

CAROLYN HOSKINS KRUSE

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SUMMARY

Extensive experience in multinational pharmaceutical development, international and US regulatory affairs including submission preparation and regulatory strategy for small molecules, biologics, vaccines, veterinary products, drug device combinations, pharmaceutical manufacturing, technology transfer and project management. Conduct audits of preclinical, clinical and manufacturing sites for GMP, GLP and GCP compliance. Conduct of integrity audits of information submitted to regulatory agencies. Proven leadership, organizational and presentation skills combined with strong technical and academic achievement. Proven ability to work effectively with project teams and diverse company and country cultures. Extensive experience with preparation for and conduct of FDA and EU regulatory agency meetings covering CMC, preclinical and clinical issues. Experience with US and EU pediatric and Orphan Drug applications. Experience with applications for multiple therapeutic areas including CNS, oncology, cardiovascular, dermatology and dental, and others.

PROFESSIONAL EXPERIENCE

KRUSE CONSULTING, LTD.

2001 - Present

Principal Partner, Macclesfield, United Kingdom

KRUSE CONSULTING GROUP, INC.

1995 – Present

President and Founder, Cheyenne, WY

Professional Services:

Provide regulatory and drug development consulting services for pharmaceutical, biotechnology, veterinary medicine and device firms as well as contract research organizations with a focus on the drug discovery and development process through Phase IV, including the development of comprehensive regulatory strategies, project plans and SOPs.

Prepare documentation required by US and EU regulatory authorities for the initiation of clinical trials through marketing authorizations including GCP and Pre-Approval Inspections for CDER, CBER and CVM as well as preparation of CTA, IMPD and MAA applications for the EU.

Prepare Briefing Packages and Meeting Request Letters for Regulatory Agencies, INDs, NDAs, ANDAs, DMFs and BLAs for submission to FDA as well as CTA's and IMPD's for EU Clinical Trial initiations and EU Marketing Applications in the CTD Format. Experience includes but is not limited to work on drugs for diabetes (including the Actos® NDA as regulatory liaison and Project Manager and others), for cardiovascular disease (including Plavix® as Project Director), antioxidants for closed head injury, oncology drugs (including Velcade®), antibiotics, antivirals, vaccines, drug device combinations and veterinary products.

Conduct GMP audits, mock Pre-Approval Inspections, documentation reviews for due diligence activities and integrity audits of manufacturing documentation. Design development programs and supporting project plans to ensure the timely submission and approval of regulatory dossiers.

PROFESSIONAL EXPERIENCE (continued)

Design, customize and present Global Training Courses for In-house, Public Courses and Webinar presentations in the US, UK, Northern Ireland, France, The Netherlands, Belgium and Israel. Collaborate with clients and/or training institutions including Bioforum Applied Knowledge Center (Israel), PTI, Ltd., formerly IIR (UK), The Center for Professional Advancement, The Center for Professional Innovation and Education, PERI, Schering Plough (Ireland), Stiefel (UK), DuPont, Elan, Thomson Pharma, Sanofi Aventis, and Warner Chilcott. Sample Course titles are listed below. Over 160 course modules are available.

CMC Considerations in Drug Development
CMC Submissions in the Common Technical Document Format
CMC Variations & Post Approval Changes for Human & Veterinary Drugs in the US
Controlled Substances Compliance Seminar
Developing the Chemical and Regulatory International Strategic Plan (CRISP)
Drug Development Simulation (The NDA Game)
European Regulations: MAA Phase (Webinar)
FDA Submission Procedures (2 Days)
FDA Requirements for Packaging & Labeling
Food and Drug Administration Act (FDAAA): What Companies Need to Know (Webinar)
From the Lab Bench to the Marketplace
Introduction to Drug Development and the IND Process
Introduction to International Regulatory Affairs and Global Drug Development
Meeting the Regulatory Requirements for Biologic License Applications (BLA's)
Meeting the Regulatory Requirements for New Drug Applications (NDA's)
Overview of CDER and the New Drug Review Process (Webinar)
Overview of the Pharmaceutical Industry (In-house, Amsterdam)
The Drug Development Process: Getting from "Hit" to "Lead"
Understanding US-FDA Drug Submission Procedures
Understanding FDA's Pre-Approval/Pre-License Inspection Program
Understanding US FDA Regulations: FDA's approach to CTD

STERLING WINTHROP, INC. (now Sanofi Aventis)

1989 - 1994

Project Director, Therapeutics, Collegeville, PA

Defined and implemented global development strategies for drug projects in a variety of therapeutic areas including cardiovascular, endocrine and antioxidant projects. Project Director for Plavix.

Led multinational development project teams to create and implement comprehensive, world-wide development plans.

Supervised project managers to ensure that the tactical aspects of project plans were scheduled and completed to meet target dates.

Assistant Director, Project Planning and Analysis, Sterling Drug, Inc., Malvern, PA

Managed worldwide development efforts for discovery and Phase III, IV development projects.

Directed the Project Planning and Analysis group, supervising the creation and update of a project management database that was used company wide for forecasting and tracking project budgets and development progress.

PROFESSIONAL EXPERIENCE (continued)

Project Manager, Sterling Drug, Inc., Malvern, PA

Developed and maintained worldwide development plans for antioxidant and oncology projects in conjunction with project leaders.

Prepared project reports and presented critical project issues to upper management.

SMITH KLINE & FRENCH LABORATORIES, LTD.
(now Glaxo SmithKline, Ltd.)

1976 - 1989

Senior Registration Officer, SmithKline & French Lab., Ltd., Welwyn Garden City, England

Supervised preparation/quality assurance of submissions to the MCA (UK), NDAB (Ireland) and other EU countries.

Prepared Review/Renewal applications (9), variations, CTX (9) and PL/PA applications (2 submitted 1988, approved 1990: 1 submitted 1989, approved 1991). Therapeutic areas included marketed/new vaccines, genetically engineered products, antimalarials, analgesics, hematinics, psychotropics, osteoporosis and cardiovascular drugs.

Ensured submission of all FDA required investigator documentation for ex-US, multicenter trials conducted under IND's.

Prepared UK Patient Information Leaflets for marketed products.

Regulatory Affairs Associate, SmithKline Beckman Corp., Philadelphia, PA

Prepared chemical/pharmaceutical, preclinical, clinical and administrative sections of IND's, NDA's, amendments and annual reports.

Senior Medicinal Chemist, SmithKline Beckman Corp., Philadelphia, PA

Medicinal Chemist, SmithKline Beckman Corp., Philadelphia, PA

Associate Medicinal Chemist, SmithKline Beckman Corp., Philadelphia, PA

EDUCATION

Massachusetts Institute of Technology, Cambridge, MA

M.Sc. in Organic Chemistry

H. E. Russell Fellowship (1976)

Trinity College, Hartford, CT

B.S. in Chemistry with Honors in Chemistry
and General Scholarship (1974)

Christ Church College

Oxford University, Oxford, England

Courses: Modern English, History of Oxford,
English Architecture, Shakespeare (1969)

PROFESSIONAL DEVELOPMENT

Center for Creative Leadership, Brussels, Belgium 1994
Course: Dynamics of Leadership

Cornell University, Ithaca, NY 1994
Course: Executive Development Program

University of Pennsylvania, Graduate Professional Development Program 1984
Philadelphia, PA
Courses: The Art and Practice of Negotiation

Temple University, Philadelphia, PA 1981 - 1982
Courses: Organization and Management, Personnel Management

Wharton Evening School, Philadelphia, PA 1977 - 1979

PROFESSIONAL ASSOCIATIONS

American Chemical Society (ACS) 1974 – 1987

The Organisation for Professionals in Regulatory Affairs (TOPRA, formerly BIRA and EUDRA) 1987 - Present

Member of working parties for meetings on "Global Registration" and "Chemistry/Pharmacy Guidelines."

Drug Information Association (DIA) 1986 - Present

DIA Program Committee Member and Session Chair for the Annual Meeting, Project Management Track 1997-2006

2006 Session Title: "Cross Cultural Communication – More than Just a Time Zone Difference"

2006 Session Title: "Successful Intercultural Communication in Drug Development: More than a Time Zone Issue"

2005 Session Title: "Does Breaking up Have to be Hard to Do? Dissolving Partnerships, Changing CROs"

2004 Session Title: "Heroic Project Management: Meeting the Impossible Deadline"

2004 Talk Title: "March Madness: Six People, Six Weeks, and Six Submissions!"

2003 Session Title: "Success Factors in Managing the Phases of Co-Development and Partnership Projects: The Courtship, the Honeymoon and the Marriage"

2002 Session Title: "Company Approaches to Project Management: Responsibilities, Authority, Structure and Function"

PROFESSIONAL ASSOCIATIONS (continued)

2002 Talk Title “Managing the People Factor: The Real ‘P’ in ‘PM’, Or, Success Factors in Managing Organisms with 1.5 the DNA of a Fruit Fly

2001 Session Title: “Company Approaches to Project Management: Responsibilities, Authority (?), Structure and Function”

2000 Session Title: “Project Management: The View from the Top”

2000 Session Title: “Intercompany Project Management: Coordinating Multiple Companies and CRO’s”

2000 Talk Title “The External Ombudsman: A Successful Approach to Managing the Sponsor/CRO Interface”

1999 Session Title: “Project Planning For Successful Registrations”

1999 Session Title: “Project Planning for Commercial Success”

1998 Session Title: “Managing Projects in the Virtual Development Company” and

1998 Session Title: “Project Management from the Mother Ship: Running Development From A Different Continent”

1997 Session Title: “The Merging Pharmaceutical Industry: Keeping Projects on Track”

DIA Session Chair for the Annual Meeting, Regulatory Affairs Track 1999

1999 Session Title: “Success Factors in Generic Registrations”

DIA Panel Member for the Joint FDA and DIA Project Management Training Workshop Oct. 29-31, 1997
Roles of Industry and Agency, Project Management and Regulatory Staff in Drug Development and Review

DIA Program Committee Member and Session Chair 1996 Annual Meeting 1996

European Society for Regulatory Affairs, Member (ESRA) – now TOPRA 1989 - Present

MIT Alumni Committee: Board of Directors 2005/2006

Pharmaceutical Education & Research Institute, Inc. (PERI), Boston, MA

PERI Faculty Member for Global Webinars

European Regulations: MAA Phase 2009

Overview of FDA 2009

Food & Drug Administration Act (FDAAA): What Companies Need to Know 2009

PERI Faculty Member & Course Presenter for Basic Training Course in Drug Development Course in Washington, DC 2007, 2008

PERI Faculty Member & Course Presenter for Global Regulatory Affairs: Overview of Drugs and Biologics 2007, 2008

PERI Co-Chair, Faculty Member & Course Presenter for the Global Regulatory Affairs: Overview of Drugs and Biologics 2006

PROFESSIONAL ASSOCIATIONS (continued)

PhRMA Meeting Chair for the Annual Meeting for the PERI Regulatory Affairs Professional Development Group	1997
PhRMA Vice Chairman (1996) and Chairman (1997) for the PERI Regulatory Affairs Professional Development Group	1995 - 1998
PhRMA Program Committee Member for the 1993 and 1994 Annual Meetings of the Project Management and Finance Section	1992 - 1994
<u>Philadelphia Section ACS Chemistry Consultant's Group</u>	1996 – Present
<u>Philadelphia Women's Network</u> : Secretary (1985), Vice President (1986)	1982 – 1987
<u>Regulatory Affairs Professional Society (RAPS)</u>	1986 – Present
<u>The Organization for Professionals in Regulatory Affairs (TOPRA)</u>	1986 – Present

PRESENTATIONS AND ABSTRACTS

1. "A Multisubstrate Approach to Inhibitors of Tyrosine Protein Kinases," C. H. Kruse, K. G. Holden, P. H. Offen, P. E. Bender, M. L. Pritchard, J. A. Feild, D. J. Rieman, R. G. Greig and G. H. Post. Presented at the 190 National ACS Meeting, Chicago, IL, September 8, 1985. Abstract 12.
2. "Multisubstrate Enzyme Inhibitors," C. H. Kruse, K. G. Holden, R. D. Sitrin, M. L. Pritchard, J. A. Feild, D. J. Rieman, R. G. Greig

PUBLICATIONS

1. "A truncated v-abl-derived tyrosine-specific tyrosine kinase expressed in *Escherichia coli*," M. L. Pritchard, D. Rieman, J. Feild, C. Kruse, M. Rosenberg, G. Poste, R. G. Greig and B. Q. Ferguson, Biochem. J., 257, 321 (1989).
2. "Synthesis and Evaluation of Multisubstrate Inhibitors of an Oncogene-Encoded Tyrosine Specific Protein Kinase, 1," C. H. Kruse, K. G. Holden, M. L. Pritchard, J. A. Feild, D. J. Rieman, R. G. Greig and G. Poste, J. Med. Chem., 31, 1762 (1988).
3. "Synthesis and Evaluation of Multisubstrate Inhibitors of an Oncogene-Encoded Tyrosine-Specific Protein Kinase, 2," C. H. Kruse, K. G. Holden, P. H. Offen, M. L. Pritchard, J. A. Feild, D. J. Rieman, P. E. Bender, R. G. Greig and G. Poste, J. Med. Chem., 31, 1768 (1988).
4. "An Approach to the Syntheses of the Unsymmetrical α , α -Glycoside Bond in Tunicamycin," C. H. Kruse, K. G. Holden and R. D. Sitrin, Carbohydrate Research. Accepted for Publication.
5. A Convenient Method for the Preparation of N-Blocked Amino Acids," C. H. Kruse and K. G. Holden, J. Org. Chem., 50, 2792 (1985).

PUBLICATIONS (continued)

6. "Study of Aromatic Functional Group Conformations in Solution by Nuclear Overhauser Enhancement and Relaxation Techniques: Detection of p-Electron Density and Correlation with Chemical Reactivity," L. I. Kruse, C. W. DeBrosse and C. H. Kruse, J. Am. Chem. Soc., 107, 5435 (1985)
7. "Imidodisulfamides, 2. Substituted 1, 2, 3, 4-Tetrahydroisoquinolinylsulfonic Imides as Antagonists of Slow-Reacting Substance of Anaphylaxis," F. E.-F. Ali, J. G. Gleason, D. T. Hill, R. D. Krell, C. H. Kruse, P. G. Lavanchy, and B. W. Volpe, J. Med. Chem., 1235 (1982).
8. "Imidodisulfamides, 1. A Novel Class of Antagonists of Slow-Reacting Substance of Anaphylaxis," F. E.-F. Ali, P. A. Dandridge, J. G. Gleason, R. D. Krell, C. H. Kruse, P. G. Lavanchy and K. M. Snader, J. Med. Chem., 25, 947 (1982).
9. "Synthesis of b, g-Unsaturated Amino Acids, " J. E. Baldwin, S. B. Haber, C. J. Hoskins and L. I. Kruse, J. Org. Chem., 42, 1239 (1977).
10. "Synthesis of Chloroisoxazoline Amino Acids," J. E. Baldwin, C. J. Hoskins and L. I. Kruse, J.C.S. Chem. Commun., 795 (1976).

INTERESTS

Foreign Languages, Cooking, Travel