Bridge Associates International LLC

"Partners for Quality and Manufacturing Excellence"

Associated Professionals

Richard G. Einig, Ph.D., RAC, CQA

Summary

Consultant to the pharmaceutical industry with extensive senior management experience in commercial manufacturing and research-based operations

Experience:

EINIG & ASSOCIATES, Inc. 2002 - Present
President

Assist clients to institute quality systems, submit regulatory documents, perform audits, develop and present training programs, and conduct quality improvement programs. Clients include The Quantic Group, Center for Professional Advancement, and large and small international pharmaceutical, generic, biotechnology and device manufacturers.

PharmEco Inc. (Johnson Matthey Company) 1998 - 2001
Corporate Headquarters, Devens, MA
Director, Quality Unit

Responsible for all quality related activities of international API contract manufacturer registered with FDA and certified ISO 9001.

Directed Analytical Chemistry, QA/QC/RA and Material Control functions.
Member of due-diligence team during sale of Company.
Reviewed and approved validation/qualification protocols and reports.
Represented Company in all communications with Regulatory Agencies.
Assisted clients with regulatory filings and other scientific issues.
Prepared DMFs and CMC sections for client IND/NDA submissions.
Awarded Regulatory Affairs Certification by *Regulatory Affairs Professional Society*.

Hybridon, Inc. (Avecia Biotechnology) 1995 –1998
Hybridon Specialty Products, Milford, MA
Director, Analytical Development & Quality Control

Responsible for control and release of synthetic oligonucleotides formulated as parenteral and oral antisense therapeutics and medical device diagnostic probes.

Member of clinical program development team in U.S. and France.
Planned the development and validation of novel analytical methods.
Managed technology transfer system for domestic and international suppliers.
Responsible for validation of classified production suites and WFI water system.

Hoechst-Celanese Corporation (Sanofi-Aventis) 1988 – 1995
Pharmaceutical Production Division, Coventry, RI
Manager, Quality Unit

Responsible for ensuring product quality at commercial API production facility.

Approved final release of over $50 M of APIs for innovator and generic drug products.
Awarded Hoechst-Roussel Pharmaceutical's Supplier of the Year for six successive years in recognition of the Division's outstanding product quality and customer service.
Prepared CMC sections for human and veterinary new drug applications.
Established and maintained DMFs for six commercial APIs.
Prepared and conducted formal manufacturing training program for production workers that resulted in 16% improvement in API release rate.

Warner-Lambert Company (Pfizer Inc.) 1983 – 1988
Clinical & Regulatory Affairs Division, Morris Plains, NJ
Senior Manager

Manager of product development and regulatory compliance at consumer products research organization.

Joined with marketing and research groups on product innovation project teams.
Contracted with academic and commercial laboratories for external scientific services.
Harmonized methods and procedures with worldwide suppliers and customers.
Received Division's Scientific Achievement Award for efforts in development and successful launch of *Promega*.

Training Programs for Center for Professional Advancement (www.cfpa.com):

Active Pharmaceutical Ingredient Production *(Director)*

Three-day course presenting operational, quality and regulatory issues that impact production of APIs for human and veterinary drug products

ICH Q7A Guidance (Director)

Two-day course giving an in-depth explanation of the operational, quality and regulatory guidance for active pharmaceutical ingredients production

Education:

Ph.D. Food Science University of Missouri, Columbia, MO	1983
M.A. Business Administration Webster University, St. Louis, MO	1979
M.S. Analytical Chemistry St. Louis University, St. Louis, MO	1969
B.S Chemistry St. Louis University, St. Louis, MO	1964

Professional Affiliations and Offices:

American Chemical Society (ACS)
Rhode Island Section:
Chairman 2002; Vice-Chairman 2001; Executive Committee 2003 - 2006
Executive Committee 1992 – 1995; Chairman 1991; Vice-chairman 1990

American Society for Quality (ASQ)
Rhode Island Section:
Executive Committee 2005

Certified Quality Auditor (CQA)

Regulatory Affairs Professional Society (RAPS)

Regulatory Affairs Certified (RAC)

Selected Publications:

Gonzalez, J.E., Einig, R.G., Puma P., Noonan, T.P., Kennedy, P.E., Sturgeon, B.G., Wang, B.H. and Tang, J.Y. 1998. Commercial Scale Manufacturing of Oligonucleotides Under Good Manufacturing Practices. In Clinical Trials of Genetic Therapy with Antisense DNA and DNA Vectors, E.Wickstrom (Ed.), p53. Marcel Dekker, Inc., NY.

PhRMA 1996. PhRMA Guidelines for the Production, Packing, Repacking, or Holding of Drug Substances. Part II, Pharm.Technol. 20(1): 50-63.

PhRMA 1995. PhRMA Guidelines for the Production, Packing, Repacking, or Holding of Drug Substances. Part I, Pharm.Technol. 19(12): 22-32.

Einig, R.G. and Bailey, M.E. 1988. Soy Proteins and Thermal Generation of Alkylpyrazines in Meat Flavor. In Thermal Generation of Aromas, T. Parliament, R. McGorrin and C-T. Ho (Ed.), p. 479. American Chemical Society, Washington, DC.

Bailey, M.E. and Einig, R.G. 1988. Reaction Flavors of Meat. In Thermal Generation of Aromas, T. Parliament, R. McGorrin and C-T. Ho (Ed.), p. 421. American Chemical Society, Washington, DC.

Einig, R.G. and Ackman, R.G., 1987. Omega-3 PUFA in Marine Oil Products, J.A.O.C.S. 64(4): 499.

Selected Presentations:

Einig, R.G., October 2001. Regulatory Concerns in Commercial Production of Drugs by Chromatographic Procedures, CPhI, London, U.K. Invited Speaker.

Einig, R.G., 2001. FDA Compliance Issues for Large-scale SMB Production of Enantiomerically Pure Drugs, SMB at the Belfry, Birmingham, U.K. Invited Speaker.

Einig, R. G., 2000. Manufacturing API for Clinical Trials: A Regulatory Perspective. Pharmaceutical Drug Association, Cambridge, MA. Guest Speaker.

Einig, R. G., 2000. Optimize Flexibility and Maintain Control through Outsourcing Stability Testing Projects. CBI's 2nd Annual International Stability Programs, Philadelphia, PA. Invited Speaker.

Einig, R.G., 1997. The Quality Unit in Large-Scale Therapeutic Oligonucleotide Production. International Business Conference, San Diego, CA. Invited Speaker.