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**Personal Details**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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|  | ***Name*** | | |  |  |  |  | K. R. PRAKASH | | | |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | |  |  |  |  |
|  |  |  |  |  |  |  |  | M. S. Pharmaceutical Technology, Vinayaka Mission University, | | | | | | | | | | |  |
|  |  |  |  |  |  |  |  | Salem.(Tamil Naidu) | | | | | | |  |  |  |  |  |
|  | ***Highest Degree & Institute*** | | | | |  |  | B. Pharm, Dr MGR medical University (formerly Bharathiar | | | | | | | | | | |  |
|  |  |  |  |  |  |  |  | university, Coimbatore),Tamil Naidu. | | | | | | | | | | |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | ***Marital status:*** | | |  |  |  |  | Married | | | |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | |  |  |  |  |
|  | ***Address :*** | | |  |  |  |  | Flat No. A-1303,Goodwill Paradise,Sector-15,Kharghar, | | | | | | | | | | |  |
|  |  |  |  |  | Navi Mumbai-410210 | | | | | | |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | ***Age*** | | |  |  |  |  | 49 | |  | Years |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | **1: Family Profile** | | | | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  |  |  |  |
|  |  | **S.No.** |  |  | **Name** |  | **Age** | |  |  | **Relation** |  |  | **Qualification** |  |  | **Profile** |  |  |
|  | |  |  |  |  |  |  | |  |  |  |  |  |  |  |  |  |  |  |
|  | | 1 |  |  | S.Geetha |  | 42 | |  |  | Wife |  |  | BBA |  |  | Housewife |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | |  |  |  |  |  |  | |  |  |  |  |  |  |  |  | |  |  |
|  | | 2 |  |  | P.Pranay |  | 17 | |  |  | Son |  |  | B-Tech Engg. |  | ----- | |  |  |
|  | |  |  |  |  |  |  | |  |  |  |  |  |  |  |  | |  |  |
|  | | 3 |  |  | P.Aashik |  | 10 | |  |  | Son |  |  | Schooling |  | ----- | |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  | 4 |  |  | K.R.Suresh |  | 53 | |  |  | Brother |  |  | M.Sc Applied |  |  | Assistant commissioner |  |  |
|  | |  |  |  |  |  | (Elder) |  |  | Physics |  |  | RAW (Intelligence Bureau) |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | |  |  |  |  |  |  | |  |  |  |  |  |  |  |  |  |  |  |
|  | | 5 |  |  | K.Radhalakshmi |  | 69 | |  |  | Mother |  |  | H.Sc |  |  | Housewife |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  | (Late) |  |  |  |  |  |  |  |  |  |  |  | (Retd.) Dy. Director Rural |  |  |
|  |  | 6 |  |  |  | -- |  |  |  | Father |  |  |  |  |  | Development board (Tamil |  |  |
|  | |  |  | K.Ramachandran |  |  |  |  |  |  | MA |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | Nadu Govt.) |  |  |
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**2: Educational Profile**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **S.No.** |  | **Title** |  | **Institution/ University** |  | **Position held** |  |  |
|  |  |  |  |  |  |  |  |  |
| 1 |  | Pre degree |  | University of Calicut, Kerala. |  | First division |  |  |
|  |  |  |  |  |  |  |  |  |
| 2 |  | B.Pharm |  | MGR medical University, Tamil Nadu. |  | First division |  |  |
|  |  |  |  |  |  |  |  |  |
| 3 |  | MS (Pharmaceutical |  | Vinayaka Mission University, Salem.(Tamil Naidu) |  | First division |  |  |
|  |  |  |  |  |  |  |
|  |  | Technology) |  |  |  |  |  |
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**3: Training Profile**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **S.No.** |  |  | **Title** |  |  | **Details/ Organized by** |  |  |
|  |  |  |  |  |  |  |  |  |
| **Most recent** | | | |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 1 |  |  | IDMA workshop with USFDA,EMA Key |  |  | IDMA |  |  |
|  |  | associates |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 2 |  |  | Workshop on Data integrity |  |  |  |  |  |
|  |  | Workshop on Quality Matrics |  |  |  |  |  |
|  |  |  |  |  | UBM |  |  |
|  |  |  |  |  |  |  |  |  |
| 3 |  |  | Workshop on QBD, Analytical Method |  |  |  |  |  |
|  |  | validations |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  | |  | |  |  |  |  |  |
| **Previous Years** | | | |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 1 |  |  | 24/7, all time readiness for regulatory |  |  | ISPE, India affiliate |  |  |
|  |  | audits |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 2 |  |  | cGMP – streamlining QA and FDA |  |  | Compliance Online |  |  |
|  |  | compliance by Wayne A Mazanec |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 3 |  |  | Quality Management Systems |  |  | By S R Choda from PQMC |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  | Practical Internal Auditing of quality |  |  |  |  |  |
| 4 |  |  | management systems as per ISO |  |  | By S R Choda from PQMC |  |  |
|  |  | 9001:2008 & 19011:2002 | |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 5 |  |  | Quality by Design |  |  | International business conferences, by |  |  |
|  |  |  |  | Dr. Line Lundsberg |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 6 |  |  | cGMP Training – all modules |  |  | Mr.Anthony Plane (USFDA Consultant |  |  |
|  |  |  |  | & Ex MCA auditor) |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 7 |  |  | Aseptic processing & Sterile API |  |  | John M. Lindsay (USFDA, M/s Aseptic |  |  |
|  |  | manufacturing |  |  | Solution Inc.) |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 8 |  |  | Pharmaceutical filtration |  |  | M/s Millipore (INDIA) |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  | Regulatory guidelines & Sterile API |  |  | M/s Lachman consultant services, Inc. |  |  |
| 9 |  |  |  |  | (Consultants to the pharmaceutical |  |  |
|  |  | manufacturing |  |  |  |  |
|  |  |  |  |  | and allied industries) |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  | ISO 9000:2001 Standards & Auditor |  |  | Mr.S.M.Choda (Lead auditor cum QSM |  |  |
| 10 |  |  |  |  | 2000, Principal auditor – Chief |  |  |
|  |  | certification |  |  |  |  |
|  |  |  |  |  | associate) |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 11 |  |  | BOOT camp on sterilization |  |  | Haneyman Inc, UK |  |  |
|  |  |  |  |  |  |  |  |  |

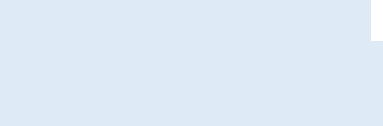
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**4: Professional Experience:**

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **4.1 : Total Experience.** |  | 25 Years | ***Middle Management*** |  |  | 8 Years |  |
|  |  | ***Senior Management*** |  |  | 13 Years |  |
|  |  |  |  |  |  |  |
|  | **4.2 :Current Title:** |  | **President – Quality & Compliance** |  |  |  |  |  |
|  |  |  | ***Organisation*** |  |  | Lifepharma |  |
|  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  | ***Location*** |  | Dubai | ***Duration*** |  |  | May 2018 To Present |  |
|  |  |  |  |  |  |  |  |



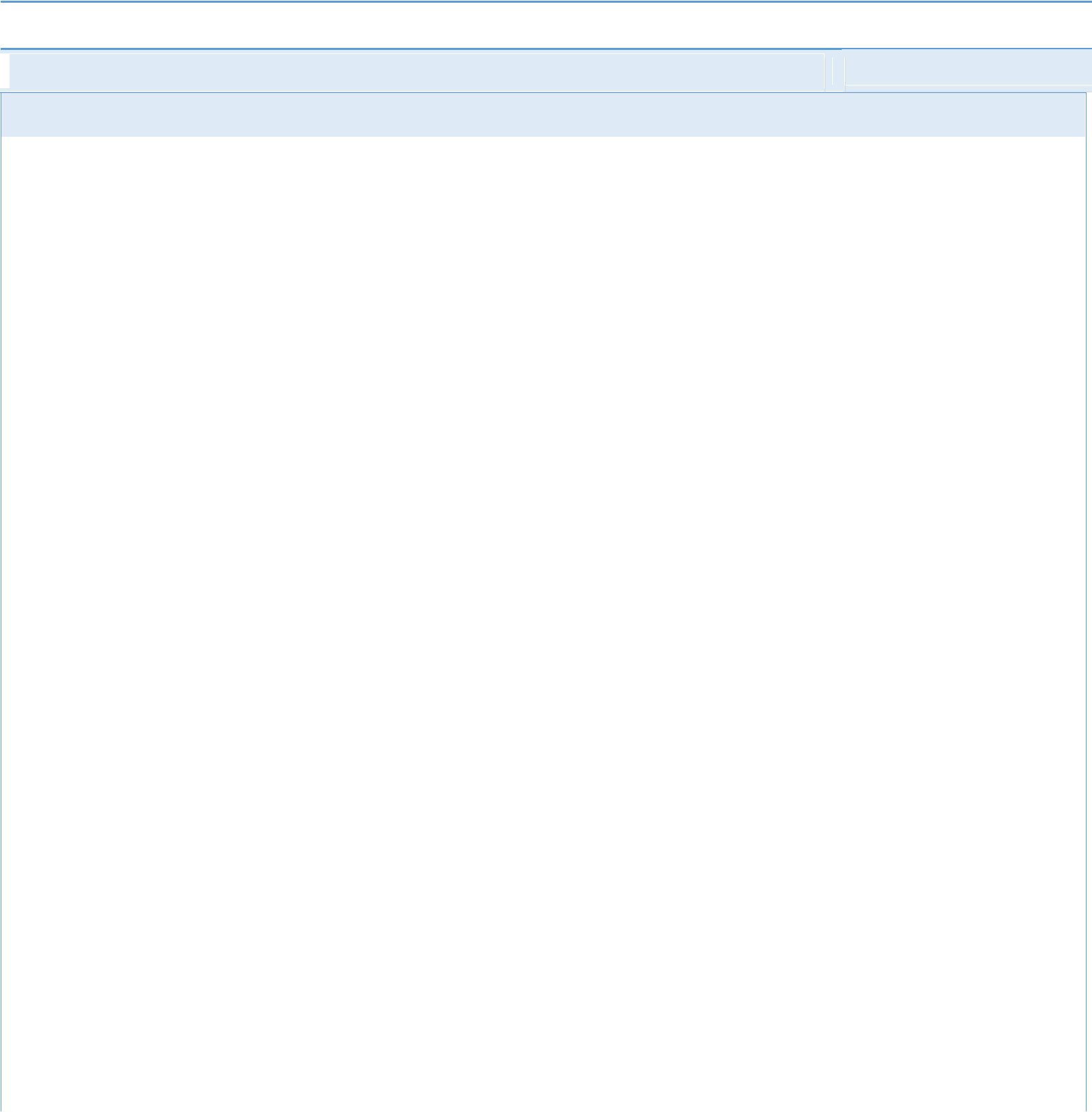
***Role :*** 

Responsible for Quality & Compliance Function of Manufacturing site for assuring highly

Compliant Operations per USFDA.MHRA, GCC.TGA, Health Canada viz International

Regulations. Accountable for Quality &compliance function within organization

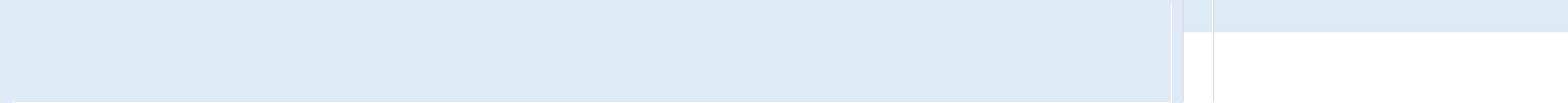
.Reporting to Director.

 ***4.3:* Previous Experience :**

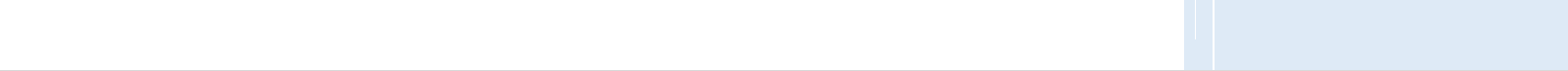
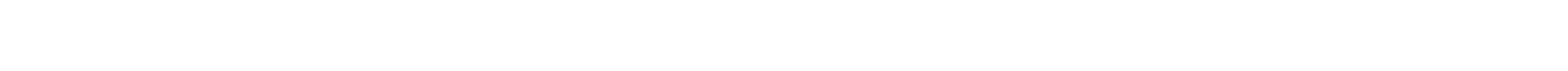
**(Mentioned all Managerial Roles held since 1997,in descending order )**

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|  |  | ***From – To*** |  |  |  |  | ***Designation & Role*** |  | ***Company Name*** |  |  |
|  |  | May 2017 – April 2018 |  |  | **Designation: Senior Vice President-Quality Operations** | | |  | Cipla Ltd |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  | **Role:** Responsible for Quality Function of Manufacturing sites for assuring highly compliant Quality Operations & corporate governess for overseeing the site Quality performance matrices. Reporting to President Quality (Global) | | |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  | |  |  |  |  |
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|  |  |  |  |  |  | | |  |  |  |  |
|  |  | Jan 2017 – May 2017 |  |  | **Designation: Senior Vice President, Corporate Quality.**  **Role: Heading the Corporate Quality & Site Quality**  **Function of 3 sterile facilities**.Responsible as No. 1 in  Quality Organogram and reporting to Chairman & MD. | | |  | **CLARIS** Injectable  (acquired by **BAXTER ,**  **USA.**) Ahmedabad. |  |  |
|  |  | Oct 2013 -Jan 2017 |  |  | **Designation: Vice President & Head of Corporate Quality.** | | |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  | **Role**: Heading all Indian Manufacturing sites- 2 API, 7 DP | | |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  | |  |  |  |  |
|  |  |  |  |  | sites, BE centre, RD Quality & CQA**.** Responsible as No. 1 in | | |  | **ALKEM LABORATORIES** |  |  |
|  |  |  |  |  | Quality Organogram, reporting to Managing Director & CEO | | |  | Mumbai. |  |  |
|  |  |  |  |  | of the organisation, driving the Quality Function within the | | |  |  |  |  |
|  |  |  |  |  | organisation. | | |  |  |  |  |
|  |  |  |  |  |  | | |  |  |  |  |
|  |  | July 2012-Oct 2013 |  |  | **Designation**: **Associate Vice President Corporate Quality** | | |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  | (Joined as Deputy General Manager, grown within the | | |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  | organisation as General Manager, Senior General Manger | | |  |  |  |  |
|  |  |  |  |  | and further to Associate Vice President-) | | |  |  |  |  |
|  |  |  |  |  | **Role**: As Subject Matter Expert for Quality Management | | |  |  |  |  |
|  |  |  |  |  |  |  | |  |  |  |  |
|  |  |  |  |  | System compliance &aseptic assurance process for the | | |  |  |  |  |
|  |  |  |  |  | Indian manufacturing sites. Also initiated and headed CQA | | |  |  |  |  |
|  |  |  |  |  | SQM(Supplier Quality Management) overseeing the | | |  |  |  |  |
|  |  |  |  |  | Compliance and for assisting continuous up gradation in | | |  |  |  |  |
|  |  |  |  |  | GMP & regulatory compliance of Overseas Joint Ventures, | | |  | **AUROBINDO Pharma** |  |  |
|  |  |  |  |  | Subsidiaries & Key suppliers. Reporting initially to board Director at site level, and to President Quality at corporate role. | | |  |  |  |
|  |  |  |  |  |  | **Ltd**, Hyderabad |  |  |
|  |  |  |  |  |  | | |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  | April 2004- July 2012 |  |  | **Designation**: **Head of Site Quality** (Sterile API, DP & Non- | | |  |  |  |  |
|  |  |  |  |  | Sterile API/DP) sites | | |  |  |  |  |
|  |  |  |  |  | **Role**: Heading the site Quality Function of Asia’s largest | | |  |  |  |  |
|  |  |  |  |  |  |  | |  |  |  |  |
|  |  |  |  |  | sterile cephalosporin manufacturing site, including sterile | | |  |  |  |  |
|  |  |  |  |  | API, sterile Injectable & Solids as single point of Quality | | |  |  |  |  |
|  |  |  |  |  | contact with key business partners. Responsible for QA /QC | | |  |  |  |  |
|  |  |  |  |  | / Microbiology & Plant RA, leading compliance of all Quality | | |  |  |  |  |
|  |  |  |  |  | operations within sites. | | |  |  |  |  |
|  |  |  |  |  | Reporting to Director Technical(Regulatory operations) | | |  |  |  |  |
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|  | From – To |  |  |  | Designation & Role |  |  |  | Company Name | | |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Jan2002-April 2004 |  | **Designation**: **Manager – Quality.** | | |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  | **Role:** Heading Site Quality (QA/QC/ Microbiology and plant | | |  |  | **HETERO DRUGS Ltd** | | | |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  | RA) reporting to Director. Responsible for Quality system | | |  |  |  |  |  |
|  |  |  |  |  |  | Hyderabad | | |  |  |  |
|  |  |  | and practices, documentation, qualification and validation, | | |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  | regulatory filing. | | |  |  |  |  |  |  |  |  |  |
|  |  |  |  | |  |  |  |  |  |  |  |  |  |  |
|  | Nov1999- Jan 2002 |  | **Designation: Deputy Manger-Quality Assurance** (site - | | |  |  |  |  |  |  |  |  |  |
|  |  |  |  | |  |  |  |  |  |  |  |  |  |  |
|  |  |  | sterile API/DP/Dosage forms) | | |  |  |  |  |  |  |  |  |  |
|  |  |  | **Role**: Responsible for site quality operations and heading | | |  | **AUROBINDO Pharma** | | | | |  |  |  |
|  |  |  |  |  |  | **Ltd** Hyderabad | | |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  | the QA, QC and Microbiology/plant RA Departments. | | |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  | Reporting to Senior Manager Quality | | |  |  |  |  |  |  |  |  |  |
|  |  |  |  | | |  |  |  |  |  |  |  |  |  |
|  | Nov 1997-Nov 1999 |  | **Designation: Assistant Manager Quality Assurance** | | |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  | **ALKEM Laboratories** | | | | |  |  |  |
|  |  |  | **Role**: Responsible for Site Quality Operations (Sterile | | |  |  |  |  |
|  |  |  |  |  |  |  | Mumbai | |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  | DP/Solids)Reporting to General Manager Quality. | | |  |  |  |  |  |  |  |
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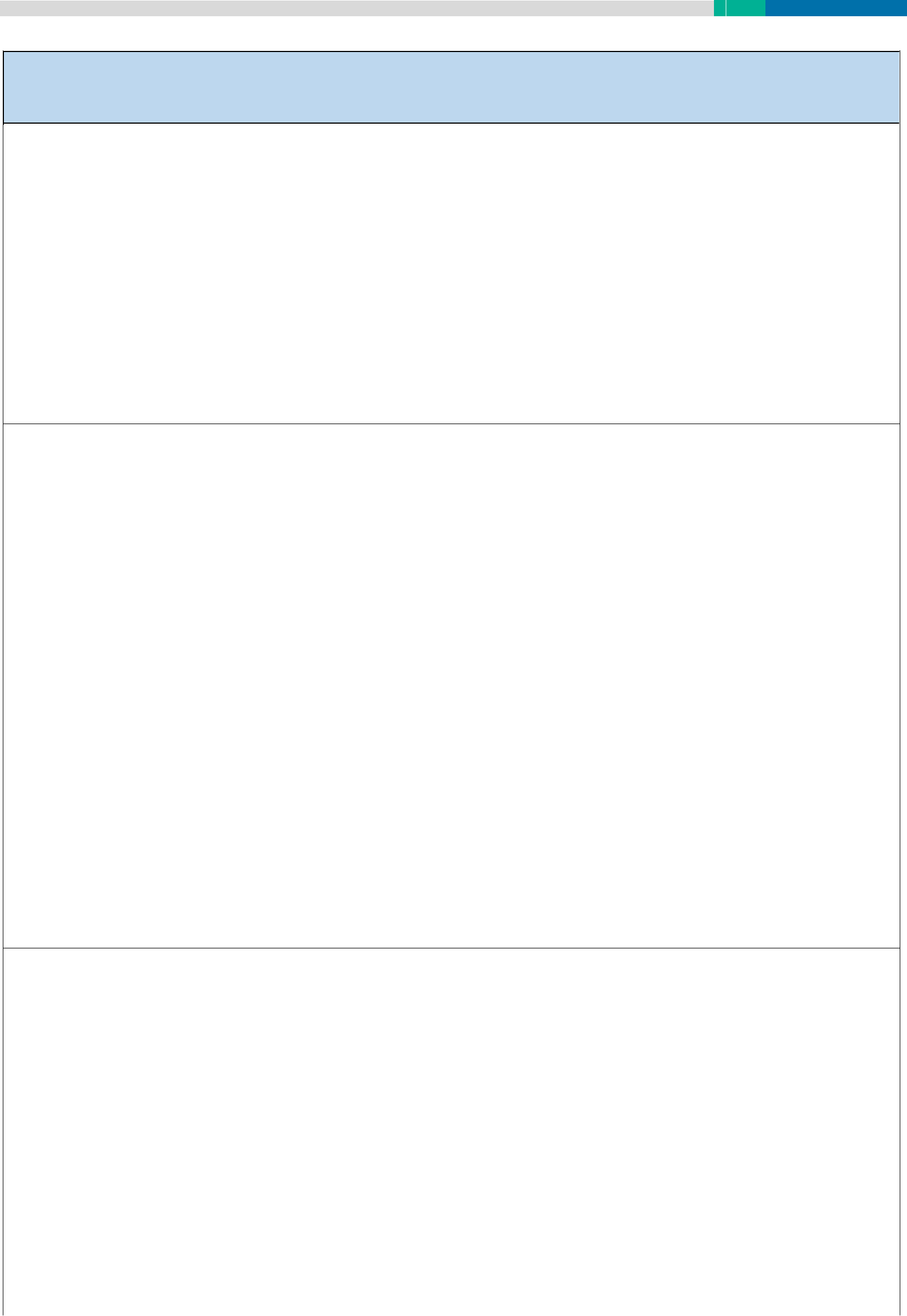


**4.4 Preliminary Experience Details(prior to 1997):**



|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **From – To** |  |  |  |  |  | **Designation & Role** |  |  | **Company Name** |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  | 1995 – Nov 1997 |  |  | **Designation**: **- Senior Executive-Quality QA.** | | | | |  |  |  |  |
|  |  |  |  |  |  |  |  | |  |  |  |  |
|  |  |  |  | **Role:** | | Responsible for Quality systems, documentation | | |  | **Kopran Limited.** | |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  | ,GMP audits ,IPQA & Validations .Reporting to Senior | | | | |  |  |
|  |  |  |  |  | Mumbai | |  |
|  |  |  |  | General Manager Quality. | | | | |  |  |  |  |
|  | 1992- Oct 1995 |  |  | **Designation**: **Incharge-Quality Control.** | | | | |  | **Gujarat Inject, Kerela** | |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  | **Role:** | | Responsible for Site Quality (QA/QC/ Microbiology | | |  | **Limited** | |  |
|  |  |  |  |  |  | | | |  | Palghat ,India | |  |
|  |  |  |  | and plant RA) reporting to General Manager –operations.. | | | | |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |

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1. Detailed Role Profile with accomplishments (For all Managerial Tenures held from 1997)

**As Senior Vice President, Corporate Quality with CLARIS Injectable (acquired by BAXTER , USA.) Ahmedabad**

Heading the Corporate Quality & Site Quality function of 3 large sterile Manufacturing sites and responsible for driving Quality function across the organisation reporting to Chairman & Managing Director. Played a key role in strategic alliance with US based Multinational Company.

1. Driven the QUALITY & COMPLIANCE systems across 3 FDA approved Sterile injectable site s.1ANVISA ,1 WHO audit & multiple due diligence audits by US strategic business

partner.

1. Accountable for smooth Technology transfer and new PROJECT/facility implementation, whil

e strategic alliance with US MNC.

1. Driven Training, QMS function to harmonize systems and practices. And to formulate QS POL ICIES/ DIRECTIVES, including Electronic Quality Management System initiatives.

**As Vice President & Head of Corporate Quality with ALKEM Laboratories Mumbai**

**Accountable for Quality function of all Indian manufacturing sites & Third party contract manufacturing functions. As a no 1 in Quality Organogram lead Corp Quality Assurance ,all site Quality functions( 2 API ,8 DP locations, & Quality Function of BE Centre.**

**Successfully hosted 10 USFDAs ,3TGA ,1 MHRA,3 EU ,1 WHO Geneva . Also set forth a smooth process for maximum Filing of new product Dossiers/ANDAs and product launches .Implemented a complete integrated electronic Quality Management system software & GAMP compliant automated process controls in manufacturing operations .Consolidated 125+ CMO sites based on Quality Risk Approach following product mix,volumes &GMP compliance standards.**

**Notable initiative and bench marking achievement include Percolation of QUALITY CULTURE across the Organisation.**

1. Have successfully lead 10 USFDAs (including one inspection with one day notice & 1 inspecti on without notice),3 TGA, 1 MHRA. All USFDAs, were successful & received EIRs. (3-non-ste rile API PLANT, 3-for Solid Dosages, DP ,1- R&D, validation/controlled testing lab. 3 –for Bio
2. Implemented Integrated Electronic Quality Management System across the organization. o Implemented GAMP compliance automated manufacturing process controls.

o Lean Management in Smart QC laboratories.

o RISK based Audits &system harmonization, simplification and compliant Quality Systems.

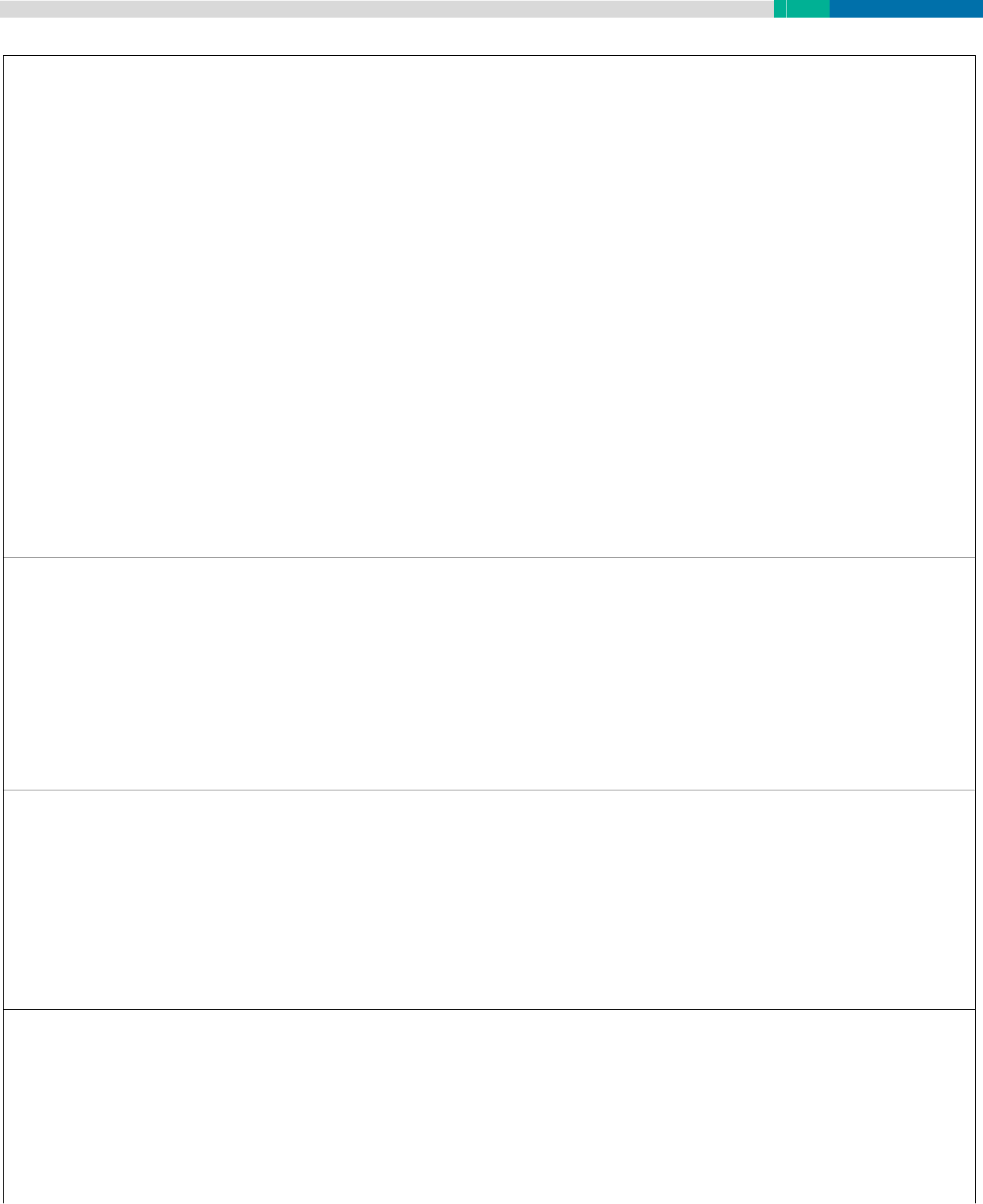
**As Associate Vice President Corporate Quality/Site Quality Head with AUROBINDO Pharma Ltd, Hyderabad**

**Worked in Aurobindo Pharma from April 2004 till 2013 october .The successful stint include different roles in the Quality Department. In the most recent portfolio as Associate Vice President Corporate Quality Assurance**

* **was responsible as Subject Matter Expert for Quality Management System compliance and sterile assurance process for all manufacturing sites**. In addition lead the SQM(Suplier Quality Management )for assuring thecGMP/Regulatory compliance of JVs/subsidiaries/Associated companies & potential suppliers.(overseas).SQM drive was an first of its kind for coordinating regulatory submissions planning, ,technical guidance for overall facility improvement and assisting in cGMP inspections .

**As Site Quality Head & no1 in site Quality Organogram ,lead the site team in to many a firsts like DMF submission ANDA submission, PAI and product Lunches. Grew with the organisation, from Deputy General Manager ,General Manager, Senior General Manger to Associate Vice President Quality**.

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Contd/

**As Associate Vice President Corporate Quality/Site Quality Head with AUROBINDO Pharma Ltd, Hyderabad.**

Instrumental in the facility up gradation of Formulation manufacturing sites (injectable/solids),New facility Commissioning and qualification, validation of sterile API facility ,Media fills, Aseptic practise implementation, Training

* framing the documentation for all the departments (sops/protocols, and various other cGMP records), Assisting in Tech Transfers ,submission batch planning/execution DMF/ANDA /MA,/dossiers filings, PAI,/Post compliance inspections from most of the Global Regulatory agencies, viz USFDA,TGA,MHRA,EDQM,HEALTH CANADA, MCC,ANVISA, GCC, NDA,& many other ROW health agencies.

Notable achievements include sustaining the post commercial compliance of the site ,Project execution of many contract manufacturing under TA for global MNCs based in EU/US, leading the plant team of various cross functional area for fulfilling the business targets and innovative ideas for percolation of cGMP/ASEPTIC concepts and improving

overall Quality Culture at site.

* 8 USFDA inspections, 8 EU inspections, 3TGA, 2 HEALTH CANADA, 6 Brazil ANVISA, 2 MCC, & v arious other 20++ROW inspections as Head, SITE Quality Operations.
* Active contribution and coordination (CFT team & Quality) to result Highest Regulatory filings in to US (240+USANDAs, 150+USDMFs) & similar higher nos. of filings in to EU/ROW market.

As Manager –Quality with HETERO DRUGS Ltd Hyderabad

**Heading the new formulation site Quality Operations, leading various cross functional team implementing the Quality Systems & Practices. Successful in hosting the site to many ROW /ANVISA /NDA /WHO Geneva Inspections .Key Quality contact for PEPFAR registrations, and many business tie ups .**

1. *I WHO GENEVA, 2 Brazil ANVISA, 1 NDA, various other ROW inspections (7), in the assignment as Quality Head.*
2. *Product Dossier registrations in many ROW,WHO &Brazil .*

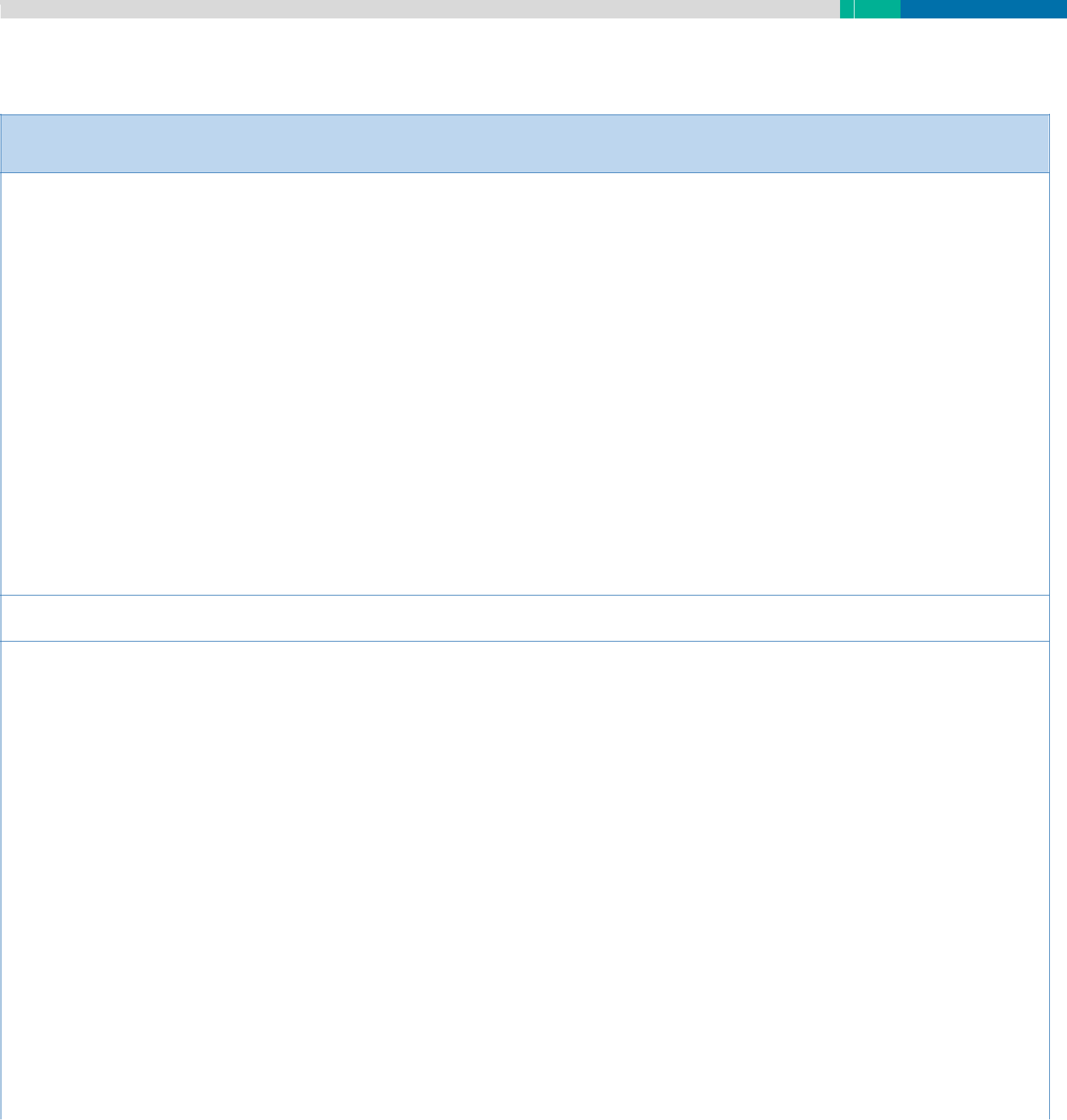
**As Deputy Manger-Quality Assurance with AUROBINDO Pharma Ltd Hyderabad**

**Responsible for the site Quality Operations, heading the QA/QC/MICROBIOLGY of the sterile API/DP site and initiation and implementation of all systems and documentation across the site .Successfully completed the MCC SA, ISO UK, NDA, ANVISA Inspections of the site. Notable contributions in customer support with technical query deficiency, troubleshooting of product Quality issues and assisting in project planning and execution in liaison with RD, marketing, Business Development, Packaging Development and Logistics.**

**As Assistant Manager Quality Assurance with ALKEM Laboratories, Mumbai**

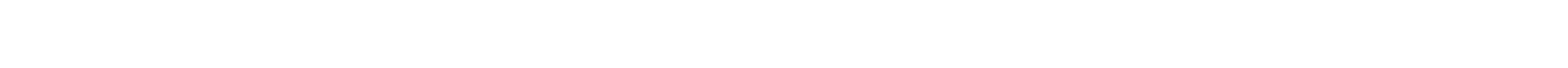
**Responsible for Site Quality Operations (Sterile DP/Solids).Active involvement in site, facility commissioning and qualification of two large sterile &solids manufacturing site .Implemented documentation (SOPs, Protocols) and training of personnel .Also hosted site for NDA, WHO Inspections. Site was prequalified for MHRA inspection.**

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**6 Role functions at Cipla :**

* Accountable for highly compliant Quality Operations in Manufacturing Locations.
* Review & Compliance for all Microbiological/aseptic Quality Operations & their enhancements.
* Talent Built up, Internal SME grooming for enhanced review
* Strengthening Investigations within the site QMS events.
* Simplification, harmonization of systems/practices across the sites.
* Problem resolutions, analysis and helping to trouble shoot site process, product non-conformances.
* Review of site performance based on Quality metrics.
* Resource allocation, review and optimum utilization to meet business deliverables.
* Hands on assistance to site on all issue resolution, Regulatory Audits.
* Evaluation of current people, process, systems & identify opportunities for improvement and instrument the implementation.
* Monitoring the registration lots, submissions and Launches in a timely manner and formed a DEDICATED team at each site to act specifically on this.



**7 Key significant highlights in role at Cipla :**

 Articulated an in depth thought process for enhancement of compliance & percolated amongst team through consistent perseverance of each issue/ event reviewed at my level.

* Building up a strong QA eye in review, vigilance (begin to detect near miss events, Quality of review in to investigation and boldness to say NO when situation needs) is being put in place.
* Hands-on assistance to Site regulatory inspections (2 USFDA inspections, 1 MHRA,1 TGA,1INVIMA). Also lead theremediation & Response to form 483 at both locations.
* Close Communications and easy to approach: A strong communication closeness-whatsapp group/ spontaneous response to emails has helped to make distance shorter, closeness to issues/persons and freedom to express amongst my team.
* Simplified the much discussed OOS SOP, Product Review SOP. (Made it less prescriptive, more compliant, short &precise)
* Introduced fortnightly manning of OOS and recently an effective Year on YEAR trending summary of OOS across locations.

 Formed a dedicated team at each site for Dossier submission, launches review. Also, dedicated QC analysts for testing of ANDA lots.

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