

Curriculum Vitae



Roger W. Koops, Ph.D.
Consultant
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SUMMARY OF EXPERTISE

- 19+ Years Experience in the Pharmaceutical and Biotechnology Fields
- 10+ Years Experience in Quality Assurance; 5+ Years at Director Levels
- Experience in Small Molecule APIs, Solid Oral Dosage Forms, Live Virus Vaccines
- Multinational Experience with Contract Organizations/Partners in Europe, Canada, and Japan
- Experience in Validation (Facility, Process, QC Test Methods, Shipping)
- Regulatory Experience in IND, NDA, ANDA, and BLA filings, Inspections, etc.

EDUCATION

Ph.D. *Philosophy, Chemistry*, University of California (1990)

M.S. *Chemistry*, Western Washington University (1983)

B.A. *Chemistry*, Western Washington University (1981)

EXPERIENCE

BCG-Japan., Consultant

Tokyo, Japan (Oct. 2008 - present)

- Provide advice in the areas of pharmaceutical and biotechnology, quality assurance, quality control, manufacturing, CMC, development, and validation

Independent Consultant

Pacifica, CA / Kumamoto, Japan (Aug. 2005 – present)

- Provide advice in the areas of pharmaceutical and biotechnology, quality assurance, quality control, manufacturing, CMC, development, and validation

VaxGen, Inc., Director of Quality Assurance

Brisbane, CA (Nov. 2002 – Aug. 2005)

- Responsible for all QA activities
- Quality Team Leader for LC16m8 Smallpox Vaccine Project

Roger W. Koops, Ph.D.

Genelabs Technologies, Inc. *Director of Quality*
Redwood City, CA (Aug. 2002 – Nov. 2002)

Genelabs Technologies, Inc., *Associate Director of Quality*
Redwood City, CA (Mar. 2000 – Aug. 2002)

- Oral Therapeutics - Responsible for all QA and QC activities.

Pharmacyclics, Inc., *Manager of Quality Assurance*
Sunnyvale, CA (Jul. 1999 – Mar. 2000)

- Injectable Therapeutics - Responsible for all API QA activities.

Gilead Sciences, Inc., *Quality Assurance Specialist*
Foster City, CA. (Mar. 1996 – Jul. 1999)

- Oral, Topical, and Injectable Therapeutics - Responsible for all API QA activities.

Aerojet, *Sr. Chemistry Specialist*
Rancho Cordova, CA (Jul. 1995 – Mar. 1996)

- Custom APIs and Fine Chemicals - Responsible for custom API process development projects and establishing cGMP systems.

Abbott Laboratories, *Process Development Chemist*
North Chicago, IL (May 1990 – May 1994)

- Custom and Generic APIs - Responsible for custom and generic API process development.

Schering-Plough, Inc., *Research Scientist*
Bloomfield (now Kenilworth), NJ (Feb. 1986 – Feb. 1987)

- Antifungal/Antiviral Medicinal Chemistry - Synthesis of medicinally active compounds

Biophysica Foundation, *Development Chemist*
La Jolla, CA (Jul. 1985 – Jan. 1986)

- Radiocontrast Imaging Agents - Process Development of novel imaging agent

PROFESSIONAL ORGANIZATIONS

PDA

Sigma Xi

American Association for the Advancement of Science (AAAS)

American Chemical Society (ACS)

PUBLICATIONS AND SEMINARS

10/2005 Professional Instructor, IBC-ASIA, Singapore, Process Validation Course (2 Day)

6/2002 Professional Instructor, IVT, Dublin, Ireland, Process Validation Course (1 Day)

Roger W. Koops, Ph.D.

- 2002** *R.W. Koops*, **Journal of Validation Technology**, No. 2, p. 102. Process Validation of Synthetic Chemical Processes for the Production of Active Pharmaceutical Ingredients (APIs)
- 1998** *Deshpande, Cain, Patel, Singam, Brown, Gupta, Barkalow, Callen, Patel, Koops, Chorghade, Foote, Pariza*, **Organic Process Research and Development**, No. 2, p. 351.
- 1995** *Bhatia, Chamberlin, Davis, Hayes, Klix, Koops, Rojas*, **Tetrahedron Letters**, No. 36, p. 1791.
- 1992** *Midland, Koops*, **Journal of Organic Chemistry**, No. 57, p. 1158.
- 1990** *Midland, Koops*, **Journal of Organic Chemistry**, No. 55, p. 5058.
- 1990** *Koops*, **Doctoral Dissertation**, University of California, Riverside.
- 1990** *Midland, Koops*, **Journal of Organic Chemistry**, No. 55, p. 4647.
- 1987** *Gupta, Johnson, Lampman, Koops*, **Journal of Organometallic Chemistry**, No. 326, p. 281.
- 1985** *Olden, Lampman, Koops*, **Journal of Chemical Education**, No. 62, p. 267.
- 1983** *Koops*, **Master's Thesis**, Western Washington University