Liam Curran

Data & Systems Professional

Experience

Nov 2020 - present

El G Consulting

Principal Consultant

El G Consulting is focused on Life Sciences data, systems, strategy and management; with more than 20 years of experience in start-up to top tier pharmaceutical and biotech companies working across functional disciplines, geographies, and technologies. Strong focus on research and development operations, solutions, and strategies:

- Data and information management including strategy development, technology selection, implementation, validation, and integration
- Operational experience across regulatory, quality, clinical, and pharmacovigilance business functions with proven capabilities in delivering product approvals
- Expertise in common data challenges such as MDM, Data Integration, Data Quality, Data Strategy, RIM, and IDMP

Nov 2018 - Nov 2020

Gilead Sciences, Inc., Dev Ops Systems & Process

Senior Director

The Development Operations Systems & Process Department functions as a centralized framework to provide strategic and technical consultation, as well as internal customer service for Development.

Head of the Dev Ops Innovative Solutions and Collaboration Team (DISCO) focused primarily on Regulatory Affairs and Pharmacovigilance applications and initiatives, as well as Dev Ops-wide strategy, alignment, and collaboration.

Organization - Developed and led organization of up to 72 personnel on 3 continents:

- International Systems Training and Support – Application support for Intl HQ & Affiliates
- US Systems Support – Application support for HQ and Americas
- Platform Development and Maintenance – Implementation and management of global use platforms
- Systems Project Management Office – Digital Strategy Portfolio Management and System Projects PMO
- Knowledge Management and Development – US, Intl, and Offshore application development and information collaboration management (i.e., SharePoint sites & collections, visualizations, data standards)

Accomplishments :

- Global Regulatory Information Management (RIM) Initiative
- Developed Dev Ops Digital Capabilities and Strategy
- New Systems Implementations:
  - GPARC – Veeva based RA & PVE safety reporting distribution portal
  - LCT – Custom SharePoint based global CCDS implementation tracking
  - Kainexus – SaaS based strategic initiative tracking repository
  - Reg Intel Database – Custom regulatory intelligence tracking application
  - Submission Information Management System (SIMS) – Custom submission information tracking application

Personal Info

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Key Skills

International Management and Leadership

Strategic Planning and Cross-functional Governance

Business Development

Global Regulatory Submissions

Computer System Validation (GxP)

Compliance and Change Management

Technical Skills

Enterprise Content Management (ECM): Architecture, design, implementation, and validation in multiple technologies

Submission Production: Production, viewing, and validation technologies

Applications & Databases: docuBridge 19.2, Cara 3.11.4.5, Documentum 7.2, Veeva SafetyDocs 20R2, Liquent Insight 6, FDRD FirstDoc 6.3, SharePoint 2010-16, EndNote X8, Text Verification Tool 8, DocXTools, KaiNexus, TrackWise 8.7.9.1, Office 365, Teams, Azure, SQL Server, Oracle, Filemaker Pro

- Regulatory Document Management System (RDMS) – CARA based replacement for global Regulatory submission content management
- Submission Production System (SPS) – docuBridge based replacement for global submission production in paper and eCTD
- C/U Portal – Quickly developed a compassionate use portal to support global COVID-19 patient treatment with remdesivir

Jan 2013 - Nov 2018

Gilead Sciences, Inc., Regulatory Information Systems

Director

Head of Regulatory Information Systems (RIS): The Regulatory Information Systems department is dedicated to providing high-quality systems, training, and user support to enable Development Operations to meet obligations for regulatory submissions at all Gilead sites. This includes review, selection, implementation, and maintenance of all platforms, connectivity, and software tools necessary for daily operations and Regulatory Submissions, globally

- Developed function to 26 individuals working across nearly 30 technologies in the US and the UK in support of global Regulatory Affairs business processes
- Analyzed trends and evaluated potential impact of changes in government regulatory activities in order to provide expert analysis and advanced planning to meet obligations around emerging regulations and technologies
- Led long-term initiatives focused on building global efficiencies in the department. These included custom SharePoint applications in support of global document inventories for major submissions and global coordinated responses, as well as label, license, safety compliance, and commitment tracking
- Key participant and lead in long-term strategic planning for Development Operations and Regulatory Affairs

Jan 2010 - Dec 2012

Gilead Sciences, Inc., Regulatory Information Systems

Associate Director

Head of RIS: Formed new Regulatory Information Systems department at Gilead for all software, platform, and application implementation, maintenance, training, and support for global Regulatory Affairs

- Centralized and implemented all business technical tools management under a single function
- Managed team responsibilities to assess and implement technology solutions for unmet or inefficient business needs including commercial off-the-shelf (COTS) software, as well as custom developed applications
- Analyzed trends to provide expert analysis around emerging regulations and technologies
- GxP risk assessment, deviation, change management, and CAPA controls
- Computer System Validation development & execution; SDLC, and SQA

Mar 2007 - Dec 2009

Gilead Sciences, Inc., Regulatory Operations

Associate Director

Head of Regulatory Operations:

- **Responsible for 5 sites**
  - Boulder, CO (03/2007-12/2009)
  - Foster City, CA (03/2007-12/2008) (US Headquarters)
  - Seattle, WA (03/2007-12/2008)
  - Durham, NC (03/2007-12/2008)
  - Cambridge, UK (03/2007-06/2008) (International Headquarters)

Connectivity, Visualization, & Training: Citrix GADI & VMWare (VDI), US and EU Submission Gateways, Secure File Transfer Protocol(s), Tableau, PowerBI, Spotfire, Articulate 360, Captivate, Pluralsight

Authoring & Templates: Authoring, conversion, and production technologies; collaborative authoring and review, templates, custom toolbars

Education

University of Arizona, Bachelor of Science

Major: Molecular & Cellular Biology

Minors: Physics and German

- Managed global teams responsible for electronic submissions, publishing, and archiving across geographies
- Transitioned Gilead Sciences from paper to electronic submissions including eCTD & NeeS
- Implemented regulatory operations strategies aimed at gaining the earliest possible regulatory approvals
- Assisted in the development and execution of global regulatory plans

Jul 2004 - Mar 2007

Gilead Colorado, Inc. (Formerly Myogen, Inc.), Regulatory Operations

Senior Manager

Head of Regulatory Operations: Established and led Regulatory Operations function at small start-up - Myogen, Inc. (acquired Nov 2006)

- Researched, identified, and implemented systems necessary to become fully compliant with emerging electronic submissions technologies
  - Implemented and validated Livelink EDMS for company-wide document management
  - Submitted complete Pilot eCTD in June 2005
  - Submitted Gilead's first marketing application in eCTD format in December 2006
- Led the organization and production of daily domestic and international regulatory submissions
- Interfaced with Regulatory authorities for NDA planning and strategy
- Leader in Clinical and Regulatory strategy development for Myogen

May 2003 - Jul 2004

Alza (A J&J Company), Regulatory Affairs Operations

Manager

- Managed Regulatory Operations submissions team responsible for all submissions in support of local Regulatory Affairs Department
- Submitted company's largest and first fully electronic eNDA in less than 6 months from date of hire
- Designed and implemented a Documentum 5 Webtop EDMS
- Developed customized Access database to track submissions and work requests, as well as custom templates to facilitate consistency in document authoring

Apr 2000 - May 2003

Pharmacyclics, Inc., Regulatory Information

Senior Manager

- Coordinated and oversaw preparation of all regulatory paper and electronic submissions including eNDA format
- Executed "ground-up" installation, implementation, validation, and support of hardware and software for Documentum v.4i EDMS, and CoreDossier v.4.0 Publishing System
- Supervised change management, support, and upgrades of various submission software tools and platforms
- Job History: Sr. Associate: April 2000-February 2001; Manager: February 2001-February 2003; Sr. Manager: February 2003-June 2003

Mar 1999 - Apr 2000

Xoma, LLC, Quality Assurance and Control

Quality Assurance Associate II, Compliance

- Responsible for oversight and review of Manufacturing Batch Records
- Documentation specialist and archive maintenance specialist using Interleaf's Regulatory Document Management (RDM) system
- Job History: QA Associate II - Compliance: November 1999-April 2000; QA Associate I - Document Control: March 1999-November 1999