

Laura Schiavoni, RAC

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EDUCATION **UNIVERSITY OF ILLINOIS AT URBANA-CHAMPAIGN**
Bachelors of Science in Biology, 2004

WORK EXPERIENCE **BAXTER HEALTHCARE, INC.** Round Lake, Illinois
Global Regulatory Affairs Associate *Jan. 2008- Present*

- Member of global core team responsible for bringing CE marked devices into compliance with requirements of MDD 2007/47/EC
- Coordinated Baxter comments to FDA and GHTF draft guidances
- Provided regulatory support for clinical trials in Critical Limb Ischemia (CLI) and Chronic Myocardial Ischemia (CMI)
- Researched and presented options for expedited review of market application
- Assisted in preparing for and conducting FDA meetings
- Prepared numerous IND submissions including original protocols, protocol amendments, safety reports, investigator updates, and formal meeting minutes
- Prepared IND and PMA annual reports and Somatic Cellar Therapy Response Letter
- Responsible for monitoring Federal Register and informing team of relevant guidances, postings, and upcoming meetings

HOSPIRA, INC. (THROUGH KELLY SCIENTIFIC) Lake Forrest, Illinois
Registration Coordinator *Nov. 2007- Jan. 2008*

- Compiled support packages for international registration of devices
- Reviewed and updated technical files for marketed medical devices

PONIARD PHARMACEUTICALS, INC. Seattle, Washington
Regulatory Coordinator *June 2006-Sep. 2007*

- Organized and attended multiple meetings with FDA
- Assisted in writing and submitting an IND, Special Protocol Assessment, and Request for Fast Track Designation
- Assisted in writing and submitting an Application for Orphan Drug Designation in the EU
- Worked with CROs in the EU, Eastern Europe, and India to assure regulatory requirements were met for Phase II and III studies conducted OUS
- Prepared numerous meeting requests and briefing documents for meetings with FDA
- Prepared and submitted IND and Orphan Drug Annual Reports
- Prepared and submitted over 40 submissions to FDA including Safety Reports, Protocol Amendments, and Investigator Updates
- Authorized shipments of drug to clinical sites
- Authored various Regulatory SOPs
- Approved IBs, ICFs, and Clinical and Regulatory SOPs
- Renewed DEA and Department of Pharmacy Licenses

MIDWESTERN UNIVERSITY Downers Grove, Illinois
Laboratory Technician *Aug. 2004- July 2005*

- Trained and supervised graduate students, medical students, and laboratory technician
- Maintained monolayer cultures of Human Retinal Pigment Epithelium Cells including feeding, passaging, collection, and quantification of protein
- Performed SDSpage, semi-dry transfers, and immunoblotting of protein
- Carried out RNA extraction, quantification, and amplification
- Executed PCR and gene microarray procedures
- Managed and maintained maintenance logs, budget expenditures, and supply orders

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- CONTINUED EDUCATION**
- Regulatory Affairs Professional Society, July 2009
“Ensure Compliance with the New EU Medical Device Directive Requirements-2010 Deadline.”
 - **US RAC (Regulatory Affairs Certification)**, June 2009
 - Advanced Medical Technology Association (AdvaMed)
Investigational Device Exemptions (IDE) Seminar, February 2008
 - Advanced Medical Technology Association (AdvaMed)
Premarket Approval (PMA) Submissions Workshop, February 2008
 - Drug Information Association
Regulatory I: The IND Phase, March 2007
 - University of Washington
Biomedical Regulatory Affairs Certificate Course, August 2005 – June 2006

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- Professional Associations**
- Regulatory Affairs Professional Society, Member since 2006
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