Regulatory Affairs Masters and Certificate Programs

Education to enhance excellence and career advancement in pharmaceutical, biotechnology, and medical device industries

SAN DIEGO STATE UNIVERSITY
College of Sciences
CORE FACULTY

- **Linn Bekins**, PhD, Associate Professor
  Rhetoric and Writing Studies, SDSU
- **Lorah Bodie**, EdD, Associate Director
  Regulatory Science, SDSU
- **Scott Harris**, MS, RAC, Exec. VP
  RA & Product Development, Adynxx, Inc.
- **Barney King**, MD, MBA, CEO
  Macnas Consulting, Inc.
- **Gautam Maitra**, Fil.Lic., MS, Head of Regulatory and External Affairs, AC Immune
- **Darrel Moellendorf**, PhD, Professor
  Goethe University, Frankfort, Germany
- **Norma Schafer**, MS, MT(ASCP), RAC, VP,
  Regulatory Affairs & Quality Assurance,
  SteadMed Medical
- **Mitchell Seymour**, PhD, RAC, Research Faculty
  Univ. of Michigan Medical School, Founder & Principal, R&D Advisors & SciMedLit, LLC
- **Katia Sharikova**, MS, PMP, Global Oncology Operations Manager, Novartis Institute for Biomedical Research
- **K.A. Ajit Simh**, MS, Principal Consultant
  Shiba Biotechnology Consultants
- **Rita Tomlin**, MA, MT(ASCP), Owner/Medical Writer, Tomlin Consulting, LLC
- **Gretchen Vik**, PhD, Professor
  Management Information Systems, SDSU
- **Kim Walker**, MS, RAC(US & EU), Consultant
  Kim Walker Consulting
- **Mary Wilhelm**, MS, CQA, RAC, Sr. Director
  Regulatory Affairs Halozyme Therapeutics, Inc.

REGULATORY AFFAIRS COURSES

- **RA 601** Pharmaceutical, Biotechnology and Medical Device Industries
- **RA 602** Food and Drug Law
- **RA 605** Medical/Scientific Writing
- **RA 705** Project Planning
- **RA 750** Leadership for Change
- **RA 770** Current Good Manufacturing Practices
- **RA 772** Post-Approval Activities
- **RA 773** Medical Device Regulations
- **RA 774** Investigational and Marketing Applications for Drugs and Biologics
- **RA 775** Clinical Trials
- **RA 778** Quality Control and Quality Assurance
- **RA 779** International Regulatory Affairs Ethics
- **RA 781** Effective Communication

All course are online and designed for maximum flexibility. Faculty bios and complete course descriptions: regsci.sdsu.edu

*Course required for RA certificate*
Students in our WASC-accredited Masters Degree Program build foundational knowledge on laws, regulations, and good quality practices mandated by the FDA and international counterparts. The 4-course Advanced Certificate Program is a subset of the MS Program and can be count toward that degree. Students gain a working knowledge and practical understanding from globally recognized industry faculty experts.

An Advanced Certificate in Intellectual Property and Regulatory Affairs is offered in partnership with the USD School of Law.

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