Business Intelligence, Crystal City, VA, April 28-29, 2008 [keynote/lead presentation].
- "Federal Labs and NIH are Number One in Bio-Technology Transfer," *NIH CRADA Forum II*, September 1994.
- "Federal Biomedical and Biotechnology Inventions and Technology Transfer," combined session of the Division of Chemical Information and Division of Chemistry and Law, *American Chemical Society National Meeting*, August 1994.
- "Biotechnology and Chemical Information," Division of Chemical Information, *American Chemical Society National Meeting*, August 1990.
- "Trends in Biotechnology Patenting," Division of Chemistry and Law, *American Chemical Society National Meeting*, August 1990.
- "The Status of the Infrastructure of Information Resources Supporting U.S. Biotechnology," *Capital Area Biotechnology Information Network (CABIN)*, December 1989.
- "Information Resources for AIDS and Antiviral Drug Development" session Chairman and presented "Information Resources for Antiviral Drug and Vaccine Development," Division of Chemical Information, *American Chemical Society National Meeting*, 1988.
- "Biotechnology Information" session Chairman (the first such session on this topic in the U.S.) and presented "The Status of the Infrastructure of Information Resources Supporting Biotechnology," Division of Chemical Information, American Chemical Society National Meeting, 1986.