

SALLY A. LOOK, Ph.D.

Regulatory Interlinx, Inc.

EDUCATION

- 1977-1983 **Ph.D. Oceanography/Marine Chemistry**, Scripps Institution of Oceanography, University of California, San Diego, La Jolla, California
- 1972-1977 **B.S. Chemistry**, University of California, Santa Barbara, Santa Barbara, California
- 1972-1977 **B.A. Zoology**, University of California, Santa Barbara, Santa Barbara, California

PRESENT POSITION

1996-present **President and Managing Director**, Regulatory Interlinx, Inc., Spicewood, Texas

Provide consulting services related to the research and development of FDA-regulated pharmaceutical drugs, biologics, and veterinary drugs. Capabilities include the following:

- Prepare and review Chemistry Manufacturing and Controls (CMC) technical reports and the CMC section(s) of regulatory submissions such as: Investigational New Drug Applications (INDs), New Drug Applications (NDAs), Product License Applications (PLAs), Drug Master Files (DMFs), Abbreviated New Drug Applications (ANDAs), and related amendments, supplements, and annual reports
- Assist in reformatting CMC regulatory documentation into Module 3 CTD format and interpret new requirements for submissions
- Write Quality Overall Summary (Module 2.3 section) for regulatory submissions
- Interpret current FDA CMC regulatory guidelines, policy statements, and trends that impact overall drug development strategies
- Prepare for and participate in CMC meetings with FDA reviewing divisions at the pre-IND, End-of-phase 2, and pre-NDA stages of drug development
- Assist in identification of contract facilities to carry out CMC development, Quality Control, and/or production tasks

- Conduct current Good Manufacturing Practice (cGMP) and CMC regulatory training
- Advise on Quality Assurance matters
- Conduct data integrity audits to confirm traceability to source documents
- Conduct cGMP audits of facilities performing manufacturing and QC functions
- Conduct mock Pre-Approval inspections
- Perform due-diligence technical and regulatory audits in connection with acquisitions, mergers, licensing, and litigation
- Review and write standard operating procedures (SOPs)

PREVIOUS POSITIONS

1993-1998 **Special Government Employee (SGE)**, Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), Rockville, Maryland

Consulted to the Deputy Center Director for Pharmaceutical Science, Office of Pharmaceutical Sciences [Project Topic: *Regulatory and Technical Aspects of Chemistry Issues Related to the International Conference on Harmonization (ICH)*].

1993-1996 **Managing Associate**, The Weinberg Group Inc., Washington, D.C.

Provided consulting services and regulatory advice to the pharmaceutical industry in the areas of CMC, analytical methods development, cGMP compliance, regulatory affairs, and project management.

1992-1993 **Review Chemist**, Office of Drug Evaluation I, FDA CDER, Rockville, MD

Developed FDA guidelines, policy statements, and scientific positions related to regulatory chemistry issues including stability, impurities, and analytical methods validation; supported the Chemistry Manufacturing and Controls Coordinating Committee (CMCCC).

1989-1992 **Review Chemist**, Division of Oncology and Pulmonary Drug Products, FDA CDER, Rockville, MD

Reviewed CMC information submitted in support of oncolytic and pulmonary drug applications including INDs, NDAs, and related amendments, supplements, annual reports and supporting documents such as DMFs; reviewed ANDAs for OGD; advised industry applicants/sponsors on FDA's CMC requirements for regulatory submissions.

PREVIOUS POSITIONS (Continued)

1988-1989 **Scientist/Taxol Project Manager**, Chemical Synthesis and Analysis Laboratory, Program Resources, Inc., NCI-Frederick Cancer Research Facility, Frederick, MD

Developed analytical methods and procedures for the pilot scale isolation of the anticancer agent, taxol, from primary extracts of the bark of the Pacific yew; discovered and identified alternate sources of taxol in the needles of ornamental yews.

1986-1988 **Postdoctoral Research Fellow/Bio-Organic Chemist**, Chemistry of Carcinogens Section, BRI-Basic Research Program, NCI-Frederick Cancer Research Facility, Frederick, MD

Examined oligonucleotide sequence specificity of natural product-nucleic acid photoadducts; applied fundamental chromatographic and DNA sequencing methods to characterize sites of DNA inter-strand crosslinks formed by triazene alkylating agents and natural products.

1985-1986 **Scientist/Spectroscopist**, Analytical Research Group, Allergan Pharmaceuticals, Irvine, CA

Managed and coordinated a multi-user Fourier Transform (FT) Nuclear Magnetic Resonance and FT Infrared spectroscopy facility; maintained and operated the instruments; trained users; performed experimental studies; and participated in R&D project teams.

1984-1985 **NIH Postdoctoral Research Fellow**, Marine Biology Research Group, Scripps Institution of Oceanography, University of California, San Diego, La Jolla, CA

Studied secondary metabolite biosynthesis and the physiology of bioluminescent marine microbes and nematode symbionts.

1983-1984 **NIH Postdoctoral Research Fellow**, Department of Chemistry, Columbia University, New York City, NY

Synthesized allenic retinol analogs; synthesized tritium-labeled "super hormone" derivatives of an insect molting hormone.

1977-1982 **NOAA Sea Grant Predoctoral Trainee**, Marine Resources Institute, Scripps Institute of Oceanography, University of California, San Diego, La Jolla, CA

Carried out the isolation and structure elucidation, and studied the chemical reactivity of new biologically active natural products purified from marine invertebrates; discovered over 20 new natural products; patented three series of anti-inflammatory compounds.

PROFESSIONAL ACTIVITIES

- 1992-1993 **Proposal Reviewer of Master Agreements**, Project Title: *Large-scale Isolation of Antitumor and anti-AIDS Agents from Natural Sources*, Source Evaluation Group, Developmental Therapeutics Program, National Cancer Institute, National Institutes of Health, Bethesda, Maryland USA
- 1990-1993 **Guest Researcher**, Project Title: *Dynamics of Drug-DNA Interactions*, Basic Research Program, Frederick Cancer Research and Development Facility, Frederick, Maryland USA
- 1992-1993 **Special FDA Technical Consultant**, Generic Drug Investigations Task Force, Assistant U.S. Attorney, U.S. Department of Justice, Baltimore, Maryland, USA

AWARDS

- 1993 **Commissioner's Special Citation as a Member of the Taxol Review Group**, U.S. Food and Drug Administration, Rockville, Maryland
- 1992 **Chemistry Reviewers Group Recognition Award**, U.S. Food and Drug Administration, Rockville, Maryland
- 1983-1985 **National Research Service Award**, National Institutes of Health, Bethesda, Maryland
- 1977-1982 **NOAA Sea Grant Predoctoral Traineeship**, Scripps Institution of Oceanography, University of California, San Diego, La Jolla, California

PUBLICATIONS

Look, S. and Witkin, K.M. 1995. "Process validation principles: application to the manufacture of IVDs," IVD Technology May, 1995: 30.

Chmurny, G., Hilton, B.D., Brobst, S., Look, S.A., Witherup, K. and Beutler, J.A. 1992. "¹H and ¹³C-NMR assignments of taxol, 7-epi-taxol, and cephalomannine," J. Nat. Prod. 55(4):414.

Beutler, J.A., Chmurny, G., Look, S.A., and Witherup, K. 1991. "Taxinine M, a new tetracyclic taxane from *Taxus brevifolia*," J. Nat. Prod. 54(3):893.

Witherup, K.M., Look, S.A., Stasko, M.W., Ghiorzi, T, Muschik, G. and Cragg, G.M. 1990. "*Taxus* spp. needles contain amounts of taxol comparable to the bark of *Taxus brevifolia*: analysis and isolation," J. Nat. Prod. 53(5):1249.

PUBLICATIONS (Continued)

Stasko, M.W., Witherup, K.M., Ghiorzi, T.J., McCloud, T.G., Look, S.A., Muschik, G.M. and Issaq, H.J. 1989. "Multimodal thin layer chromatographic separation of taxol and related compounds from *Taxus brevifolia*," J. Liq. Chromatogr. 12(11):2133.

Witherup, K.M., Look, S.A., Stasko, M.W., McCloud, T.W., Issaq, H.J. and Muschik, G.M. 1989. "High performance liquid chromatographic separation of taxol and related compounds from *Taxus brevifolia*," J. Liq. Chromatogr. 12(11):2117.

Elespuru, R.K. and Look, S.A. 1988. "Gilvocarcin V, a photodynamic DNA damaging agent of unusual potency," In: New Directions in Photodynamic Therapy, Douglas C. Neckers, Ed., Proc. SPIE 847:107.

Groweiss, A., Look, S.A. and Fenical, W. 1988. "The solenolides, new antiviral diterpenoids from a Palauan octocoral," J. Org. Chem. 53:2401.

Look, S.A. and Fenical, W. 1987. "The seco-pseudopterosins, new anti-inflammatory diterpene-glycosides from Caribbean gorgonian octocorals of the genus *Pseudopterogorgia*," Tetrahedron 43:3363.

Look, S.A., Fenical, W., Jacobs, R.S. and Clardy, J. 1986. "The pseudopterosins: a new class of potent anti-inflammatory and analgesic natural products from the sea whip *Pseudopterogorgia elisabethae*," Proc. Natl. Acad. Sci. USA 83:6238.

Look, S.A., Fenical, W., Matsumoto, G. and Clardy, J. 1986. "The pseudopterosins, a new class of anti-inflammatory and analgesic diterpene pentosides from the marine sea whip *Pseudopterogorgia elisabethae* (Octocorallia)," J. Org. Chem. 51:5140.

Look, S.A., Burch, M.T., Fenical, W., Qi-tai, Z. and Clardy, J. 1985. "Kallolide A, a new anti-inflammatory diterpenoid, and related lactones from the Caribbean octocoral *Pseudopterogorgia kallos* (Bielschowsky)," J. Org. Chem. 50:5741.

Look, S.A., Fenical, W., Zheng, Q. and Clardy, J. 1984. "The calyculones, new cubitane diterpenoids from the Caribbean gorgonian octocoral, *Eunicea calyculata*," J. Org. Chem. 49:1417.

Look, S.A., Fenical, W., Van Engen, D. and Clardy, J. 1984. "Erythrolides: unique marine diterpenoids interrelated by a naturally occurring di- π -methane rearrangement." J. Am. Chem. Soc. 106, 5026.

Kokke, W.C.M.C., Epstein, S., Look, S.A., Rau, G.H., Fenical, W. and Djerassi, C. 1984. "On the origin of terpenes in symbiotic associations between marine invertebrates and algae (zooxanthellae): culture studies and application of carbon isotope ratio mass spectrometry." J. Biol. Chem. 259:8168.

Look, S.A., Buchholz, K. and Fenical, W. 1984. "12-Hydroxy-5E- γ -bisabolene, a new sesquiterpene alcohol from a Caribbean sea whip of the genus *Pseudopterogorgia* (Gorgonacia, Cnidaria)," Experientia 40:931.

PUBLICATIONS (Continued)

Look, S.A. 1983. "Studies of the natural products chemistry of selected Caribbean gorgonians." Ph.D. dissertation. Scripps Institution of Oceanography, UC San Diego.

Look, S.A. and Fenical, W. 1982. "New bicyclic diterpenoids from the Caribbean gorgonian octocoral, *Eunicea calyculata*," J. Org. Chem. 47, 4129.

ABSTRACTS

Blumenstein, J., Look, S.A. and Michejda, C. 1990. "Bistriazenes: a new class of multifunctional alkylating agents," Proceedings, 81st Annual Meeting of the American Association for Cancer Research, Proc. Am. Assoc. Cancer Res. 31:409.

Witherup, K.M., Look, S.A., Stasko, M.W., McCloud, T.G., Issaq, H.J. and Muschik, G.M. September 1989. "Chromatographic separation of taxol and related compounds from plant extracts: high performance liquid chromatography," Abstracts, Eastern Analytical Symposium, 28th Annual Symposium and Exposition, New York City, New York.

Stasko, M.W., Witherup, K.M., Ghiorzi, T.J., McCloud, T.G., Look, S.A., Muschik, G.M. and Issaq, H.J. September 1989. "Chromatographic separation of taxol and related compounds from plant extracts: multimodal two dimensional thin layer chromatography," Abstracts, Eastern Analytical Symposium, 28th Annual Symposium and Exposition, New York City, New York.

McGregor, G.N., Look, S.A., Hilton, B.D. and Chmurny, G.N. September 1989. "Zero-field decoupling (ZFD) of NMR spectra taken at high field: a Sun based program for the organic chemist; application to the analysis of a typical structural problem using taxol," Abstracts, Eastern Analytical Symposium, 28th Annual Symposium and Exposition, New York City, New York.

Elespuru, R.K., Andrews, A.W. and Look, S.A. March 1988. "Sequence specificity and DNA repair requirements for mutagenesis by photoactive intercalating compound gilvocarcin V," Abstracts, 19th Annual Meeting, Environmental Mutagenesis Society, Environmental Mutagenesis 11 (Suppl. 11):31.

Farrelly, J.G., Gordon, J.A., Look, S.A., Mullin, P.D., Stewart, M. and Elespuru, R.K. April 1987. "Mutational fingerprint analysis of chemical intermediates generated by DMN, DEN, and related compounds," Abstracts, 18th Annual Meeting, Environmental Mutagenesis Society, Environmental Mutagenesis 9 (Suppl. 8):35.

Look, S.A. and Elespuru, R.K. June 1987. "Studies of the photochemically mediated DNA binding of the antitumor agent, gilvocarcin V," Works-in-Progress Poster, 15th Annual Meeting of the American Society for Photobiology, Bal Harbour, Florida.

Fenical, W., McEnroe, F.J. and Look, S.A. March 1978. "New anti-bacterial sesquiterpenoids from Caribbean sea fans," Abstracts, ACS Div. of Org. Chemistry, 175th ACS National Meeting, Anaheim, CA.