DR. ZUHOUR YAHIA SHAMSELDIN

Senior Regulatory Affairs & GMP Compliance Consultant | Former Regulatory & Manufacturing Manager-Saudi Arabia

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EXECUTIVE PROFILE

Senior Regulatory Affairs, GMP & Pharmaceutical Compliance Consultant with more than 20 years of leadership experience in pharmaceutical and veterinary medicines regulation, product registration, GMP inspections, post-marketing surveillance, pharmacovigilance, regulatory harmonization, quality systems, and compliance.

Former Director of Veterinary Medicines Registration and Director of Post-Marketing Surveillance at Sudan's National Medicines and Poisons Board (NMPB), and also Director of Veterinary Medicines Registration Department with extensive expertise in regulatory policy development, medicines oversight, GMP compliance, inspection systems, pharmacovigilance, and institutional capacity building.

Currently serving as an independent consultant to six pharmaceutical companies across Sudan, Saudi Arabia, and Canada, providing strategic support in Regulatory Affairs, product registration, licensing, GMP compliance, technical agreements, quality agreements, and contract manufacturing.

Successfully supported the registration and lifecycle management of more than 80 pharmaceutical and veterinary products and participated in GMP inspections and technical assessments of pharmaceutical manufacturing facilities in India, Turkey, Egypt, Sudan, Czech Republic, Italy, and Tunisia.

Recognized for contributions to medicines regulatory harmonization initiatives through WHO, IGAD, and UNDP programs and for delivering professional training and capacity-building programs for pharmacists, veterinarians, customs officers, and healthcare professionals.

KEY CAREER ACHIEVEMENTS

- More than 20 years of experience in pharmaceutical and veterinary regulatory affairs.
- Regulatory consultant to 6 pharmaceutical companies across Sudan, Saudi Arabia, and Canada..
- Former Director of Veterinary Medicines Registration and Director of Post-Marketing Surveillance at NMPB Sudan.
- Successfully led Regulatory Affairs operations at Arab Factory for Drugs for more than six years, overseeing registration, lifecycle management, compliance activities, pricing submissions, and regulatory interactions.
- Supported the registration and lifecycle management of more than 80 pharmaceutical and veterinary products across Sudan and Saudi Arabia.
- Participated in GMP inspections and technical assessments in 7 countries.
- Contributor to medicines regulatory harmonization initiatives under IGAD.
- Collaborated with WHO and UNDP in regulatory strengthening and capacity-building programs.

- Delivered training programs to pharmacists, veterinarians, customs officers, and healthcare professionals.
- Extensive experience in drafting, reviewing, and negotiating Technical Agreements, Quality Agreements, Commercial Agency Agreements, and Contract Manufacturing Agreements.
- Implemented pharmacovigilance reporting systems and strengthened post-marketing surveillance programs.

CORE COMPETENCIES

Regulatory Affairs & Compliance

- Regulatory Strategy
- Product Registration
- Regulatory Intelligence
- Market Access
- Lifecycle Management
- CTD Assessment

Quality & GMP

- GMP Compliance
- GDP Compliance
- Quality Systems
- GMP Audits
- Pharmaceutical Inspections
- Quality Agreements

Commercial & Technical Support

- Technical Agreements
- Commercial Agency Agreements
- Contract Manufacturing Agreements
- Regulatory Due Diligence
- Licensing & Importation

Leadership & Capacity Building

- Team Leadership
- Regulatory Harmonization
- Professional Training
- Stakeholder Engagement
- Policy Development

PROFESSIONAL EXPERIENCE

Independent Regulatory Affairs, GMP & Pharmaceutical Compliance Consultant

2024 – Present

- Currently providing regulatory and compliance consulting services to 6 pharmaceutical companies across Sudan, Saudi Arabia, and Canada.
- Supported product registration, licensing, GMP compliance, and market access activities.
- Drafted and reviewed Technical Agreements, Quality Agreements, Commercial Agency Agreements, and Contract Manufacturing Agreements.
- Provided strategic regulatory advice for product registration and commercialization.

Regulatory Affairs Manager

Arab Factory for Drugs
2018 – 2024

- Reduced regulatory approval timelines by approximately 70% through improved dossier preparation and regulatory follow-up.
- Maintained a 95% first-cycle approval rate for submitted regulatory applications.
- Contributed to expanding the company regulatory portfolio and maintaining compliance with applicable regulatory requirements. Supported registration and lifecycle management of more than 60 products.
- Coordinated regulatory submissions, artwork approvals, variations, renewals, and pricing applications.
- Served as a key liaison between the company and national regulatory authorities.
- Participated in Pricing and Purchasing Committees supporting strategic business decisions.
- Supported GMP compliance, quality systems implementation, and inspection readiness.

Director, Post-Marketing Surveillance Directorate
National Medicines & Poisons Board (NMPB), Sudan
2015 – 2018

- Directed surveillance activities covering 1,000+ registered pharmaceutical products.
- Conducted and supervised 250+ pharmaceutical distribution and market inspections.
- Strengthened pharmacovigilance reporting and adverse event monitoring systems.
- Led investigations related to substandard and counterfeit medicines.
- Coordinated regulatory enforcement actions and product recal

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Director, Veterinary Medicines Directorate
National Medicines & Poisons Board (NMPB), Sudan
2012 – 2015

- Led the assessment and registration of veterinary medicinal products.
- Improved dossier review processes and reduced technical deficiencies in submissions to about 50%
- Participated in GMP inspections of pharmaceutical manufacturing facilities in multiple countries.
- Contributed to the development of veterinary medicines regulatory guidelines.

Registration Officer
National Medicines & Poisons Board (NMPB), Sudan
2005 – 2012

- Evaluated pharmaceutical and veterinary medicines dossiers.
- Participated in GMP inspections.
- Conducted technical assessments of registration applications.

Registration Officer
Ministry of Animal Resources & Fisheries
2005 – 2008

- Supported veterinary medicines regulation and registration activities.

- Supported veterinary medicines licensing and importation

INTERNATIONAL GMP INSPECTION EXPERIENCE

Participated in GMP inspections, technical assessments, and regulatory evaluations of pharmaceutical manufacturing facilities.

INTERNATIONAL & REGIONAL CONTRIBUTIONS

- World Health Organization (WHO)
- United Nations Development Programme (UNDP)
- Intergovernmental Authority on Development (IGAD)
- African Medicines Regulatory Harmonization Programs
- Reinforcing Veterinary Governance in Africa (VET-GOV)

Contributed to:

- Regulatory Harmonization
- Capacity Building
- Regulatory Systems Strengthening
- Quality Assurance Programs
- Technical Assessments

TRAINING & CAPACITY BUILDING

Speaker

Second IGAD Regional Medicines Regulatory Authorities Conference on Regulatory Collaboration and Harmonization
Khartoum, Sudan

Presenter

Workshop on Control of Veterinary Drug Residues in Food Derived from Animals
Audience: 250 Participants

Presenter

Workshop on Registration of Veterinary Medicines
University of Khartoum
Audience: 40 Participants

Presenter

- India,Turkey,Egypt,Sudan,Czech Republic,Italy, Tunisia

Workshop on Control of Veterinary Medicines- Good Distribution Practice
State Ministry of Agriculture and Animal resources
Khartoum-Sudan
Audience: 30 Participants

Trainer

Counterfeit Medicines in Sudan
Joint Workshop with Sudan Customs and World Customs Organization

Trainer

Control of Medicines
Pharmaceutical Forum
Audience: 250 Participants

Participant

- Sudan First Conference for Medicines Regulatory Authorities and Neighboring Countries-Sudan

- 2nd Biennial Scientific Conference on Medicines Regulation in Africa-Ethiopia
- 4th African Medicines Regulators Conference-Ethiopia
- OIE Conference on Veterinary Medicinal Products-Syria

PROFESSIONAL COMMITTEES

- Veterinary Medicines Registration Committee-National Medicines and Poisons Board
- Cosmetics Registration Committee- National Medicines and Poisons Board
- Pharmacovigilance Committee- National Medicines and Poisons Board
- Internal Audit Committee- National Medicines and Poisons Board
- Training Committee- National Medicines and Poisons Board
- Pricing Committee-Arab Factory for Drugs
- Purchasing Committee- Arab Factory for Drugs
- National EPI Committee- Ministry of Health(Sudan)
- IGAD Medicines Regulatory Harmonization Working Groups(IGAD-WHO)

PUBLICATIONS & TECHNICAL CONTRIBUTIONS

- Sudan Veterinary Formulary-Prescription book
- Contribution on Sudan Veterinary Index a book containing all registered veterinary Medicines in Sudan
- Technical Presentations on Veterinary Drug Residues
- Technical Presentations on Counterfeit Medicines
- Research in Toxicology and Veterinary Medicines-Paper

PROFESSIONAL CERTIFICATIONS

Regulatory Affairs & Compliance

- European Professional Certificate in Regulatory Affairs (PTI)
- CTD Assessment According to International Standards-WHO

Quality & Auditing

- IRCA Certified ISO 9001:2015 Quality Management Systems Auditor
- ISO 9001:2015 Quality Management Systems
- ISO 9001:2008 Quality Management Systems

International Programs

- WHO Bioequivalence Studies Assessment
- WHO Healthcare Waste Management

Specialized Programs

- Quality Control and Regulatory Affairs in Cosmetic Science
- Pharmaceutical Management Program – Shanghai, China
- Veterinary Drug Residue Analysis Program – Turkey
- Harvard Medical School – The FDA Prescription Drugs: Drug Development and Approval

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EDUCATION:

Master of Science (MSc)–Toxicology-2008-

Faculty of Veterinary Medicine

University of Khartoum**-Sudan**