# Curriculum Vitae

**Tanya M. Scharton-Kersten, Ph.D., RAC**
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Scientist. Global Regulatory Affairs Professional (20+ years and RAC). PhD in Immunology; experience with bacterial, metabolic, neurologic and viral disease prevention and treatment. Focused on innovative biologics, gene therapies, and vaccines. Motivated by developing AND implementing global regulatory strategies for novel and emerging platform technologies. Engaged, get things done, risk-based decision maker and 'doer' for complex CMC projects.

## SUMMARY OF REGULATORY EXPERTISE

- FDA and worldwide health authority meetings and negotiations
- CMC expert for innovative biological, device and drug technologies
- 20+ years of experience in regulatory filings for gene therapy, bacterial and viral vectored vaccines, DNA and RNA constructs, proteins, and nanoparticles
- IND/CTA, BLA-MAA, and post marketing submissions and approvals
- Authoring and review of gap analyses, risk assessments, white-papers, RTQ (responses to questions) for investors, funding agencies and health authorities
- International GxP expertise: GMP, GLP, GDP, GCP, GCLP, QC, QA
- Regulatory Affairs Professional Society member and global certified professional.

## EXPERIENCE

**Kersten Compliance Services, LLC**
Independent Consultant, Global Regulatory Affairs, Innovative Technologies (2018 to present) Dobbs Ferry, New York

Regulatory Affairs services for innovative products and technologies including product designations, FDA / health authority consultations, negotiation of cell substrate/ host cell topics, and First-in-Human regulatory submissions.

Planning and/or authoring of IMPD/IND/CTAs, white papers, risk assessments, analytical comparability protocols and reports, and responses to FDA and other health authority questions.

**Syneos Health (**formerly **Inventiv Health)**
Regulatory Senior Executive (2017 to 2020)
Dobbs Ferry, New York (long term contract assignment)

Vaccine related post licensure marketing supplements for 10+ bacterial and viral products: annual reports, CBE0, CBE30, PAS filings.

**Population Council Inc (Non-Profit Organization)**
Manhattan, New York

Director (Head) of Global Regulatory Affairs for Research (2016 – 2017)

- Led CMC and Quality activities for the Council's Center for Biomedical Research (CBR) at Rockefeller University (Weiss Research Building, New York, New York). (http://www.popcouncil.org/research/united-states)
- Initiated new INDs (biologics and devices), maintain open INDs (twelve) and support new NDA filing (one) for male/female contraceptive drugs and devices (vaginal rings).
- Interfaced with internal and contract manufacturing groups on behalf of the Council and government partners (USAID; NIH).
- Managed RA-QA team and mentored interns to achieve organizational goals.
- Clinical Trials.gov examples of applications: NCT03230539 (novel IUD, contraception); NCT02875119.

**International AIDS Vaccine Initiative (IAVI, Non-Profit Organization)**
Manhattan, New York

Senior Director (Head) of Regulatory Affairs and Quality (2014 – 2016)

- Led RA-QA activities for IAVI's sponsored INDs for novel anti-HIV vaccine products.
- Led RA-QA activities the for the Bill and Melinda Gates Foundation, Vaccine Development Center (VxPDC), a 50 Mio funded contract program, through IAVI, for HIV product development (https://www.cavd.org).
- Supported new IND/CTAs for multiple first in human novel vaccine products (proteins, viral vectors, small molecules).
- Volunteer RA professional with the World Health Organization (WHO) during international Ebola outbreak (2014-2015).

**Novartis Vaccines and Diagnostics** (2007-2014)

Holly Springs, North Carolina (1 year) – RA- US Health and Human Services Liason
Marburg, Germany (3 years), CMC Group Head, Regulatory Affairs
Basel, Switzerland (3 years), Global Head, Quality Control

- Selected to initiate and manage Chiron-Novartis Regulatory CMC function.
- International CMC responsible for all Chiron/Novartis Vaccines.
- Integrated US, UK, Italian, German regional offices and started Hyderabad, India regulatory CMC office. Managed international staff of 30 regulatory professionals.
- Supported annual influenza license renewal for five distinct manufacturing processes in over 50 countries. Led first influenza, cell-culture, vaccine registration in Japan.
- Led pharmacopoeial, scientific writing and technical education training of RA professionals.
- Managed site and global change control operations for over a dozen licensed products.
- Quality Control head (Italy, 2013-2014) responsible for 300 permanent and contract

laboratory staff, release/recall of Chiron/Novartis vaccines licensed products from its Siena/Rosia manufacturing facilities and all laboratory preapproval and routine inspections (Italian government, FDA, Health Canada etc).

**Biologics Consulting Group, Inc.**
Cary, North Carolina (2001- 2007)

CMC Consultant (50%)
GLP/Non-clinical Consultant (50%)

- Regulatory strategy and submissions, IND CMC (Module 3 drafting); first India external HIV manufactured clinical trial application.
- Nonclinical facility qualifications for client, study sponsors (examples: BioReliance, Charles River Laboratories, Covance, CTBR, HLS, MPI).
- Nonclinical study management including monitoring of more than a dozen toxicology studies at US and international CROs for client, study sponsors.

**IOMAI Corporation**
Washington, DC (1997-2000)

CMC RA and Quality Responsible
Senior Scientist / Basic Science Program Manager

- First employee of Walter Reed Army Institute of Research (WRAIR) based, transdermal, protein delivery biotechnology company.
- Established and managed organization's quality system and standards.
- Prepared and submitted INDs for first in human clinical trials for LT (cholera heat labile enterotoxin) and LT facilitated protein based tetanus vaccines.

**EDUCATION**

- Regulatory Affairs Certification (RAC), Global Regulatory Affairs
- Postdoctoral fellowship, National Institutes of Health (NIH), National Institute of Allergy and Infectious Diseases, Bethesda, MD: Postdoctoral fellowship
- PhD, University of Pennsylvania, Philadelphia, PA: Ph.D. *Immunology*
- B.A, University of California, Berkeley, CA: B.A. *Microbiology and Immunology*

## HONORS AND AWARDS (representative)

- Novartis Group Quality Foundation Award (2012) for Lean Lab / Operational Excellence program
- Novartis (V&D) Development recognition for support of new product licensure process (2011) – *Japan Market License for Cell Based Influenza Vaccine*
- Novartis (V&D) Tech Ops and Quality Annual Leadership award (2010) for QC Laboratory Strategic Plan introduction and execution

## BIBLIOGRAPHY (representative)

Over 40 publications listed in Medline (Scharton and/or Scharton-Kersten) in fields of immunology; vaccine development and process improvements.


- Scharton-Kersten et al. (2013) Incorporating Lean Principles into Pharmaceutical QC Laboratory Design: Building design influencing laboratory behaviours and effectiveness. White Paper.
- Scharton-Kersten,T., Yu, J., Vassell, R., O'Hagan, D., Alving, C., and Glenn, G. (2000). Transcutaneous immunization with bacterial ADP ribosylating exotoxins, subunits, and unrelated adjuvants. *Infection and Immunity*. 68:5306.
- Scharton-Kersten, T, Glenn, G.M., Vassell, R., Yu, J., Walwender, D., and Alving, C.R. (1999). Principles of transcutaneous immunization using cholera toxin as an adjuvant. *Vaccine*. 17:S37.
- Walker, P.S., Scharton-Kersten, T., Krieg, A., Rowton, E., Udey, M.C., and Vogel, J.C. (1999). Immunostimulatory oligonucleotides promote protective immunity and provide systemic therapy for leishmaniasis via IL-12- and IFN-gamma dependent mechanisms. *Proceedings of the National Academy of Science.* 96:6970.
- Scharton-Kersten, T., Nakajima, H., Yap, G., Sher, A., and Leonard, W.J. (1998) Infection in mice lacking the common cytokine receptor gamma-chain (gamma(c)) reveals an unexpected role for CD4+ T lymphocytes in early IFN-gamma-dependent resistance to *Toxoplasma gondii. Journal of Immunology* 160:2565.
- Scharton-Kersten, T.M., Contursi, C., Masumi, A., Sher, A., and Ozato, K. (1997) ICSBP deficient mice display impaired resistance to intracellular infection due to a primary defect in IL-12p40 induction. *Journal of Experimental Medicine* 186:1523.
- Scharton-Kersten, T.M., Yap, G., Magram, J., and Sher, A. (1997) Inducible nitric oxide is essential for host control of persistent but not acute infection with the intracellular pathogen, *Toxoplasma gondii. Journal of Experimental Medicine* 185.
- Scharton-Kersten, T.M. and Sher, A. (1997) The role of natural killer cells in innate resistance to protozoan infections. Current Opinion in Immunology 9:44.
- Scharton, T. M. and Scott, P. (1993) Natural killer cells are a source of interferon- gamma that drives differentiation of CD4+ T cell subsets and induces early resistance to *L. major* in mice. *Journal of Experimental Medicine* 178:56.