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Summary

Results-driven IVD manufacturing and quality professional with extensive experience in medical device plant setup, production, and cross-functional operations. ISO 13485:2016 Certified Auditor with strong expertise in WHO-PQ, MDSAP, and MD-QMS. Proven track record of working with international manufacturers and overseas vendors across Europe and Asia, primarily in Germany, China, South Korea, and the U.A.E., supporting audits, technology transfer, and regulatory compliance. Provides freelance consultancy services in compliance, process optimization, and operational excellence, and is actively engaged as an IVD educator and YouTube content creator, promoting industry
knowledge-sharing and regulatory awareness.

Professional Experience

S. No	Employer	Location	Joining Date	Relieving Date	Designation	Duration
1	Inito Health Tech Private Limited	Bengaluru Karnataka	26/02/2024	15/06/2026	Sr.Manager Production	2.5 Years
2	Genes 2Me Private Limited	Guragaon Harayana	01/11/2022	07/02/2024	Plant Head	1.3 Years
3	EMPE Diagnostics Private Limited	Hyderabad, Telangana	17/08/2020	30/09/2022	Manager Production , Deputy Manager Production	2.1 Years

4	Advy Chemical Private Limited	Mumbai Maharashtra	23/04/2018	08/08/2020	HOD, Manager Production	2.3 Years
5	Abbott Rapid Diagnostic(Formerly Alere Medical Private Limited)	Guragaon, Harayana	08/05/2017	06/04/2018	Sr.Executive Manufacturing	0.9 Years
6	Avantor Performance Material India Limited (Formerly Ranbaxy Fine Chemical Limited)	Dehradun, Uttrakhand	28/12/2016`	02/05/2017	Officer Production	0.4 Years
7	J Mitra Co.Private Limited	New Delhi	01/07/2014	03/09/2016	Production Supervisor, Production Chemist , Production Trainee	2.2 Years

Key Achievements

Employer	Achievements
inito	1. Handling Strip Operations 2. Setting Up and smooth on boarding of Contract Manufacturer Organization 3. Overseeing operation of 3 Contract Manufacturer Organization located in India 4. Overseeing operation of Uncut Sheet Manufacturer located in Europe , South Korea , China & U.A.E 5. Strip Production Set Up & making Scaleable 6. Supply Chain Optimization 7. Vendors Audit 8. Looking Strip Quality (QA/QA/RA) 9. Acting as Programme Manager Role 10. Costing Optimization 11. Budgeting

G2M	1. Handling Plant Operations & Quality | ISO 13485:2016 | EU MDR & CDSCO Compliance 2. Directly managing Quality Control, Quality Assurance, and Regulatory Affairs operations 3. Indirect oversight of Production, Maintenance, Stores, Purchase, Logistics, HR/Admin, EHS, Marketing, Sales, and R&D to ensure smooth operations and on-time delivery. 4. Filled and CDSCO approved 250+ Test License for POCT Based Product 5. Filled and CDSCO approved 15+ Manufacturing License for POCT Based Product 6. Planning and setting up In-Vitro Diagnostics plants, reviewing plant layouts, and monitoring overall plant performance and P&L 7. Handling CAPEX, plant facilities, and equipment optimization 8. Acting as Management Representative to implement ISO 13485:2016 QMS, including documentation, SOPs, and records 9. Leading Risk Management, Clinical Evaluation, Post-Market Surveillance, and liaising with certification & regulatory bodies. 10. Ensuring compliance with EN ISO 13485:2016, EU MDR, and CDSCO MDR 2017. 11. Conducting ISO & CE audits, handling NCRs, CAPA, Deviations, and Change Control 12. Managing CDSCO online portal, including Test and Manufacturing License applications
EMPE DIAGNOSTICS	1. Assisted in Commissioning of Facility Set Up as per ISO13485:2016 requirements. 2. Successfully faced Audit and got the ISO13485:2016 certification 3. Taking lead over Purchase and Maintenance Functions 4. Saved 18% of the total amount against quoted equipment and machine price by successfully doing negotiation. Quoted Price 197 Lacs (INR/-), final negotiated price 162 Lacs (INR/-) 5. Scale up of manufacturing from pilot scale level. For example, in Unconjugated GNP scale up from 100 ml batch to 2250 ml via In Direct Scale Up similarly many other processes. 6. COGS Optimization by working on few key critical items –In case of Lateral Flow Materials NCM Replacement from X Manufacturer to Y Manufacturer saving cost by 53% with current supplier hence in future our GC% Margin will increase multiple fold. Cost/Meter of X Manufacturer 320 INR/- & Y Manufacturer 150 INR/-.Cassette Vendor Replacement after successful negotiation saving cost by 62.5% 7. Involved in Tech Transfer from EMPE-Sweden to EMPE-India and delivering 3 Test Batches of 8255 T with 2 Month span of time.
ADVY CHEMICAL Partnering with you	1. Part of WHO-PQ Team and successfully got WHO-PQ for one of the products namely AdvDx™ Malaria Pf Rapid Malaria Ag Detection Test. 2. Faced Surveillance Audit for ISO13485:2016 where TUV SUD was the notified body. 3. Reduction in the CPU for AdvDx™ Malaria Pf Rapid Malaria Ag Detection Test by 40% hence increase of GC% Margin. 4. Play key role in designing the Lateral Flow Technique based product's (Malaria, Dengue NS-1 Ag) 5. Handle Team Size of 250+ Workman involving Direct and In-Direct Workman.

	6. Handle CAPEX and Departmental Related Budget for Year against the Market Requirements. 7. Lead for PPIC Meeting. 8. Controlling of Manpower and Energy Cost.
Abbott	1. Successfully implemented Lean Manufacturing Culture Principles such as 5S, VSM, OEE , Takt Time and so on. 2. Worked with the Korean Team during the Tech-Transfer of Alere TrueLine HIV Rapid Test Kit and successfully passed the requirements. 3. Implemented Semi-Automatic Assembler Machine and Horizontal Pouch Sealing Machine from M/s Zeta Corp. Driven the Production & Maintenance Team by fostering the culture of T.P.M and training them in the setting of Online Vision System Camera. 4. Meet the market requirements by handling 2 Assembly Lines and delivering 2lac Test per day by running 2 Shifts. 5. Direct reporting of 150 + Workman. 6. Faced Surveillance Audit for ISO13485:2016 7. Controlling of Manpower and Energy Cost.
avantor	1. Handling Haematology , Biochemistry and Rapid Test Production. 2. Responsible for reagent manufacturing 3. Direct reporting of 75 + Workman.
J. Mitra & Co Pvt. Ltd a vision to serve mankind	1. Transform the manual process into an automation process by installing the Device Manufacturing M/c, Form Fill Sealing M/c 2. Done the modification in Malaria Cassettes so that it can run on the Automatic M/c 3. Handling of SFG & FG Process for Rapid Test Kits 4. Prepared and effective new proposed layout of area overwriting the existing layout at the time of installation of machine 5. Faced WHO Audits . 6. Knowledge of operation of following machines in respect to some of its calibration & validation purpose Reel to Reel Machine, Ink Jet Coding Machine, Bio- Dot, Dispensure, LaminationMachine,Coding&Labelling Machine, Strip Cutting Machine, Device Sealing Machines, Electronic Weighing Balance, Repeater Pipette, Pad Printing Machine, Form Fill Seal Machine, Twin Tray Kit Assembly Machine, Device Manufacturing Machine, Filling Nozzle Pressing & Capping Machine, Dropper Sorting Counting & Packaging Machine, Vial Pouching Machine 7. Handle CAPEX and Departmental Related Budget for Year against the Market Requirements. 8. Lead for PPIC Meeting. 9. Controlling of Manpower and Energy Cost.

International Exposure & Global Collaboration

1. Collaborated with international manufacturers and OEMs across Germany, China and South Korea, to support manufacturing and quality operations.
2. Led technical and quality coordination during overseas vendor audits, supplier qualification, and inspections, ensuring compliance with global standards.
3. Conducted international factory audits, vendor assessments, technology transfers, and compliance verification.
4. Managed cross-border communications and collaborations in alignment with ISO 13485 and Country of Origin Regulation requirements

Skills

1. Manufacturing Operation Management
2. Project Management
3. Strategic Planning
4. Operational Planning
5. Quality Management System
6. Design & Development
7. Molecular Diagnostics
8. In Vitro Diagnostics
9. Regulatory Submission
10. Lean Manufacturing
11. Assay Development
12. Change Management
13. MDSAP
14. WHO-PQ
15. Microsoft Office
16. ERP
17. CAPA
18. Technology Transfer
19. Plant Set Up
20. Statutory Compliance
21. Regulatory Compliance
22. ISO 13485
23. Quality Tools
24. Risk Management
25. Procurement & Negotiation
26. Equipments Qualification
27. Microsoft Office
28. Adobe

Education

1. Master of Technology (Manufacturing Management) – *Work Integrated Learning Programme (WILP)*
   Birla Institute of Technology & Science (BITS) Pilani | 2021 CGPA:
   9.16 / 10

2. Bachelor of Technology (Biotechnology)
   M.I.E.T, Meerut, Uttar Pradesh | 2014
   Percentage: 81.38%
3. Senior Secondary (Class XII) – *ISC Board*
   St. Paul's School, Gorakhpur, Uttar Pradesh | 2010
   Percentage: 70.60%
4. Secondary (Class X) – *ICSE Board*
   St. Paul's School, Gorakhpur, Uttar Pradesh | 2008
   Percentage: 62.85%

Certification

1. ISO 13485:2016 Certified External & Internal Auditor – Accredited by DQS Inc. & TUV SUD
2. SAS Base Training Certification | 2014
3. Certificate of Participation – *National Seminar on Recent Advancements in Forensic Biotechnology* | 2014
4. Certificate of Appreciation – *Manthan National Competition* | 2013
   (Shortlisted among finalists)
5. Certificate of Merit – *UPTU Academic Session* (3rd Year)
6. Departmental Coordinator Certification – *Technical Festival*, MIET, Meerut
7. Selected Candidate – *Biocon KGI Certificate Program in Biosciences*
   (16-week full-time program offered by Biocon Academy in collaboration with Keck Graduate Institute, California; selection secured, program not pursued)

I hereby declare that the information furnished above is true and correct to the best of my knowledge and belief.

(Amar Dinesh Singh)