



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, Frankfurt, 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

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

**Course required for RA certificate*



Regulatory Science



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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regsci.sdsu.edu