

# MERCY JOSEPH

Pharmaceutical Compendial Analyst | Drug Product Development | Regulatory Compliance

Chennai, India | +91 9150263186 | mercyjo2000@gmail.com | linkedin.com/in/mercy-joseph

## PROFESSIONAL SUMMARY

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Results-driven Pharmaceutical Compendial Analyst with 4 years of experience managing compendial compliance across all major global pharmacopoeias (USP, EP, BP, JP, ChP, IP) for multinational pharmaceutical clients. Proven track record in compendial cycle management, regulatory documentation, multi-site coordination, and quality system maintenance using COMET, Veeva, and Change Control systems. Skilled at translating complex pharmacopoeial requirements into actionable compliance workflows that ensure zero compliance lapses.

## CORE COMPETENCIES

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- Compendial Compliance & Cycle Management
- Regulatory Affairs Support & Documentation
- Quality Management Systems (COMET, Veeva, ETS Trackwise (Change Control))
- Gap Assessment & Impact Assessment
- SOP and Work Instruction Development
- Cross-Functional and Multi-Compendial Coordination
- Data Analytics & Reporting (SQL, Tableau, LIMS)
- Training & Mentoring of New Analysts
- Commitment Record Management
- Change Control Processes

## TECHNICAL SKILLS

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**Quality & Compliance Systems:** COMET Quality System, ETS Trackwise (Change Control), Veeva, CVC Templates, Commitment Record

**Pharmacopoeias:** USP, EP, BP, JP, ChP, IP — compendial monitoring, impact assessment, and equivalency reporting

**Data & Analytics:** SQL, Tableau, LIMS, Jaspersoft, Excipedia, Microsoft Excel (Advanced), PowerPoint, Word

**Bioinformatics & Visualization:** PyMOL, Schrodinger Suite, Molecular Modelling, Python (Data Structures, Genomics)

**Cloud Platforms:** AWS

## PROFESSIONAL EXPERIENCE

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**Professional Analyst, Global Value Web Technologies Pvt. Ltd.**

**Aug 2022 - Present**

*Client: Johnson & Johnson Innovative Medicine | Function: Drug Product Development & Supply Chain (DPDS-SMPD)*

- Managed end-to-end compendial cycle activities for 6 major pharmacopoeias (USP, EP, BP, JP, ChP, IP) across multiple pharmaceutical development and supply chain sites, ensuring zero compliance lapses.
- Created, reviewed, and maintained compendial deliverables including Impact Assessments, Gap Assessment Reports, Multi-Compendial Comparison Reports, Material Identification Reports, and Aggregate Files, reducing turnaround time through standardized templates.
- Served as the central multi-site point of contact for compendial items, coordinating with Subject Matter Experts (SMEs), Regulatory Affairs, QA, and Manufacturing stakeholders to drive timely resolution.
- Submitted SME-reviewed proposal comments to pharmacopoeia bodies (USP, EP), contributing to industry-level standard-setting.
- Generated and presented monthly compliance metrics dashboards to client leadership, enabling data-driven decisions on compendial readiness.
- Created and maintained Commitment Records in the COMET Quality System, ensuring all compendial obligations were tracked to regulatory deadlines.

- Authored and managed Specification, Reference, Technical, Methods & Validation, and Memo documents in Veeva, maintaining full audit-trail integrity.
- Developed and delivered training sessions for new analysts on CVC template creation, Compendial Database uploads, and COMET Commitment Record workflows.
- Managed material inventory, SharePoint trackers, and Supplier Compliance Statements (PSCI).
- Created, updated, reviewed, and managed technical documents including Safety Evaluation Reports, EIRA Reports, PSCI Reports, Material Transfer Reports, Kenvue Transfer Reports, and Supplier Alignment Risk Assessments; performed ELIMS trend data extraction and created Statistical Analysis Reports.
- Updated, reviewed, and generated reports from the Excipedia automation database (FSRA, PSCI).
- Authored and updated Work Instructions, SOPs, and Checklists, strengthening the team's compendial compliance framework.
- Maintained a 100% on-time training completion rate in line with company compliance standards; received the Quality of the Month Award.

## EDUCATION

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**M.Sc. Bioinformatics - Stella Maris College, Chennai, India** **2022 | 81%**

*Postgraduate Research: Molecular Docking Studies of Secondary Metabolites (Annona squamosa, Syzygium aromaticum, Ocimum sanctum) Against Influenza Virus, using Schrodinger Suite.*

**B.Sc. Advanced Zoology & Biotechnology - Stella Maris College, Chennai, India** **2020 | 80%**

## CERTIFICATIONS & ACHIEVEMENTS

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- Python for Genomic Data Science - Coursera (Johns Hopkins University)
- Python Data Structures - Coursera
- Quality of the Month Award - recognized by client for exceptional delivery quality
- Contribution of the Month Award - recognized by client for ownership and contribution
- Multiple Client Appreciation Awards - for on-time, accurate compendial deliverables