# BalaSubramanian U

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## Objective:

To establish a global career that offers challenge and growth with opportunities to enrich my knowledge, experience and skills in the field of API Quality.

## Career accomplishments:

Totally 24 years of experience in pharmaceutical quality, this includes **Quality control, Analytical Quality Assurance, Quality Management System (QMS) and Audits and Compliance.** Experience of successful handling of Regulatory audits like USFDA, Eu.GMP, TGA, Health Canada, PMD, China FDA, KFDA,ISO and Customer audit etc., which includes surprise audit from USFDA.

## Leader Ship and Administrative Qualities:

- ❑ Strategic Thinking
- ❑ Micro Planning and Macro Execution
- ❑ Developing Others
- ❑ Delivery Focus
- ❑ Obeying to CGMP

## *Professional Experience*

**Company: M/S Jubilant Generics Limited** **Since: 16-Aug 2020 to till date**

**Position: QC Incharge** **No. of people reporting: 55**

(M/S.Jubilant Generics having the certification from USFDA, TGA, PMDA, Health Canada and other regulatory certificates.

## Highlights:

- ☐ *Execution for the corrective and preventive actions which are related to FDA observations.*
- ☐ *Involving the Implementation of Labware LIMS in QC Systems, which include the Standard management, column management, calibration, stability studies and etc.*
- ☐ *Responsibility to reduce the paper work by implementing the Data sheet/Format for all analytical activities in LIMS.*
- ☐ *Introducing the Electronic COA for RM,INT,API in SAP*
- ☐ *Implementing the online monitoring and review of investigations (OOS, OOT, Incidents, CAPA) in Trackwise software.*
- ☐ *Controlling the overdue training by verifying in Compliancewire software.*
- ❖ Taking Care for releases of Raw material, Inproces, Intermediate, API and other releases which are related to QC.

- ❖ Ensuring the compliance in the Quality control by reviewing audit trials for all the instruments.
- ❖ Facing Regulatory, Customer and QP audits.
- ❖ Responding to audit observations and RA queries within the stipulated timeline.
- ❖ Ensuring investigations and closure for OOS, OOT, deviation and Incident investigations.
- ❖ Taking care of documentation team for the revision of specifications, SOPs and other protocol studies in QC.
- ❖ Execution of analytical Method validations, method transfers and other studies in QC.
- ❖ Training pertaining to GMP, STP and SOP to personnel engaged in Quality control Activities.
- ❖ Execution and review of standard qualifications.
- ❖ Planning and execution for improving the TAT for all the QC activities.
- ❖ Involving the Manpower recruitment for QC.

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**Company: M/S Dr. Reddys Laboratories Limited** **Since: 15-Sep 2015 to 10 Aug 2020**

**Position: Associate Director** **No. of people reporting: 32**

(Dr. Reddys has been audited after the warning letter and approved by the UDFDA.I have explained the QC systems, audit trial review, deviations, OOS and etc. to the auditors. Further TGA, Health Canada and KFDA audited and approved the facility.

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**Highlights:**

- ✔ Taken the responsibility for successful completion of remedial actions in QC for the observations (483) from USFDA. Based on the preventive action plan the following systems has been implemented in QC
- ✔ Newly formed the Analytical Quality assurance (AQA) team and responsibilities, lead the team.
- ✔ Introduced the Audit trial review for all the instruments on routine basis and while doing the release to ensure the Data Integrity.
- ✔ Implementation of SAP system for releasing of Raw material, Intermediate, API and stability. Newly introduced the Electronic COA for RM, INT and API in SAP.
- ✔ The Labware LIMS has newly implemented in QC Systems, Taken the responsibility for the successful completion and ensured the compliance. Involved in the routine discussion and troubleshooting
- ✔ Introduced the AQA review in Analytical development lab as like QC.
- ✔ Chromatographic integration practice has been introduced in QC.
- ✔ Introduced the approval of Pre-startup activity, signoff-2 activity, audit trial review
- ✔ for all the QC activities.
- ✔ Review of and approval of investigations in online Portal software systems
- ✔ All the QC responses were completed within the targeted time and submitted to FDA
- ✔ Introduced the online change control system in SAP,

- ✔ Preparation of SOP/STP in Document management system (DMS).
- ✔ Based on the completion of Response the FDA audit was scheduled and successfully completed without any major or critical observations. I have explained about the AQA investigation and AQA review process
- ❖ Facing Regulatory, Customer and QP audits.
- ❖ Taking care of QC QMS team activities like OOS, OOT, Incident investigations.
- ❖ Verification and Approval of Change control and CAPA
- ❖ Review and approval of Method validations, instrument validation protocols and approval.
- ❖ Training pertaining to GMP, to personnel engaged in Quality control Activities.
- ❖ Execution and review of standard qualifications for API .
- ❖ Review of all specifications for quality control activities like Routine activities, Non-Routine activities, Raw material and In-process

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**Company:M/S. SyngeneIntl.Ltd(BIOCONCOMPANY) Since:01-July 2010 to 10-Sep 2015**
**Position: Manager No. of people reporting: 30**

(Syngene has been audited and approved by the USFDA in the month of September 2013 and July 2014. I have explained about the QC systems, deviations, OOS and etc. to the FDA auditor)

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**Job Profile: Leading QC department**

- ❖ Verifying the audit trials, responding to audit compliance and monitoring the GMP in lab.
- ❖ Facing customer, QP and Regulatory audits
- ❖ Performing Vendors evaluation & Audits
- ❖ Review of Analytical development lab documents like method transfer, development reports, IOP's, Analytical method procedure etc.
- ❖ Release of Raw material, In-process, Intermediate and Finished products.
- ❖ To implement and maintain the Quality procedures in quality control.
- ❖ To ensure all the records are kept as per the approved procedure in compliance with regulatory requirement.
- ❖ Training pertaining to GMP, to personnel engaged in Quality control and Manufacturing Activities.
- ❖ To organize internal GMP audits and follow up for compliance.
- ❖ Execution and review of analytical validations for API and Drug product.
- ❖ Co-ordinate, review and approve the investigation of deviations, OOS and customer complaints in quality control.
- ❖ Approval of Cleaning Validation protocols and reports for API and Drug product.
- ❖ Review of all specifications for quality control activities like Routine activities, Non-Routine activities, Raw material and In-process
- ❖ Review of DQ, IQ, OQ and PQ for all laboratory documents
- ❖ Review of QC SOP'S for quality control lab and analytical development lab.
- ❖ Review of QC documents for DMF and other regulatory filings.

- ❖ Review of stability study protocols and reports for API and Drug product.
- ❖ Analytical Lab set up, Procurement of analytical equipment, preparation of URS, installations and qualification as per the internal protocols.
- ❖ Coordination with contract research laboratories for the projects outsourced for timely deliverables.
- ❖ Execution and review of standard qualifications for API and Drug product.
- ❖ Taking care of initiation, execution and reporting of analytical method transfer from client to Syngene QC lab and vice versa.

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**Highlights:**

- ✔ Standardized to use of MS -Excel in all quality control like calculation involving assay, impurities, Residual solvent content by introducing excel validation. This was much appreciated by regulatory auditors and clients.
- ✔ Sudden USFDA inspection was triggered threw a client. The audit was announced one day prior to and it was successfully completed without any observations and 483. Same way the USFDA audit was announced one day prior for another client on July 2014 and it was successfully completed without any 483.I interacted with FDA auditor during the audit while explaining the OOS, change control, deviations, audit trials and all the quality control activities.
- ✔ Completely familiar with QC related requirements for NDA, which include analytical method validation, Process cleaning equipment method validations etc.
- ✔ Stability chambers Gap analysis was conducted and qualification of stability chambers were performed to meet the current requirement.
- ✔ Implemented the Archival procedure for Quality control documents

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**Company: M/S. HIKAL Limited** **Since 02-December 2009 to June 2010**

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**Job Profile: Quality control**

- ☐ Taking care QC activities Routine and Non-Routine activities
- ☐ Review of Analytical Method Validations
- ☐ Trouble shooting of Lab instruments like GC, HPLC, Polari meter, UV etc.
- ☐ Preparation of specification for API, Raw materials and In-process.
- ☐ Review of analytical results for Process Validation reports.
- ☐ Review and approval of stability Studies documents.
- ☐ Approval for Calibration documents of Analytical Instruments
- ☐ Reviews of technical documents for the regulatory filings of USDMF, EDMF and Dossiers.
- ☐ To ensure that all the pharmaceutical products manufactured by the Company meets the quality standards and requirements of the cGMP and FDA regulations

- ☐ To ensure that all raw materials, intermediates, packaging components and formulated products are analyzed as per STPs (pharmacopoeia and/or in-house).

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**Company: M/S. BIOCON Limited** **17-May 2004 to 24-November 2009**

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**Job Profile: Quality control**

- ❑ Taking care of all Analytical method validations like Residual solvents by GC, Assay, related substance by HPLC, Forced degradation study, Hold time study, Cleaning validation etc for API and Drug product.
- ❑ Taking care of stability studies for API and Drug product.
- ❑ To get the product analyzed and tested within TAT as per the sampling procedures giving approval of its release
- ❑ Handling of Customer Complaints.
- ❑ Preparation for regulatory audits and making the compliance for the same.
- ❑ Doing internal audit in various department.
- ❑ Taking care of EHS activity in lab.
- ❑ To assist in imparting training to QC Chemists
- ❑ To monitor and co-ordinate all In process Q.C. activities.
- ❑ Analytical HPLC/GC testing: Raw materials, In-process, finished product, stability testing
- ❑ Preparation of Instrument qualification DQ, IQ, OQ protocols and reports.
- ❑ Analytical method-transfer for validated analytical testing methods for for API and Drug product.
- ❑ Preparation of SOP, STP, GTP relating to Quality Control.
- ❑ Operation, Calibration, Maintenance and trouble shooting of Instruments like HPLC, GC, Head Space GC, UV-Vis Spectrophotometer, FT-IR, Particle size Analyzer (Malvern), Polari meter, Autotitrator, etc.,

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**Company: M/S. CIPLA Limited** **22- Jan 2003 to 14- May 2004**

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**Job Profile: Quality control**

- Taking care of Non-Routine team
- Analytical Method Validation for API and Drug product as per ICH by HPLC, GC, etc.
- Conducting Forced degradation study and Hold time study.
- Review of Cleaning validation protocols and reports for API and Drug product.
- Analysis of Residual solvent in API with Headspace Technique
- Development of newer analytical methods for API's
- Review of Analytical reports
- Conducting stability study as per guidelines
- Analysis of in-process, intermediate and Finished product analysis
- Preparation of SOP, STP, GTP relating to Quality Control
- Determination of Particle Size Distribution of API by Malvern Particle Size Analyzer using dry and wet method.
- Wrote test methods, validation protocols and reports, and other required documents suitable for regulatory submission

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**Company: M/S. SANMAR Chemicals Limited** **3- Oct 1996 to 21- Jan 2003**

**Job Profile: Quality control**

- Analysis of Raw materials, In-process samples, Intermediates samples, API and Stability samples in various instruments like HPLC, Residual solvents by Head space technique.
- Qualification and calibration of analytical Instruments
- Review of Analytical reports
- Process validation of API's
- Validation of Analytical methods for assay, related substance and residual solvents
- Performing the Olfactory tests for fine chemicals.

**Company: M/S. Pharmed Chemicals Limited** **11- Feb 1995 to 30- Sep 1996**

**Job Profile: Quality control**

- ☐ Analysis of Raw materials, In-process, Intermediates, Finished product for API and Drug product samples.
- ☐ Calibration of analytical Instruments.

**Company: M/S. Aswathi Chemicals Limited** **1- Mar 1993 to 9- Feb 1995**

**Job Profile: Production**

- Worked as a production supervisor
- Involved in Hydrogenation reaction, oxidation reactions
- Operated the distillation unit and different type of driers
- Maintaining the WIP stocks in shop floor

***Educational background***

Qualification: M.Sc. Industrial chemistry, First Class (68%) **Year of passing 1989-1991**
Bharathidasan University, Tiruchirappalli.

Qualification: B.Sc. Chemistry, First Class (67%) **Year of passing 1986-1989**
Bharathidasan University, Tiruchirappalli.

***Personal details***

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|---|---|---|
| Date of birth | : | 1st June 1967 |
| Marital status | : | Married |
| Languages Known | : | Tamil, English |
| Interests | : | Music collection, Reading books, Net browsing |
| Passport number | : | J0271344 Validity : 14.01.2011 to 13.01.2021 |
| Father | : | M. Uthirapathi |
| Mother | : | G. Saroja |
| Spouse | : | C. Raja Lakshmi MA. MPhil |

***References*** *: Shall be available on request*

## BalaSubramanian U

### *Achievements and Training:*

- Got the Quality Excellence award for successfully implementation of LIMS in QC Systems in Dr.Reddys Ltd.
- Three times received the Best performer award in Syngene on Jan 2013, Sep 2013 and Aug 2014.
- Got the BIOCON contribution award on March 2014.
- Kaizen award for outstanding contribution to the company M/S Sanmar Ltd – March 2002.
- Certificate received from TUV ISO9001 for Qualified Internal Auditor.
- Got training in Regulatory requirements for ICH GMP Guide for API"s by Cipla Ltd in Mumbai.
- Got training in Agilent Chemstore software in Singapore**.**
- Participated the USP seminar in Hyderabad on 11.02.2009 to 12.02.2009
- Implementation of 21 CFR Part 11 compliance

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### *Strengths:*

- Hands on experience in Analytical validation, Instrument Qualification and routine activities of releasing the API.
- Performing investigation and approval of OOS, Deviations and change control documents.
- Ability to handle the instruments of HPLC, GC, FTIR, UV, Auto Titrator,

  Polari meter, Particle size analysis, TGA, DSC and pH meter.
- Instrument Qualification, System implementation and Documentation for regulatory audits and filing
- Facing regulatory, customer and Internal quality audits.
- Doing vendor evaluation & audits and Internal Audits.

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### *Computer Knowledge:*

Proficient with the use of Microsoft Windows, MS Office applications – MS Word, MS Excel, MS Power point and the internet.

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**Audit Faced:**

M/S Jubilant Generics : TGA and PMDA

M/S Dr. Reddys Lab : USFDA, TGA, PMD, Health Canada, KFDA, China FDA, and Customer audit

M/S SYNGENE LTD : USFDA, Eu.GMP, EHS and Customer and QP Audits

M/S HIKAL LTD : ISO, EHS and Customer Audits

M/S BIOCON LTD : USFDA, EUGMP, EHS, IOS 9001, KFDA and Customer Audits

M/S CIPLA LTD : USFDA, TGA, MHRA, EHS and Customer Audits

M/S SANMAR LTD : ISO 9001, EHS, Customer and QP audits.