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Objective:

Seeking leadership position in management of Quality Operations.

Summary of Experienceand Career Profile

I have 14 years of experience in Quality Operations (QA/QC, Validation, Regulatory and R&D) and Production with leading pharmaceuticals manufacturers in Pakistan having approx. 6 years as QC / QA and Production Manager. Comprehensive knowledge and working experience of **ICH, USP, BP**, **EU** and **DRAP guidelines**related to pharmaceutical validation, stability, laboratory operations, product development, Quality management system, documentation and product release.Have wide experience of dealing with Multinational foreign auditors and DRAP. Experienced in investigating testing abnormalitiesand determination of root causes of non-conformances(OOS, Atypical), CAPA, Deviation and Change control management. Partook in several cost optimization projects, Quality improvement projects and establishment of Quality Assurance System projects.

Education

University of Karachi (Karachi, Pakistan)

* **M.Sc. Organic Chemistry** (2000) –1st Division: Published research thesis at HEJ Institute.
* **Chemical research and publication (Thesis)**- One year Research in H.E.J. Research Institute on *Extraction and Structural Elucidation of Chemical Compounds*from Medicinal important plant *Lawsonia Alba* and published a Thesis book on same research
* **B.Sc. (Hon.) in Chemistry, Microbiology & Physiology**(1999) – 1st Division.
* Post-graduate Degree – Mathematics (1999).

Experience

1. **Ismail Industries Limited March 2015 ~ Till date ScreenHunter_10 Jan. 06 14.16.jpg**

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| **Designation: Manager Quality Operations** | **March 2015 ~ Till date** |

To ensure the implementation of HACCP plan as per ISO 22,000 (Food Safety Management) requirement on all Snacksproduction lines, ensure all raw Materials, primary and secondary packaging materials and finished products meet their quality standards. To establish Quality inspections plan for food production lines and SOPs. To ensure the Quality plans be implemented and strictly followed the GMP guidelines in **UNICEF and WFP (World Food Program , US-AID)** production of Ready to use Supplementary and Therapeutic foods **(RUSF / RUTF)** to meet all the quality standards before final release.

1. **Sante Pvt Limited November 2013 ~ February 2015**

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| **Designation: Manager Quality Operations** |  |

To Ensure all Raw Materials, primary and secondary packaging materials, semi-finished and Finished products meet their quality standards and to build a competent and reliable quality team. To establish the new Lab in a new facility up to the mark and purchase instruments. To establish SOPs, Quality policies and procedures, most importantly to establish a competent and effective Quality Assurance system and procedures in newly built plant.

**Key Accountabilities**

* Head and Lead all Quality Operations Management activities.
* Lead, oversees and coordinates the activities of laboratory operations, stability, compliance, documentation and product release, incoming inspections, validations, qualifications and process improvements.
* To lead and manage new methods’ development, assist the analysts in this and ensure all methodsbe validated as per ICH Q2.
* Establish Stability Study plan and manage / conduct review of stability testing and data for both commercial and under development products.
* To investigate testing abnormalities, determining root causes of non-conformances(OOS, Atypical), CAPA, Deviation and Change control management.
* To take initiatives and lead cost reduction projects, proposals for enhancing the production (yield), improving formulations, reducing cost /unit projects.
* To develop Quality Operation’syearly goals and objectives and to prepare QO yearly budget (chemical / Micro).

**Key Results/Achievements**

* Got appreciation from management for reducing cost of several running products by decreasing surplus overages of APIs along with scientific rationale study.
* Got appreciation from management for significantly increasing yieldof almost all running products and some costly products by setting up logical dose volume filling range as per USP.
* Established the comprehensive Validation Master Plan for whole new manufacturing plant, equipment and processes. Prepared the execution plan and supervised all activities.

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| 1. **October 2007 ~ October 2013** | **Macter Intl. Ltd.**([www.macter.com](http://www.macter.com)) |

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| **Designation: Manager Production, Penicillin Facility** | **July 2013 ~ Oct 2013** |

To ensure to comply the monthly production planning, coordination and control of manufacturing processes. To ensure that goods and services are produced efficiently and that the required amount is produced at the right cost and level of quality.

**Key Accountabilities**

* Overseeing the production process of Penicillin based Dry-Suspensions, Capsules, Tabletsand dry powder injections of Macter, Wyeth and Novartis (Sandoz).
* Drawing up a production schedule according to given monthly schedule by Planning department and splitting it into weekly schedule and ensure successfully complying the weekly schedule within given timeframe.
* Timely coordinate with planning with materials’ unavailability and other bottle necks to keep production flow smooth.
* To improve productivity and yields, reduce losses, down time, and idle time. To improve effective utilization of resources.

**Key Results/Achievements**

* Identified the bottlenecksduring dry suspension filling machine that helped increased productivity.
* Successfully removed slugging process of Wymox capsule (Wyeth) by replacing with higher bulk density Amoxicillin compacted powder. Also identified the capacity to double the batch size and got the process revalidated.
* Wet granulate of Ospamoxsusp(Sandoz) took about 3 to 4 hrs to pass through granulator before FBD drying. After my proposal and suggestion, my team did work on it to first half-dry the granules for 10 minutes in FBD and then pass through granulator, it takes then about 20 minutes for whole batch to pass and hence this bottleneck is removed.

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| **Designation: Manager Quality Control** | **July 2010 ~ June-2013** |

To Ensure all Raw Materials, primary and secondary packaging materials, semi-finished and Finished products meet their quality standards, Products’ releases and to build a competent and reliable quality team.To ensure successful implementation of ERP (SAP) in QC and QA as a power user.

**Key Accountabilities**

* Lead all QCLab Management activities.
* To ensure timely releases and reports approval of raw materials, packaging materials and finished products.
* To lead and manage methods’ development of new / non-compendia molecules and ensure all methodsbe validated as per ICH Q2.
* Lead multiple Technology Transfer projects for new products from JnJ, Merck and Bayer fulfilling all prerequisites and headed all technical method transfer protocols executions.
* To make and provide trainings programs for all QC analysts on Instruments, Quality Procedures and GLP.
* Has been a team member of Internal Audit of different departments regarding GMP and QMS audits and preparation of Audit finding report.
* To provide performance evaluation and monthly KPIs of QC department (chemical and Micro) to the Head of QO on monthly basis.
* Lead several Investigational, Developmental and Technical Projects as Cost optimization project, Validation Project, and others as identified and proposed as a result of CAPA.
* To develop Quality Controlyearly goals and objectives and to prepare QC yearly budget (chemical / Micro).

**Key Results/Achievements**

* Got reward from management for implementing “Reduced/skip testing plan for semi-finished and finished products saving about 500 hrs of testing time with tremendous amount of cost reduction for chemicals consumption.
* Successfully got trained as a SAP power user, gap analyzed and implemented ERP (SAP) system in Quality Management module in stipulated period of time.
* Promoted as QCM from AM Validation.

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| **Designation: Asst. Manager, Validation** | **October 2007 ~ June 2010** |

To ensure all production practices and formulations validated, areas qualified and all QC testing Methods validated.

**Key Accountabilities**

* Preparation of HVAC Qualification/Validation Protocols, manage all execution activities and compilation of data and report.
* Preparation of Cleaning Validation, Process Validation, Equipment Qualification protocols and Qualification/validation reports issuance.
* Lead and managed Sterile filling process validation protocol (Media Fills) and execution.
* Have multiple toll clients’ external audits successfully conducted regarding their queries for validation.
* Lead the validation team and all validation activities and ensure to comply with VMP.

**Key Results/Achievements**

* Lead and executed Cleaning Validation of oral liquid manufacturing tanks and Syrup filling machine for J&J.
* Lead and managed Media fill runs in aseptic penicillin and cephalosporin dry injection filling line and validated compact filling line (sterilization by tunnel and autoclave).
* Successful Process validation of Macter product (Amoxicillin Capsule) that resulted in significant decrease in final mixing time (from 90 min. to 20 minutes) that improved better dissolution & DT parameters than former.
* Got acknowledged with positive performance appraisal by Macter’s management in omitting 14 hrsof tray-drying of sugar after successful validation work in WymoxSusp. (Wyeth).
* Promoted as AM Validation from Validation Incharge.

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| 1. **July 2005 ~ October 2007** | **Bosch Pharma Pvt. Ltd.**([www.bosch-pharma.com](http://www.bosch-pharma.com)) |

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| **Designation: QC Lab Incharge** | **July 2005 ~ October 2007** |

Delegation of daily job tasks and supervision of testing and release of RMs and FPs and update QC Manager about all Laboratory affairs time to time.

**Key Accountabilities**

* Analytical Methods development of non-pharmacopeial and new products on HPLC and Spectrophotometer.
* Development of key SOPs related to QC.
* Maintain the Master calibration schedule of all QC instruments.
* Contact with different Suppliers to get the Quotations for different instruments and price negotiations.

**Key Results/Achievements**

* Developed and Validated an in-house analytical method for Azithromycin raw material and capsules on HPLC using simple UV detector, Whereas USP method recommends Amperometric detector (much expensive and rare detector), while most pharma companies use Bio-Assay method.
* Hired as Sr. QC Analyst that subsequently promoted to Lab Incharge.

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| 1. **July 2002 ~ July 2005** | **Platinum Pharma. Pvt. Ltd.**(<http://platinumpharma.net>) |

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| **Designation: Sr. QC Analyst** | **July 2002 ~ July 2005** |

Testing of RMs, Semi-finished and Finished products and Stability Testing, Daily In-process Checks visit.

**Key Accountabilities**

* Chemical testing of Raw material, Semi-finished and finished drugs.
* Design and development of Testing procedures, Specifications and SOP’s
* Calibration of laboratory equipments as per schedule.
* Developed the Traceability record list of Q.C. Lab. documents and supervised the Intermediate Calibrations activities of instruments in accordance to the accreditation of I.S.O. 17025.

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| 1. **Feb. 2001 ~ July 2002** | **Zafa Pharma. Labs Pvt. Ltd.**([www.zafa.com.pk](http://www.zafa.com.pk)) |

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| **Designation: QC Analyst/ QA Inspector** | **February 2001 ~ July 2002** |

Testing of RMs, Semi-Finished and Finished products, Daily Inprocess checks and Packaging components analysis.

**Key Accountabilities**

* Sampling &Chemical testing of Raw material, Semi-finished and finished drugsas per SOP.
* In-process control of production manufacturing and packing activities.

Training & Certifications

* Power user in ERP (SAP) in QO module at Macter
* ISO-9001(2000 & 2008) at Macter
* ISO-17025 (Lab Certification) at Platinum
* ISO-14001 at Macter
* ISO-14644at Macter
* Internal Auditing at Macter
* Business Communication skills
* Time Management Skills
* Honored and got certificate as a trainer at a big forum on “Aseptic Process Validation” by Ingrope Info Services, an outsourced professional training institute
* ICH Q8, Q9 and Q10 (Pharmaceutical Quality System).
* Understanding of “Drug Act 1976 and Local MOH regulatory requirements conducted by Ingrope Info Services.

Personal Data

* Date of Birth:14-08-1978
* Citizenship:Pakistan
* Marital Status: Married , 1 daughter and 2 sons

References

* Shariq Ali Mohsin, Plant Head, Sante Pvt Ltd 0300-7044788
* Mr. Kamran Khan , Ex Head of QO, Macter Int. +1-571598-2346
* Swaleh Misbah, (MD, Macter), 0333-2288223
* Mr. Mohammad Naeem (GM Quality , CCL Pharma) 0321-5959753