

Curriculum Vitae



Kelly H. Reich, M.S.

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Associate

Biologics Consulting Group, Inc.

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EXPERIENCE

Biologics Consulting Group, Inc., Associate

Alexandria, Virginia (July 2001 - present)

- Serves as a project manager for FDA submissions
 - Including INDs and BLAs and RAC submissions to OBA
 - Familiar with FDA policies and procedures at CDER/CBER
 - Has assisted clients with Establishment Registration and Drug Listing
 - Familiar with legacy IND format (following form 1571) and CTD format
 - Can provide document formatting assistance for Word files
 - Readies documents for printing or electronic submission
- Provides electronic publishing services for FDA submissions
 - Familiar with publishing and submission of electric documents to FDA
 - Familiar with legacy IND format (following form 1571) and CTD format
- Provides regular support to US Agent clients with regard to IND and BLA maintenance

Fisher Diagnostics, Marketing Assistant, part-time.

Middletown, Virginia (Spring 2001)

- Responsible for lead generation for diagnostic contract manufacturing facility.
- Maintained database of current clients and potential leads
- Conducted internet research to establish potential leads.

Sun Biomedical, Laboratory Technician

Blackwood, New Jersey (Summer 2000)

- Researched immunochromatographic techniques for drug screening urine tests.
- Prepared reagents according to SOPs
- Evaluated and optimized the test components for rapid diagnostic tests.
- Reported and recorded the test results, keeping the records according to FDA's GLP requirements.



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- Performed in-house drug testing on walk-in subjects.

EDUCATION

M.S., *Biotechnology & Regulatory Affairs*, Johns Hopkins University (2007)

B.S., *Biotechnology*, James Madison University's College of Integrated Science and Technology (2001)

CONTINUING EDUCATION

Sept. 2009	RAPS 2009 Annual Conference & Exhibition
Sept. 2008	RAPS 2008 Annual Conference & Exhibition
Sept. 2007	RAPS 2007 Annual Conference & Exhibition
Oct. 2006	RAPS 2006 Annual Conference & Exhibition
Oct. 2005	FDA's eCTD Tutorial
Oct. 2005	RAPS 2005 Annual Conference & Exhibition
June 2005	BIO 2005
Oct. 11-13, 2004	RAPS 2004 Annual Conference & Exhibition
Sept. 20-22, 2004	PDA/FDA Joint Regulatory Conference
Oct. 19-22, 2003	RAPS 2003 Annual Conference & Exhibition
Oct. 13-15, 2003	Virginia Biotechnology Summit and Governor's Conference
Oct. 2002	RAPS 2002 Annual Conference & Exhibition
Oct. 14-16, 2002	Virginia Biotechnology Summit and Governor's Conference on Technology Transfer and University Research
April 2002	RAPS, RA/QA 101
Oct. 22-23, 2001	Virginia Biotechnology Summit and Governor's Conference on the Human Genome and the Law
Nov. 5-7, 2001	RAPS Annual Conference & Exhibition

PROFESSIONAL SOCIETIES

2001-present, member Regulatory Affairs Professional Society (RAPS)

HONORS AND AWARDS

2010	Achieved US RAC Certification
2009	BCG special appreciation peer award for electronic submission work