

# CHRISTINE BAXTER

Linwood, KS | 913.209.7112 | [christine.baxter@baxtersllc.com](mailto:christine.baxter@baxtersllc.com)



<https://www.linkedin.com/in/christinedbaxter/>



<https://christinedbaxter.github.io/christineBaxterPortfolio/>

## BUSINESS TECHNOLOGY/PROCESS CONSULTANT

*"Driving automation and efficiency by combining operations and technology expertise."*

**Motivated, meticulous, and personable business professional with an extensive background in pre-publishing, publishing, validation, and review activities for investigational and marketing applications.** Talent for quickly mastering technology – liaison between users, management, and IT department.

**Diplomatic and tactful.** Accustomed to working with internal and external customers/vendors, providing technical product and process support. Experience producing efficient processes and consistently meeting client expectations/timelines.

**Flexible and versatile.** Able to maintain composure under pressure, successful in deadline-driven environments. Excellent team-building skills. Initiative-taking, collaborator who quickly adapts to change and is committed to high quality work.

**Accomplished Regulatory Operations and Information Management professional with 25 years' experience** supporting regulatory submission operations across pharmaceutical and CRO environments. Able to prioritize tasks, work on multiple submissions, maintain confidentiality, and provide excellent customer service.

*"During the 12 years I managed Christine, she constantly and consistently worked at improving her technical skills as well as her knowledge of compiling and presenting data analytics for performance and business reviews; understanding and applying the 21CFR Part 11 requirements and eCTD requirements; developing client and submission management processes, and personnel management. Christine's strong IT background and her many years of experience working in a highly regulated industry make her an outstanding candidate for any size organization."*

*- Gina Ross, Owner/Managing Member of One-Eleven Consulting and Contracting, LLC*

*"In my 12 years working alongside and collaborating with Christine, she consistently demonstrated a very strong aptitude to understand how business data analytics and business intelligence can support sound business decisions. Further, Christine successfully developed data aggregation programs and visualization tools at Cardinal Health which both enabled data-informed decision making and provided the foundation for the regular preparation of quarterly and yearly business metrics which proved highly valuable in marketing and sales initiatives and in new client acquisition."*

*- Greg Onyszchuk, Head of Regulatory Affairs at Lexicon Pharmaceuticals, Inc.*

## SKILLS

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|------------------------------------|----------------------------|------------------------------|
| ◆ Power Platform (BI, Automate)    | ◆ System Implementation    | ◆ eCTD Publishing            |
| ◆ Microsoft Office                 | ◆ System Validation        | ◆ eCTD Structure/Lifecycle   |
| ◆ Adobe DC Pro                     | ◆ Process Documentation    | ◆ Agency Portals             |
| ◆ ToolBox Pharma                   | ◆ User/Application Support | ◆ FDA/ICH Specs              |
| ◆ ToolBox Standard                 | ◆ User Training            | ◆ SEND, SDTM, ADaM           |
| ◆ MURAL                            | ◆ Project Lead/Management  | ◆ ICSR, E2B (R2/R3)          |
| ◆ XML Coding                       | ◆ Tableau (Beginner)       | ◆ eSubmitter/eCopies         |
| ◆ SharePoint (User/Classification) | ◆ Basic Database/SQL       | ◆ eDRDL (LCR, DR, DL)        |
| ◆ Word Templates/Macros            | ◆ VBA                      | ◆ LDR Preparation/Submission |

## EDUCATION

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Keller Graduate School of Management of DeVry University (in-progress) **2023**  
**MBA | Business Intelligence & Analytics Management**

Keller Graduate School of Management of DeVry University **2021**  
**Graduate Certificate | Big Data and Analytics**

DeVry University **2003**  
**BS | Computer Information Systems | *summa cum laude***  
 Accelerated Program, 3.94 GPA

## PROFESSIONAL EXPERIENCE

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Owner/Managing Member 2020-Present  
 Baxter's LLC  
 Linwood, Kansas

Senior Consultant, Business Technology 2017-2020  
 Cardinal Health Regulatory Sciences  
 Overland Park, Kansas

Manager, Regulatory Submission Operations 2009-2017  
 Cardinal Health Regulatory Sciences  
 Overland Park, Kansas

Document Publishing Manager, Regulatory Publishing Services 2005-2009  
 Beckloff Associates, a Cardinal Health company  
 Overland Park, Kansas

Associate Document Management Specialist, Regulatory & Technical Services 2003-2004  
 Quintiles, Inc.  
 Kansas City, Missouri

## AWARDS/HONORS

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High Impact Award, chosen by Executive Leaders for successfully leading and implementing Publishing Software Validation	2016
Inspiration Award, nominated by Executive Leader for positive, can-do contagious attitude, commitment, high quality work, and sharing of knowledge	2011

## AREAS OF EXPERIENCE

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- Twenty-five plus (25+) years of publishing experience within the pharmaceutical industry (paper, eNDA, electronic Common Technical Document [eCTD], non-eCTD electronic submissions [Nees], Clinical Study Reports, INDs, Annual Reports, Clinical Trial Applications, Biologics License Applications, etc)
- Fifteen years as a top expert at Cardinal Health Regulatory Sciences on electronic publishing formats, process, specifications, and software
- Management/technical support of paper and electronic document preparation process, including establishing company format standards
- **Analytical Thinking**
  - Identified data requirements, often beyond the standard, and collected all relevant data needed to analyze a complex problem, situation, or issue
    - Listened to users regarding what steps were being completed when problem arose, analyzed information to help solve problem and get user working again
    - Implemented procedures for users to provide information that assists in troubleshooting processes
  - Advised others on a variety of topics within own functional area; accessed appropriate resources/expertise to obtain technical information as needed
    - Worked with IT department to put backup procedures in place, minimizing rework and reducing user downtime when application issues arose
    - Prepared training materials and provided group/1:1 instruction
  - Leveraged and collaborated with the appropriate resources, providing complex solutions for internal and/or external customers
    - Engaged appropriate IT individuals, management, and peers when needed
  - Rapidly learned and mastered varied computer programs and technologies
  - Served as an expert within technical area and educated others on technical issues
- **Customer Service/Problem Solving**
  - Utilized knowledge of customers' offerings and collaborated with others as necessary to make recommendations that considered the impact of key business drivers
  - Liaised between users, consultants, IT, and management

## AREAS OF EXPERIENCE (continued)

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- Resource for consultants regarding content and submission specifications
  - Kept current with Agency specifications/rules
  - Open and available for questions in area of expertise as well as higher level aspects
- Listened to customer needs and their business challenges
- Developed and implemented new innovative solutions to complex or critical work issues, applying responsible risk to maximize results and achieve operational excellence
- Kept apprised of and updated management on impending project issues
- Approached issues from multiple perspectives and collaborated with internal/external customers to generate creative, effective, and practical solutions
- **Validation project work** covering installation and maintenance of publishing application tools
  - Lead and managed platform upgrades, validation, and specialized projects (i.e., digitization of File Room, Power BI Metrics Visualizations/Dashboards)
  - Managed and coordinated work for team of 10-12 individuals on the digitization project, including developing and training on processes as well as ordering of any needed supplies
  - Collaborated closely with General Manager and Executive Leaders for metric visualizations which ended up in presentation deck for senior managers and sales department
  - Spearheaded projects and served in a variety of roles (e.g., Validation Lead/Project Manager; Author/Reviewer/Approver for validation deliverables; System administrator/configuration; Application administrator; User/process support; Liaison with DBA, corporate and local IT, vendor, and management; Mentor/Trainer of validation team members)
  - Managed and coordinated work for team of 3-5 individuals consisting of users and power users
  - Monitored project budget and made necessary adjustments to ensure projects did not exceed allocated monies
  - Overseen, collaborated, and reviewed preparation of training materials as well as conducted training for users
  - Strategized and resolved any unexpected issues
- **Technologies**
  - Worked across departments on determining current/future software subscription licensing needs, vendor communication/interactions
  - System and application admin handling security, back-end configurations, maintenance, and integrating department standards into user workflow
  - Change Adoption Champion, driving user adoption of MS 365 technologies (i.e., MS Teams, Planner)
  - Utilize Power platform, producing back-end automation for project status/tracking tasks

## • AREAS OF EXPERIENCE (continued)

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- Experienced in reading, understanding, editing, and validating XML coding for SPL submissions, eCTD index and regional index files, InSight Publisher XML override/configuration files, and ICSR XML files
  - Investigated and developed standard process for CVM/IDE submissions using FDA's eSubmitter software
  - Researched, developed, and implemented standard process for validation and submission of ICSR XML files to the Agency via ESG, coordinated with consulting staff as well as Pharmacovigilance representative as needed
  - Created scorecard and rating mechanism for evaluation of new publishing software
  - Participated in publishing software evaluations
  - Designed dashboard for publishing metrics using Excel Pivot Tables and Charts
  - Assisted non-clinical consulting staff with review of Webinar material regarding processing/evaluating SEND datasets from a publishing perspective
  - Designed standard process for ESG submissions and installation of digital certificates
  - Spearheaded and implemented standard process for SPL software, becoming troubleshooter and expert resource
  - Learned and became resource for ACA 6004 Sample Distribution SPL submissions to the Agency by researching guidelines, validating client-provided files, informing client of issues that need resolved prior to submission, and submitting XML files via ESG
  - Contributed to and lead implementation of a project tracking matrix process for our publishing department in 2009 using Excel (including Pivot Tables/Charts and Word/PDF checklists/forms) that was in place for 10 years
  - Developed and maintained Microsoft Word 2003 templates for company, trained then transitioned this work to colleague in the document processing department
- **Operations**
- Reviewed and provided impact analysis related to our publishing systems/processes on updates to Agency guidance documentation
  - Publishing lead, project lead, client interaction, and QC reviewer for variety of submissions
  - Contributed to business development activities and cost estimates for client proposals
  - Prepared and presented training programs for internal staff
  - Subject matter expert, troubleshooting, and advisor to team members and clients for complex projects
  - Client contact and interaction for project management and operation execution
  - Worked with and trained external client on configuration updates for their InSight Publisher system, enabling the company to submit more compliant submissions to the Agency

## • AREAS OF EXPERIENCE (concluded) \_\_\_\_\_

- Selected for a high-profile client NDA eCTD submission with very tight deadlines and stressful environment; provided publishing and troubleshooting support to achieve successful submission on target completion date; application received approval in 12 months
- Provided strategic decisions, communication, and coordination of work for handling client challenge of multiple presentation strategies for a single NDA due to CMC issues; created three different eCTD presentations which enabled us to meet client expectations in an efficient, time and cost sensitive manner
- Provided strategic decision and oversight on client project where NDA was prepared and ready to submit. Client postponed NDA submission by one year; due to postponement, application was submitted under a different company name and application number. Due to my decisions and strategic process, we were able to re-use the work already completed within our publishing system and only needed a high-level review of existing published content which ultimately saved our client money and enabled them to meet their tight deadline