Keli L. Rommel
Regulatory Operations

Summary. Regulatory operations and electronic publishing professional with extensive knowledge of submission and report requirements as well as experience administering document management systems.

Areas of expertise include:

- Assembly and publishing of major and routine Health Authority submissions
- Compilation and publishing of report-level submissions
- Document formatting and submission component processing
- Template creation and maintenance
- Project lead on the selection, design and implementation of regulatory content management system
- Collaboration with QA to transition paper-based GMP document tracking and approval to electronic system utilizing features in CMS and Acrobat
- Expertise in developing document standards and submission-ready component standards
- EDMS/CMS administration, including creation and maintenance of users, groups, ACLs, workflows, doctypes and their properties, and picklists

Professional Experience

Accellient Partners
Regulatory Operations: 2012

Unigene Laboratories, Inc.
Manager, Regulatory Operations/Reg Ops Specialist: 2009-2012

Aerotek Scientific
Submissions Operations Publisher, Wyeth Consumer Healthcare: 2008-2009

Apyx
Drug Regulatory Affairs Submission Publisher, Novartis: 2006-2008

Wyeth Consumer Healthcare
Sr. Documentation Coordinator, Submissions Operations: 2001-2006

Wyeth Consumer Healthcare
Senior Assistant, Global Clinical & Medical Affairs: 1996-2001

Education/Certification

2004-2006; BA Program, St. Leo University Online
2002-2002; BA Program, University of Phoenix Online