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.

All course are online and designed for maximum flexibility. Faculty bios and course descriptions: regsci.sdsu.edu
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
• **RA 781*** Ethics
• **RA 783** Effective Communication

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*Course required for RA certificate