# Dana Oxenberg

**Senior Associate, Regulatory Affairs**

Royersford, PA - Email me on Indeed: indeed.com/r/Dana-Oxenberg/787b5e56ffb87161

Authorized to work in the US for any employer

WORK EXPERIENCE

### Senior Associate, Regulatory Affairs

Ranbaxy Inc - Princeton, NJ - May 2014 to June 2015

• Submitted pre and post approval submissions for ANDA and NDA submissions (CMC, annual reports, amendments, supplements) and assisted with original IND and NDA submissions.
• Provided regulatory guidance to personnel within company and 3rd party testing, manufacturing, and packaging facilities.
• Actively participated in product/site specific meetings and provided regulatory input and filing strategies.
• Maintained a log of all FDA commitments and provided updates to the regulatory group to ensure that all FDA commitments were fulfilled by the assigned deadline.

### Regulatory Affairs Associate (OTC Products)

McNeil Consumer Healthcare - Fort Washington, PA - September 2013 to March 2014

Fort Washington, PA, September 2013 - March 2014 (Contract: Radiant Systems Inc.)
Regulatory Affairs Associate (OTC Products)
• Prepare and publish paper and electronic submissions to submit through FDA's Gateway utilizing CONNECT (Global Documentum Repository System) and DocuBridge (publishing tool)

### Regulatory Affairs Associate

Teva Pharmaceuticals - North Wales, PA - October 2006 to July 2013

• Submitted generic drug applications (ANDAs) for many high priority first to file - Paragraph IV applications in ANDA, CTD, and eCTD formats.
• Prepared change controls, provided regulatory strategy, and authored associated regulatory submissions (CMC, Annual Reports, CBE-0, CBE-30, Prior approval Supplements, Amendments, etc.) for labeling updates, site transfers, manufacturing changes, changes in testing methodology, patent certification and exclusivity updates.
• Responded to FDA deficiency letters for proposed changes, Post-marketing Safety Reports and Risk Management Program Reports (RMPs).
• Technical review of all data/reports that are incorporated into regulatory submissions to assure scientific rigor, accuracy, and clarity of presentation.
• Managed projects leading to the submission and approval of drug products.
• Maintained approved applications in compliance with current FDA regulations and guidances.Trained new employees and delegated/managed work among associates in the department
• Assisted in the transfer of products/information.
• Worked in teams to complete various regulatory projects and actively contributed ideas and implemented new processes to improve efficiency within the department.
• Maintained current with on-going changes within the regulatory environment through FDA workshops and external training.

### Engineer, Process Engineering

Teva Pharmaceuticals - Sellersville, PA - October 2005 to October 2006

• Created SOP's, Process Protocols, executed Batch Records (Production, Commercial, Process Development)
• Gained experience in using pharmaceutical equipment (high-shear mixers, V-blenders, tablet presses, mills, fluid-bed dryers, packaging equipment)
• Trouble-shooting, design of experiment (DOE) work using statistical programs (JMP, statgraphics, minitab). Served as the lead member in the group to choose a statistical program, work directly with the technical group supporting the software, completed training, and helped modify program to support the needs of the group. Provided training to group.
• Prepared all documentation required to produce a batch, Planning forms, Bill of Materials, Routers, Cleaning Validation, Stability Initiation, Packaging and labels, etc.
• Monitored/supervised the manufacture of validation batches as needed
• Compiled and analyzed data for various reports (Stability Reports, Comparative Dissolution Reports, Process Characterization Reports). Completed the necessary documentation for drug applications.
• Validated Tablet Presses (IQ, OQ, PQ)
• Attended training given by Glatt, Mixing Consultants, JMP (SAS), Emerson Resources, TA.XT., Interphex, Member of ISPE (International Society of Pharmaceutical Engineering)

### Validation Specialist I, Validation

MedImmune Vaccines - Bensalem, PA - August 2005 to September 2005

Assisted experienced employees in the validation and metrology department. Responsibilities include maintenance of database, validation of certain equipment, and calibration of instruments and measuring devices acquired by MedImmune. This also required proper documentation of records and GMP/FDA training.

EDUCATION

### B.S. in Bioengineering/Chemical Engineering Option

Pennsylvania State University, State College
May 2005

GROUPS

### RAPS

ADDITIONAL INFORMATION

COMPUTER SKILLS

• Microsoft Windows, Word, Excel, FrontPage, PowerPoint, C++, MATLAB, Mathematica, Minitab, JMP 6.0, Oracle, WISDOM, Citrix, Lotus Notes, Liquent InSight® Publisher, CONNECT, DocuBridge, GxPharma, AS400, LIMS, FirstDoc, Microsoft Outlook