

Ilir Demollari

Senior Associate, Regulatory Operations - Regulatory Operations - Accenture

Berwyn, PA - Email me on Indeed: [indeed.com/r/Ilir-Demollari/2a56c41949df7419](https://www.indeed.com/r/Ilir-Demollari/2a56c41949df7419)

Driven Regulatory Associate with profound experience in publishing submissions utilizing various technologies in the field. Fully knowledgeable in submissions publishing and associated management processes. Excellent work ethic and experience in working as a team and individually in always meeting difficult timelines. Authorized to work in the US for any employer

WORK EXPERIENCE

Submission Coordinator, Regulatory Operations

Accenture - Berwyn, PA - October 2008 to Present

- Build/Publish IND, NDA, aNDA, EMA, BLA submissions using eCTD tools including, but not limited to, Viewpoint, sCubed, eCTD Builder, eCTD Validator, Lorenz and eCTD Viewer.
- Collaborate with submission manager and regulatory affairs in planning and setting submission timelines and quality standards; Responsible for the overall quality of deliverables through validation and compilation of submissions to ensure all warnings and errors are reported and resolved in a timely fashion.
- Work in concert with many clients on multiple submission types in order to meet challenging timelines while always producing exceptional quality results.
- Involved in submission processes by executing Initial Reviews, Publishing, and QC on all documents; engage other associates to verify quality to the extent of the company's interests.
- QC for each submission module completed in eCTD backbone; bookmark structure and hyperlinks created and verified to ensure submission-readiness.
- Coordinate and manage multiple project assignments, manage workflows for all publishing tasks, and communicate issues and resolutions in an appropriate time frame
- Provide staff augmentation support to Janssen:
 - Build submissions by generating the XML backbone and populating leaf files for submissions
 - Preparation of submission ready eCTD compliant documents
 - Publishing experience - create Hyperlinks/Cross-References/Bookmarks

Head Teller

New Century Bank - Wayne, PA - May 2005 to October 2008

- Responsible for managing daily banking transactions and security.
- Create and build client relationships in order to increase the number of return customers.
- Assist customers with their financial objectives by presenting products and financial options.
- Influence and motivate the teller team to increase the level of their performance.

EDUCATION

Associate's in Liberal Arts and Sciences/Liberal Studies

Delaware County Community College - Media, PA

2008

ADDITIONAL INFORMATION

Additional Strengths/Skills

- Experienced in ISI Toolbox, ViewPoint, eCTD Builder, eCTD Viewer, eCTD Validator, Submission Lifecycle Management, Insight Gatekeeper, s-Cubed, Documentum, FTP, and eRoom.
- Very skilled in Microsoft Office products such as Excel, Outlook, PowerPoint, Word, Publisher, Project and Access.
- Possess strong interpersonal verbal and written communication skills with a committed work ethic and superior attention to detail.
- Strong organizational skills; experience in research, analysis and presentation of data.
- Self-motivated and reliable in working individually or in groups.