Joseph A. Francisco, Ph.D.

SENIOR MANAGING SCIENTIST

CONTACT INFORMATION

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PROFESSIONAL PROFILE

Dr. Joseph Francisco is a preclinical development professional with more than 25 years of experience in all phases of drug development, from early discovery through preclinical development. He has broad expertise in small-molecule drugs and biotechnology-derived products, with an emphasis on protein-based therapeutics. This body of knowledge extends to peptide and protein therapeutics, with an emphasis on monoclonal antibodies. He has an expert-level understanding of the strategic and tactical aspects of successful preclinical drug development programs, including program design, execution, and management. He is also intimately familiar with regulatory (FDA and ICH) expectations for preclinical safety assessment.

Prior to joining ToxStrategies, Dr. Francisco held senior-level positions in contract research organizations (CROs) and biopharma companies, and he worked as an independent consultant. He holds a Ph.D. in Chemical Engineering, has participated on teams awarded five U.S. patents, and is an author on over 20 publications in the peer-reviewed literature.

EDUCATION AND DEGREES EARNED

1994 Doctor of Philosophy, Chemical Engineering
University of Texas at Austin

1989 Bachelor of Arts, Chemical Engineering and Biochemistry
Rice University, Houston, Texas

PROFESSIONAL ORGANIZATIONS

American College of Toxicology, Member
Councilor, 2017–2020
Education Committee chair, 2020
Program Committee member, 2015–2017

Society of Toxicology, Member
Councilor, Biotech Specialty Section, 2015–2017

Pacific Northwest Association of Toxicologists

Scientific Liaison Coalition
ACT representative, 2015–2017

SELECTED PROFESSIONAL EXPERIENCE

As Chief Toxicologist for the preclinical division of a CRO, defined and implemented the strategic and tactical goals for the toxicology and pathology divisions; worked with the clinical division to ensure that clinical trial designs and goals were supported by nonclinical data; advised clients on scientific and regulatory strategies to support desired regulatory goals.

Provided CRO clients with scientific and regulatory advice to ensure that preclinical development strategies complied with regulatory expectations. Coordinated the study planning process and provided oversight of the laboratory. Mentored scientific staff in areas that included protocol interpretation, method development and refinement, study-related problem resolution, and technique validation. Provided scientific expertise in study conduct, design, and interpretation and led internal cross-functional teams to define and integrate process improvement.

Provided CRO clients with expert scientific and regulatory advice to ensure that preclinical development strategies were consistent with regulatory expectations. Provided advanced comprehensive program management to support the needs of internal and external clients. Involved in strategic and tactical aspects of numerous IND-enabling and late-stage preclinical development programs for US and international clients. Worked with domestic and international pharmaceutical and biotechnology companies, ranging from virtual to large multinational organizations.

At the Principal and Director levels, built dynamic departments to address R&D needs. Developed and managed numerous pre-IND (Investigational New Drug), IND, and clinical programs that used antibody-based therapies for oncology indications.

For a major international company, responsible for the purification, characterization, and safety assessment of recombinant proteins expressed in plants for agricultural and pharmaceutical purposes. Supported submissions to domestic and foreign agencies for regulatory approval.

Researched and developed novel recombinant immunotoxins and antibodies for the treatment of cancer.

PUBLISHED WORK

McDonagh CF, Turcott E, Westendorf L, Webster JB, Alley SC, Kim K, Andreyka J, Stone I, Hamblett KJ, **Francisco JA**, Carter P. 2006. Engineered antibody-drug conjugates with defined sites and stoichiometries of drug attachment. Protein Eng Design Select 19:299–307.

Law CL, Gordon KA, Toki BE, Yamane AK, Hering MA, Cerveny CG, Petroziello JM, Ryan MC, Smith L, Simon R, Sauter G, Oflazoglu E, Doronina SO, Meyer DL, **Francisco JA**, Carter P, Senter PD, Copland JA, Wood CG, Wahl, AF. 2006. Lymphocyte activation antigen CD70 expressed by renal cell carcinoma is a potential therapeutic target for anti-CD70 antibody-drug conjugates. Cancer Res 66:2328–2337.

Cerveny CG, Law CL, McCormick RS, Lenox JS, Hamblett KJ, Westendorf LE, Yamane AK, Petroziello JM, **Francisco JA**, Wahl AF. 2005. Signaling via the anti-CD30 mAb SGN-30 sensitizes Hodgkin's disease cells to conventional chemotherapeutics. Leukemia 19:1648–1655.

Law CL, Cerveny CG, Klussman K, Chace DF, Gordon KA, Meyer DL, Doronina SO, Siegall CB, Senter PD, **Francisco JA**, Wahl AF. 2004. Efficient elimination of B-lineage lymphomas by anti-CD20 auristatin conjugates. Clini Cancer Res 10:7842–7851.

Hamblett HJ, Senter PD, Chace DF, Sun MMC, Lenox J, Cerveny CG, Kissler KM, Bernhardt SX, Kopcha AK, Zabinski RF, Meyer DL, **Francisco JA**. 2004. Effects of drug loading on the antitumor activity of a monoclonal antibody drug conjugate, Clin Cancer Res 10:7063–7070.

McDonagh CF, Beam BS, Wu GJS, Chen JH, Chace DF, Senter PD, **Francisco JA**. 2003. Improved yield and stability of L49-sFv-β-lactamase, a single-chain antibody fusion protein for anticancer prodrug activation, by protein engineering. Bioconjugate Chem 14:860–869.

Francisco JA, Cerveny CG, Meyer DL, Mixan BJ, Klussman K, Chace DF, Rejniak SX, Gordon K, DeBlanc R, Toki BE, Law C-L, Doronina SO, Siegall CB, Senter PD, Wahl AF. 2003. cAC10-vcMMAE, an anti-CD30-monomethyl auristatin E conjugate with potent and selective antitumor activity. Blood 102:1458–1465.

Doronina SO, Toki BE, Torgov MY, Mendelsohn BA, Cerveny CG, Chace DF, DeBlanc RL, Gearing RP, Siegall CB, **Francisco JA**, Wahl AF, Meyer DL, Senter PD. 2003. Development of potent and highly efficacious monoclonal antibody auristatin conjugates for cancer therapy, Nature Biotechnol 21:778–784.

Wahl AF, Klussman K, Thompson JD, Chen JH, Francisco LV, Risdon G, Chase DF, Siegall CB, **Francisco JA**. 2002. The anti-CD30 monoclonal antibody SGN-30 promotes growth arrest and DNA fragmentation in vitro and affects antitumor activity in models of Hodgkin's disease. Cancer Res 62:3736–3742.

Francisco JA, Donaldson KL, Chace D, Siegall CB, Wahl AF. 2000. Agonistic properties and in vivo antitumor activity of the anti-CD40 antibody SGN-14. Cancer Res 60:3225–3231.

Francisco JA, Siegall CB. 1998. Single-chain immunotoxins targeted to CD40 for the treatment of human B-lineage hematologic malignancies, Leukemia Lymphoma 30:237–245.

Ledbetter JA, **Francisco JA**, Siegall CB, Gilliland LK, Hollenbaugh D, Aruffo A, Siadak AW, Mischel-Petty N, Grosmaire LS, Gordon ML, Brown TJ, Moran-Davis P, Mittler RS, Kiener PK, Nadler SG. 1997. Agonistic activity of a CD40 specific single-chain Fv constructed from the variable regions of mAb G28-5. Crit Rev Immunol 17:427–435.

Francisco JA, Schreiber GJ, Comereski CR, Mezza LW, Warner GL, Davidson TJ, Ledbetter JA, Siegall CB. 1997. In vivo efficacy and toxicity of a single-chain immunotoxin targeted to CD40 Blood 89:4493–4500.

Francisco JA, Gawlak SL, Miller M, Bathe J, Russell D, Chace D, Mixan B, Zhao L, Fell HP, Siegall CB. 1997. Expression and characterization of Bryodin 1 and a Bryodin 1-based single-chain immunotoxin from tobacco cell culture. Bioconjugate Chem 8:708–713.

Francisco JA, Gawlak SL, Siegall CB. 1997. Construction, expression and characterization of BD1-G28-5 sFv, a single-chain anti-CD40 immunotoxin containing the ribosome-inactivating protein bryodin 1. J Biol Chem 272:24165–24169.

Francisco JA, Kiener PA, Ledbetter JA, Siegall CB. 1996. Cytokine activation sensitizes human monocytic and endothelial cells to the cytotoxic effects of an anti-CD40 immunotoxin. J Immunol 157:1652–1658.

Francisco JA, Gilliland LK, Stebbins MR, Norris NA, Ledbetter JA, Siegall CB. 1995. Activity of a single-chain immunotoxin that selectively kills lymphoma and other B-lineage cells expressing the CD40 antigen. Cancer Res 55:3099–3104.

Francisco JA, Georgiou G. 1994. The expression of recombinant proteins on the external surface of Escherichia coli: biotechnological applications. Biochem Eng VIII: Ann NY Acad Sci 372–382.

Francisco JA. 1994. Expression of recombinant proteins on the external surface of escherichia coli. University of Texas at Austin Department of Chemical Engineering.

Georgiou G, Poetschke HL, Stathopoulos C, **Francisco JA**. 1993. Practical applications of engineering Gram-negative bacterial cell surfaces. Trends Biotechnol 11:6–10.

Francisco JA, Stathopoulos C, Warren RAJ, Kilburn DG, Georgiou G. 1993. Specific adhesion and hydrolysis of cellulose by intact Escherichia coli expressing surface anchored cellulase or cellulose binding domains. Bio/Technology 11:491–495.

Francisco JA, Campbell R, Iverson BL, Georgiou G. 1993. Production and fluorescence activated cell sorting of Escherichia coli expressing a functional antibody fragment on the external surface. Proc Nat Acad Sci, USA 90:10444–10448.

Francisco JA, Earhart CF, Georgiou G. 1992. Transport and anchoring of β-lactamase to the external surface of Escherichia coli. Proc Nat Acad Sci, USA 89:2713–2717.

PATENTS AWARDED

Siegall CB, Wahl AF, **Francisco JA.**, Fell HP. 2005. Methods for the treatment and prevention of cancer using anti-CD40 antibodies, US Patent 6,843,989.

Siegall CB, Wahl AF, **Francisco JA.**, Fell HP. 2005. Nucleic acids encoding anti-CD40 proteins and methods of producing recombinant anti-CD40 proteins, US Patent 6,838,261.

Georgiou G, **Francisco JA**, Earhart CF. 1994. Expression of proteins on bacterial surface, US Patent 5,348,867.

Francisco JA, Risdon G, Wahl AF, Siegall CB. Recombinant anti-CD30 antibodies and uses thereof, WO 02/43661.

Siegall CB, Wahl AF, **Francisco JA**, Fell HP. Recombinant anti-CD40 antibody and uses thereof, WO 00/75348.

CONTINUING EDUCATION

2016 Unique Approaches to Safety Assessment of Gene, Cell, and Nucleic Acid-Based Therapies: Society of Toxicology

2016 The Breakthrough of Oligonucleotide Therapeutics: What is Happening in between Small and Large Molecules: American College of Toxicology

2015 Juvenile Toxicity Studies: Defining and Overcoming the Challenges: American College of Toxicology

2014 Metabolites: Guidance and Considerations in Drug Development: American College of Toxicology

2009 Project Management in Preclinical Drug Development: Global Preclinical Training

2009 Interactions with Regulatory Agencies: What to Do and What Not to Do: American College of Toxicology