Omer Wasiq

▪ 164 Cheapside, Forge Place, Flat 36, Birmingham, B12 0PS
▪ +44 7587916089
▪ omer_wasiq@aol.com

Regulatory Operations Management Professional

Meticulous and detail-oriented professional with versatile experience in regulatory submissions/operations, quality control, and stakeholder collaboration within pharmaceutical industry.

Adept at streamlining processes, ensuring compliance, and navigating Veeva Vault PromoMats software to facilitate timely approvals. Skilled in leveraging industry-standard publishing systems, such as ISI Publisher, ISIToolbox, eCTDXPress, and Microsoft Word to assemble accurate and consistent submissions. Proven expertise in Medical-Legal Regulatory (MLR) review processes, project management, and process improvements aimed at enhancing overall business success. Strong background in pharmacy operations, including drug procurement, sales optimisation, and training support staff. Highly effective communicator with track record of fostering strong relationships with internal and external stakeholders.

Areas of Expertise

- Regulatory Submissions
- Process Improvement
- Strategic Planning & Analysis
- Novartis Fuse Platform
- Quality Assurance & Control
- Pharmacy Operations
- eCTDXPress & Veeva Vault
- Lorenz DocuBridge
- Microsoft Office Suite
- EMEA & FDA Compliance
- Documentation & Reporting
- GMP inspections

Certifications

- Janssen EMEA iMedical Review – Business Process Training for Agencies, 21 Sep 2022
- EMEA iMR Digital Asset Management – Agency and Internal Submitter, 21 Sep 2022
- SOP Exception Training for Pharma EMEA, 21 Sep 2022
- EMEA iMR - Complete Guide to iMR, 21 Sep 2022

Professional Experience

McCann Health, London **2025**
Medical Editor (Freelance)

- Provided end-to-end regulatory operations support across multiple pharmaceutical brands, ensuring compliance with EMA, FDA, and other regional agency requirements.
- Managed complex submission workflows from initiation to delivery, including electronic Common Technical Document (eCTD) submissions, promotional material review packages, and internal approval cycles.
- Utilized Veeva systems to create compile, QC, and route submission packages; maintained metadata accuracy, ensured document version control, and supported system optimization for efficient submissions.
- Partnered closely with Medical, Legal, Regulatory, and Project Management teams to ensure seamless coordination of materials and timely delivery of submissions.
- Acted as a quality gatekeeper by reviewing medical and promotional materials for regulatory compliance, data accuracy, and alignment with client-specific SOPs and industry standards.
- Maintained master submission libraries and document repositories to support data integrity, traceability, and audit readiness.
- Anticipated and resolved submission challenges, proactively mitigating risks related to deadlines, system bottlenecks, and content inconsistencies.
- Streamlined submission processes by introducing best practices, improving documentation workflows, and supporting continuous process improvement initiatives.
- Served as a liaison between internal regulatory teams and external client stakeholders to ensure transparent communication, timely updates, and alignment on submission strategies.
- Ensured all submission activities adhered to company SOPs, regulatory guidance, and client-specific quality standards while maintaining detailed audit trails and submission histories.

Area 23 HC, New York 2025 - current
Senior Reg Ops Specialist (Freelance)

- Delivered comprehensive **regulatory submission management** support across multiple global brands, ensuring each project met agency standards and internal compliance requirements.
- Oversaw the **end-to-end submission lifecycle**, including document preparation, QC, metadata tagging, and publishing of submission packages via Veeva PromoMats and Vault RIM platforms.
- Worked in close partnership with **Medical, Legal, and Regulatory Affairs teams** to coordinate review cycles, ensuring timely and compliant submission of promotional and medical materials.
- Managed and maintained **master submission libraries** to ensure document consistency, traceability, and version control across all assigned brands and therapeutic areas.
- Applied strong understanding of **regulatory frameworks and promotional compliance** guidelines (FDA, EMA, ABPI, and EFPIA) to review content for scientific accuracy and adherence to industry standards.
- Identified, investigated, and resolved **submission-related challenges**, proactively ensuring delivery milestones were met within tight timelines.
- Provided expert guidance to internal stakeholders and external clients, contributing to the development of efficient **submission strategies and operational best practices**.
- Supported **audit readiness and data integrity** by maintaining organized documentation, accurate metadata, and detailed submission records for all client portfolios.
- Assisted in **process optimization and workflow enhancement**, recommending improvements to documentation procedures and submission review systems.
- Served as a reliable point of contact for regulatory operations queries, ensuring smooth communication, proactive issue tracking, and consistent quality across deliverables.

Novartis Healthcare Private Limited |Hyderabad, India 2023 - 2024
Senior Associate QC Specialist

I have played a pivotal role in various aspects such as QC, contributing to the overall success of pharmaceutical projects. Here are some key highlights of my roles and responsibilities:

- Assess validity of clinical/scientific content in preclinical and clinical documents and identify deficiencies prior to
- finalization and promotion in the document management system.
- Assess validity of clinical/scientific content in preclinical and clinical documents and identify deficiencies prior to finalization and promotion in the document management system.
- Provide independent source data verification of clinical or preclinical study reports and identify content inaccuracies, e.g.: Verify accuracy (100% review) of all factual statements within summary document text compared to post-text sources cited.
- Verify numeric accuracy (100% review) of all data cited throughout text and hand derived in-text tables compared to post-text sources cited.
- Verify appropriateness of all internal/external citations noted within summary document.
- Develop and provide factual evidence to support all discrepant findings for review and approval by Submission Team or document authors.
- Provide cross-divisional support through quality review of divisional specific documents such as CSRs, CERs, Tabular Listings, etc.
- With oversight, provide clinical/scientific review of clinical summary documents, such as CERs, SCE, SCS and CO.

Fishawack Communications Ltd, London, UK (Avalere Health) 2021 to 2023
Senior Regulatory Submission Specialist

- Oversaw Medical-Legal Regulatory (MLR) review processes for clients, enabling successful planning and approval of over 100+ pharmaceutical messaging, involving document submission, retrieval, and distribution for review/revision.
- Developed strong expertise in utilisation of Veeva Vault PromoMats submission software by effectively navigating associated processes for assigned accounts.
- Managed the electronic review processes used by clients' MLR committees, including submission, retrieval, and distribution of documents for review and revision.
- Created and maintains reference libraries and claim matrices on assigned accounts.
- Understands key milestones in project delivery process and ensures required activity is met prior to moving onto the next milestone.
- Executed meticulous file specification verification to ensure compliance with client and agency standards.

- Streamlined submission processes by proficiently linking, tagging, annotating, and managing error-free submissions to facilitate prompt approval decisions.
- Delivered timely status updates to promptly shared downloads and distributed reviewed submissions for effective collaborations.
- Updated and maintained accurate and detailed compliance records.

Holiday Inn Express – Stay Belvedere Hotels Ltd - Vauxhall, Lambeth Road, UK 2021
House Officer

- Assisted in daily guest service operations, ensuring a comfortable and safe environment.
- Responded to guest needs efficiently, showcasing strong customer service.
- Supported emergency procedures, demonstrating knowledge of safety practices.
- Worked collaboratively with housekeeping and front desk teams.
- Performed regular welfare checks on service users for communicating well-being to relevant stakeholders. Developed fire safety procedures and evacuation plans to ensure preparedness in case of incidents.
- Provided support in managing GP registrations and scheduling appointments of service users.
- Supported resolution of service user issues by coordinating with Migrant Help and aided throughout process.

DXC.Technology (Computer Science Corporation) Hyderabad 2017 to 2021
Regulatory Publishing Associate Professional

Executed QC tasks within electronic publishing system for accurate published output. Conducted QC reviews of documents prepared by team. Provided valuable support to senior submissions teams in maintenance of electronic Common Technical Document (eCTD) lifecycle. Provided support for lifecycle publishing project for assisting with tasks, such as formatting Word documents, creating bookmarks, hyperlinking, and conducting quality control (QC) checks. Assisted with internal process development, such as Bristol Myers Squibb Publishing Process in ISI Publisher and PRISM Automation Process

- Achieved excellence in leading high-performing Document Level Publishing for Bristol Myers Squibb and successfully published third-party documents from PRA Health Sciences, Charles River Laboratories, and others.
- Utilised standard publishing systems and utilities, such as ISI Publisher v4.0.0200, ISIToolbox v6.3.0200, Adobe Acrobat, and Microsoft Word to effectively create and compile client deliverable documents/submissions.
- Ensured accurate/consistent quality improvements in regulatory submissions contributing to enhanced business success.

Active Pharma Labs| Hyderabad, India 2016 - 2017
QA & QC Analyst

Undergone practical training of Quality Control using HPLC, GC and UV Spectrophotometric Techniques.

CARE Hospitals, Hyderabad, India 2015 to 2016
Pharmacist

Implemented effective measures to ensure pharmacy maintains ample supply of lifesaving drugs and offers reasonable prices to meet needs of patients. Iinterpreted written prescriptions, checked for drug interactions/allergies, and entered prescription/patient data into computer systems. Interpreted and processed medication orders under supervision of pharmacy director to ensure accurate and timely fulfilment.

- Provided effective training and guidance on pharmacy support technicians.
- Reviewed physician orders to assess and ensure accuracy/safety prior to further processing.
- Conducted thorough reviews and implemented enhancements to procurement, sales, and billing systems
- Maintaining prescription files and recording issue of narcotics, and habit-forming drugs including Schedule H and Schedule X.
- Maintained accurate inventory of medications and offered information to assist patients in understanding how to properly take their prescribed medications.
- Conferring with Chemists, Engineering Professionals and other healthcare professionals about manufacturing techniques and ingredients.

Additional Experience

2015

Customer Support Associate | Amazon India Private Limited, Hyderabad, India

Resolved customer issues related to order deliveries, returns, and stock – gaining valuable insight into warehouse logistics and customer fulfilment processes.

Awards & Achievements

2020

DXC Quarterly Champ Awards, Issued by Lokendra Sethi Vice President HR India – Aug 2020

Education

Master of Pharmacy – Pharmaceutics 2015
Sultan ul uloom college of Pharmacy – Banjara Hills
Affiliated with Jawaharlal Nehru Technological University, Hyderabad, India
AQUALS from Ecctis (formerly UK NARIC) Equivalent to a UK qualification.

Languages

English – C2

References

Upon request