

Curriculum Vitae



Ruth H.G. Wolff
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Director, Therapeutics
Biologics Consulting Group, Inc.
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EXPERIENCE

Biologics Consulting Group, Inc., Director, Therapeutics
Derwood, MD (1998 - present)

- Responsible for the scientific and regulatory review and analysis of a wide range of therapeutic products at all stages of product development, from pre-IND development through post-marketing.
- Provide regulatory, scientific and manufacturing analysis and support, develop product- and facility-related regulatory documents for submission, review SOPs and validation packages, and perform facilities audits.

FDA, CBER, OTRR, Division of Application Review and Policy, Hybridoma and Hematologic Products Branch, *Chief*. (1994 - 1998)

- Products under purview included monoclonal antibodies for therapeutic or *in vivo* diagnostic use, thrombolytics, hematologic growth factors and devices used with or for therapeutic purposes, assigned to CBER by intercenter agreement.
- Reviewed scientific and regulatory analyses, as well as agency correspondence related to both market and investigational submissions, for scientific and regulatory accuracy.
- Responsible for the quality assurance review of the scientific and regulatory bases for approval of biologic and medical device submissions, including review of applicable labeling.
- Responsible for assuring adherence to review deadlines for market applications, by providing guidance on the managed review process to both branch members and other Center personnel.
- Acted as liaison between the biotech industry and the agency, routinely providing consultative services to a broad cross-section of the biotech industry at all stages of product development, from pre-clinical submission through post-marketing.
- Responsible for assuring equity of workload among the staff, assigning projects based on scientific and regulatory expertise.
- Supervised doctoral level scientific/regulatory reviewers and secretarial support staff. Member of the ICH Expert Working group on Quality of Biotechnology Products, serving as the FDA lead on the viral safety and cell substrates documents and represented the Center in the discussion on the quality portion of the Common Technical Document.
- Organized the 1995 CBER workshop on viral safety and cell substrate issues.



Ruth H. G. Wolff, Ph.D.

- Participated in Center managed review and strategic planning committees, gave scientific and policy presentations internally, before agency committees and before regulated industry, and led and performed facility inspections while continuing to have primary responsibility.

FDA, CBER, OTRR, Division of Application and Review, Hybridoma and Hematologic Products Branch, *Microbiologist*
(1992 - 1994)

- Microbiologist and regulatory reviewer/coordinator.
- Responsible for a wide variety of monoclonal antibodies, hematologic growth factors, cytokines and devices both within the investigational phase as well as post-licensure.
- Performed reviews as well as coordinated review teams, formulated and drafted review letters and worked with the team to adhere to review time lines.
- Interfaced with a broad cross-section of the biotech industry, at all stages of product development regarding INDs, Master Files, Product, Biologic and Establishment License Applications and PMAs.
- Member of the ICH Expert Working Group on Quality of Biotechnology Products as FDA lead on the viral safety and cell substrates documents and chaired the CBER/CDER group working on the ICH virus and cell substrate documents.
- Responsible for assuring adherence to review deadlines for market applications by providing guidance on the managed review process.
- Participated in facilities inspections.

Microbiological Associates, *Study Director*
(1989 - 1992)

- Managed multiple simultaneous GLP-compliant studies as varied as reverse transcriptase assays, co-cultivation and induction protocols with multiple endpoints (including infectivity assays), scanning and transmission electron microscopic analyses, assays for mycoplasma contamination in cell cultures and culture fluids as well as in raw materials, and assays to assure the sterility of both production substrates and final product formulations.
- Experience working with members of the industry and academia to design and implement testing protocols for a wide variety of products.
- Worked closely with firms to design studies to address specific concerns expressed by regulatory agencies, and prepared documents for submission to these agencies.
- Supervised one supervisory, three mid-level and one entry-level technical personnel, responsible for hiring actions and staff evaluations.



Ruth H. G. Wolff, Ph.D.

IGEN Incorporated, Senior Scientist
(1988 - 1989)

- Designed and synthesized expression vectors for a series of proprietary antibody constructs.
- Responsible for providing oligo-nucleotides for use in conjunction with a proprietary detection technology for nucleic acid analyses.
- Member of team identifying and preliminary evaluation of potential targets for catalytic antibody development.
- Involved with final review process for applications literature accompanying release of IGEN's proprietary detection technology.

Walter Reed Army Institute of Research, Research Chemist
(1982 - 1988)

EDUCATION

B.S., State University of New York at Stony Brook; Biology (1973).

Ph.D., Massachusetts Institute of Technology; Cell Biology (1978).

CONTINUING EDUCATION

Course work and training in FDA law and various aspects of cGMP.

Biochemical Regulatory Engineering Program Concentration: University of Maryland Baltimore County (1996).

HONORS AND AWARDS

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| 1997 | Group Recognition Award for the Monoclonal Antibodies Points to Consider |
| 1996 - 1997 | Performance awards for ICH participation |
| 1996 | Center Director's Award for Policy Development |
| 1995 | Performance award for organizing the CBER International Viral Safety Workshop |