

Dr. Sunil Manjarekar

<p>Skill set in a Nut shell</p>	<p>Have 18+ years of experience covering a broad range of activities viz., managing Product quality , implementing and continual improvement of Quality Management System, Laboratory accreditation, Legal liaison, Quality Group membership, Federal Auditing etc., The categories of sectors experienced includes... food, pharmacy, laboratory, manufacturing, cosmetic industry, shipping, trading and so on. He is also a active member of Dubai Quality Group and has accomplished many Quality Audits.....</p> <p>His Key area of strength includes :</p> <ul style="list-style-type: none"> • Quality Management System consultancy • Laboratory Accreditation • Quality Assurance activities of Pharmacy products • Training and Module development on ISO-QMS training and so on.....
<p>Profile:</p>	<p>Wide exposure (18 yrs) in pharmaceutical manufacturing/ perfumery and cosmetics manufacturing /Accreditation bodies (Dubai accreditation centre-Dubai Municipality) out of which 8 year in UAE with a thorough knowledge of UAE regulations, with Resource Management as well as technical back up required for pharmaceutical manufacturing/ perfumery and cosmetics manufacturing./Setting up of testing laboratories and Inspection companies in UAE and to provide consultancy to various organizations like pharmaceuticals /Perfume /cosmetics Construction, Metal mfg industry, Shipping industry ,Trading companies ,etc.</p> <p>Got strong network in U.A.E and neighboring countries as far as Certification (ISO 9001:2000/ 14000/ HACCP 18000) and inspection activities are concern .Also I am the IRCA(UK) approved auditor and consulting audits for International Certification services/SGS/CI International UK etc.</p> <p>Key areas of audits includes in inspections of Cranes/Lifts/Cradle/Construction Hoist, Pressure vessels .Also fair knowledge of setting up of Quality control labs/R&Developments labs in (Perfumes / cosmetics, pharmaceuticals, food and environmental, Petrochemicals labs).</p> <p>Having an exposure on working independently on ISO 9001:2000/ISO 17025 standards/ISO 17020 /ISO 14000/ HACCP 18001procedures/WHO GMP CERTIFICATIONS FOR FOOD ,PHARMA AND COSMETIC INDUSTRY/ USFDA APPROVALS /QUALITY MANAGEMENT SYSTEM for various types of industries with</p>

	specialties in pharmaceuticals /chemicals and perfumes and cosmetics manufacturing companies.
Academic qualification	<p>Bombay University (India) Doctorate (Ph.D.) in Analytical Chemistry -- Year 1995</p> <p>M. Sc. in Physical chemistry ---Year 1991</p> <p>B.Sc. in Chemistry ---- Year 1987</p>
Additional Qualification	<p>F.D.A. approved in Chemical & Instrumental Analysis Qualification from Maharashtra. (India)</p> <p>I have completed following courses Lead Auditor for QMS (ISO 9001:2000) Lead Auditor for EMS (ISO 14001:2004) Lead Auditor for OHSAS(ISO 18001) Lead Auditor for ISO/IEC 17025 Lead Auditor for ISO /IEC 17020 TL 9000 awareness program.</p>
Work Experience	<p>Total 18 years wide exposure in the field of Quality Assurance, Quality Control .ISO certification processes Out of which 10 years in reputed pharma industries in India in quality control laboratory , 2yrs in perfume and cosmetics industry in UAE and 5years wide exposure of auditing in Dubai Municipality</p> <p>25th Dec Worked with Dubai govt. (Dubai Municipality-DUBAI 2000 to ACCREDITATION CENTRE) as till date an Accreditation Engineer for 5 yrs (Lead Auditor -Certification , Accreditation and Inspection unit)</p> <p>Job involves the control of all the public testing Laboratories/Inspection /Certification bodies like SGS/BVQI/RWTUV/TUV (Approx. 57organisation in Dubai) as per QMS (ISO 9000/ ISO 17025/ISO 17020/EMS/HACCP requirements and Local UAE law,L.O. 52)</p> <p>So far I have conducted approximately 300 audits ,which Involves the laboratories involving in</p> <p>Nov.1998 Unistar International -DUBAI to 24th Quality Assurance Manager--Audit Dec,2000 Was worked at Dubai in a well reputed Cosmetics & Perfume Mfg. Co. having a turnover of \$60 M.Company having three manufacturing units in U.A.E. and 26</p>

offices across the world including US, UK, France, Belgium ,South Africa,China ,etc.

Job Responsibilities

Was engaged in ISO 9001:1994 project for the two factories of the group and I was the Management Representative for the Quality (MRQ) for both the factories.

Played a vital role for achieving ISO 9001 certification for the company.

As a Q.A. Manager audit ,I was solely responsible for all the Quality assurance activities of all the three plants in U.A.E.

Solely responsible for overall quality of companys products. Was Handling market complaints from 26 branches of the Companys all over the world. (Incharge of the Market Complaint cell of the group.) Was Doing Market survey /research in U.A.E. (Sharjah/Dubai) for various companys products as well as competitor products.

Conducted various Quality Awareness training programs (GMP,cGMP,House Keeping ,etc) for Workers,Management Staff of all the three factories. Was giving technical support to the factories. Also involved in collecting a Legal requirement/information network for the company for cosmetics and perfumery products(e.g. SASO regulations,EC guidelines,etc) Responsible for developing & implementing a new quality assurance systems in all the three factories. Was doing continuous Audits to the factories Area covered : Factory premises, QC, Production and process control, (Mfg. and packaging), vendor development ,vendor controls (RM/PM),Holding and distribution of finished goods, validation, Stability studies ,etc. Active Member of a prestigious quality group in Dubai called Dubai Quality Group . I have attended various international level seminars on Quality as well as on various management development seminars.

Aug. 97 Zandu Pharmaceuticals Works Ltd.-India,Mumbai.
Sept. 98 Assistant Manager QA and R&D analytical

Was looking after all the quality assurance activities of the plant located at Ankleshwar Gujarath manufacturing bulk drugs ,drug intermediates ,etc.
Also responsible for analytical method development on GC,HPLC,HPTLC,etc. Was involved in developing ISO 9001 QMS for the ankleshtar plant

May96- Ajanta pharma Ltd India (Mumbai & Aurangabad)
July97 Designation : Assistant manager Quality Assurance

Job Responsibility

Was involved in setting up of the complete bulk drug plant(antibiotics/rifampicin_)right from the grass root level.

As a Asst. manager Q.A. ,I was solely responsible for all theQuality assurance and Control activities /Affairs of the location .

I was having a responsibility of introducing cGMP concept in the day to day activities to all the staff members & workmen and involved in implementation of it in stagewise manner. Other responsibilities includes self inspections,conducting internal audits, training programmes,introduction of GLP in the laboratory,Drafting SOPs ,and all FDA matters .Was involved with registration of Export documentation for various countries .

(DRACELL). Worked on USFDA approval for the plant of Ampicillin, amoxicillin ,Cephalexin & Cephadroxyl. (Preparation of DMF I&II),looking after complete loan licence manufacturing business of the company & have experience in handling modern instruments like GC,HPLC,FTIR,HPTLC ,etc.

	June90 to May96	German Designation	:	Remedies Sr.	Ltd QC	India officer
<p>Job Responsibility Sampling supervision, Analysis of raw material and finished products (Bulk drug and formulations) GMP inspections, Documentation and all the related Quality control and Quality Assurance work . Knowledge of new method development . Major Work is on Thin Layer Chromatography, GC. Knowledge of all the modern instruments like GC, HPLC, IR, Karl Fischer , UV spectrophotometer, etc.</p>						
	May88 to June89	Eupharma Designation	:	Laboratories Production chemist-	Ltd Worked for	India
<p>Capsule, tablets, dry syrup dept.</p>						