Hanif Desai

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PERSONAL STATEMENT

An adept Regulatory Operations Consultant, specialising in Veeva RIM support, Change Control implementation and migration projects. Proven expertise in Veeva Vault System Configuration and Data Migration. Excels in streamlining processes and enhancing operational efficiencies through innovative solutions.
Reliable worker with excellent communication, time management, and computer skills. A driven and detail-oriented individual with a desire to use analytical and problem-solving skills to meet goals.

SKILLS

- Veeva R&D Suites (Quality/RIM/eTMF)
- Veeva Vault System Configuration
- Veeva Admin Certification
- Data Migration using Vault Loader Sheets
- Smartsheets
- Veeva Vault Archiving
- Manual Data Migration
- Veeva Admin Certified (2019-2020)
- CSV (IQ and UAT)
- Veeva User Provisioning Task
- Veeva Auto-On release management and coordination
- StartingPoint
- Submission Management
- Veeva Content Plan Maintenance
- System Change Control Implementation
- Promomats Submission Management
- DocuBridge as publishing tool
- eCTD Xpress as publishing tool
- Liquent Insight as publishing tool

WORK HISTORY

REGULATORY OPERATIONS CONSULTANT

Geron, July 2023–August 2024

- Ongoing Veeva RIM Support, Archiving of new submissions, Archiving of incoming agency correspondences, Support for troubleshooting of issues with Veeva, Maintenance of Submission Content Plans within Veeva,
- Promomats Submission Management.
- Migration of legacy correspondence and submissions.
- Also implementing changes in Veeva RIM via Change Control Process.

eTMF MANAGER, DOCUMENT SOLUTIONS

Mereo Bio Pharma, January 2023–May 2023

- Mereo eTMF lead for ongoing clinical studies, CRO oversight and management, Document Management activities for internal Mereo filing; across products, including legacy products, Organisational support and administration of the three vaults live at Mereo, Veeva Release assessment.

- Implemented Changes in Veeva eTMF.

eTMF ASSOCIATE

Propharma Group, November 2022–March 2023

- Migration of Clinical trials legacy documents from Box to Veeva eTMF.

BUSINESS INFORMATION SYSTEMS OPERATIONS MANAGER

Argenx, June 2022–October 2022

- Ensure all solutions and support structures are fully documented, Ensure Business-side Level-2 support capabilities are defined, staffed, integrated into the application support escalation process, Establish strong relationships with all levels of the DDQ organizations at Argenx to deliver value-added solutions that work at the operational/execution level.

VEEVA FUNCTIONAL ANALYST

Carealize, March 2021–April 2022

- Act as a functional analyst for Veeva Vault for Clinical, Quality and Regulatory Suites, Monitoring the accuracy of Person Record HR Data via Migration from SAP SuccessFactors to Person Record using Vault Loader functionality, Migration of Training assignments from Person to Person using Vault Loader and Vault Extract functionality using SQL, Managing and coordinating 3x Auto-On releases with multiple stakeholders. Change Control Implementation within Veeva RIM System.

DATA TRANSFER LEAD, SENIOR REGULATORY SYSTEMS SPECIALIST

PRA Health Sciences, October 2020–February 2021

- Support the data transfer behind a major divestment deal.

REGULATORY INFORMATION MANAGEMENT CONSULTANT

Trizell Ltd, March 2019–October 2020

- Engaged as Regulatory Information Management Consultant to implement more efficient and streamlined processes for uploading clinical and regulatory submission documents to Veeva Submissions Vault in preparation for BLA and IND submissions to the FDA.

PUBLISHING PROJECT COORDINATOR

Ipsen, November 2018–March 2019

- Engaged as Publishing Project Coordinator to provide publishing and submission management support to the operations team covering EU and ROW submissions, using Extedo eCTD Manager and Veeva Vault.

SUBMISSION MANAGER & PUBLISHER

Janssen Ltd, June 2018–November 2018

- Engaged as Emerging Markets Submission Manager & Publisher to oversee GCC and EU submissions for pharmaceutical portfolio using DocuBridge platform

REGULATORY PUBLISHING CONSULTANT

Acorn Consultancy, March 2018–June 2018

- Engaged to submit and validate NeeS and eCTD submissions for Acorn's clients using Extedo eCTDmanager and EURSvalidator.

CMC PUBLISHER

Genpact Pharmalink, May 2017–February 2018

- Engaged to manage prompt publication of electronic common technical documentation and non-eCTD electronic submission for European National Licenses.

REGIONAL SUBMISSION SPECIALIST

AbbVie Limited, June 2015–May 2017

- Engaged to coordinate submission of filings to regulatory agencies across EMEA
- Oversaw the pre- publishing and post-publishing phases of regulatory submission and supported selection of cost-effective outsourced publishers to complete tasks to deadlines.

REGULATORY ASSOCIATE

Reckitt Benckiser, April 2013–June 2015

R&D ANALYTICAL ASSISTANT

Reckitt Benckiser, March 2011–April 2013

ENVIRONMENTAL LABORATORY ANALYST

Alcontrol Laboratories, August 2010–March 2011

MATERIAL SCIENCE ANALYST

GlaxoSmithKline, December 2009–June 2010

DATA ANALYST

GlaxoSmithKline, September 2009–November 2009

ANALYTICAL CHEMIST - QUALITY ASSURANCE

GlaxoSmithKline, August 2007–August 2008

EDUCATION

VEEVA ADMIN CERTIFICATION

Veeva Vault, Expired November 2020

BACHELOR OF SCIENCE (B.S.) IN CHEMISTRY, Reading

University of Reading, July 2009

PROFESSIONAL HIGHLIGHTS

Trizell required better utilisation of Veeva Vault and improved control of documentation. As Regulatory Information Manager, engaged to implement new processes. Understood benefits of using Veeva Vault for the business; configured platform to maximise performance of system in relation to business needs; oversaw data migration; trained and educated users of benefits; implemented document workflow within system; and enabled Publishing to have access

related to their remit. Succeeded in improving utilisation of Veeva Vault, resulting in increased license users and documents held electronically, improving controls.

WEBSITE

http://www.desairegulatoryservices.co.uk/

REFERENCES

References available upon request