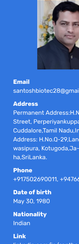

Email
santoshbiotec28@gmail.com

Address
Permanent Address:H.No.:88, North Street, Periperiyankuppam, Panruti, Cuddalore,Tamil Nadu,India. Current Address: H.No.D-291,and No.:18, Ni wasipura, Kotugoda,Ja-Ela, Gampaha,SriLanka.

Phone
+917502690011, +94766450364

Date of birth
May 30, 1980

Nationality
Indian

Link
linkedin.com/in/santhosh-kumar-s-35629115

Skills

INSTRUMENTATION ACQUAINTANCES: ☒ VITEK-2 Compact Identification System (Biomerieux), ☒ Pinocchio super II (Compressed air and Nitrogen gas analyser), ☒ Sterility test closed system (Sartorius, Tailin and Millipore), ☒ AFN Dve (Automated petridish filler – Biomerieux), ☒ PH meter (Eutech Digital pH meter), ☒ Conductivity meter (Lab India), ☒ Air sampler (Himedia-LA 637,8816 AES-Biomerieux), ☒ Microscope & Antibiotic Zone Reader, ☒ Autoclave (Horizontal & Vertical) [Machine Fabric & Pharma lab], ☒ Laminar air flow & Biosafety cabinet (ESCO-Class 2), ☒ Digital Colony Counter (Himedia), ☒ TOC Analyzer, ☒ Particle count analyzer (Lasir, Climat & Metone), ☒ BBL Crystal (Identification system), ☒ UV-VIS Spectrophotometer-Shimadzu-UV-1800, ☒ Heating block Incubator & BOD Incubator, ☒ Walkin BOD Incubators, ☒ APSS 2000 (Particle measuring system).

COMPUTER KNOWLEDGE: ☒ LIMS (Laboratory Information Management System) Operation and Validation, ☒ MS-office (MS-Word, MS- Excel, Power Point), C, Basic & Internet.

AUDIT FACED: ☒ USFDA,MCC,EU-GMP,PIC/S,UKRAIN, WHO-GMP,NDA,NMRA & INVIMA, ☒ Customer audit like Pfizer,Cipla,Ranbaxy,Biocon,Sandoz, Dr.Reddies, Sanofi,Mylan,Aurobindo,Lupin,Zydus cadilla,Sun pharma etc.,

STRENGTH: ☒ Excellent technical background and accurate analysis & Good documentation with computer knowledge. ☒ Ability to adapt quickly to an evolving work environment. ☒ Open-minded, willing to learn from others. ☒ To make use of every moment of the life in the best possible way.

• Strong leadership and decision making skills.

• Ability to work under pressure and cope with multiple priorities

Languages

English
Advanced

Tamil
Advanced

Hindi
Intermediate

Telugu
Intermediate

SANTHOSH KUMAR

Head Of Microbiology

Pharmaceutical professional with greater than 18 years experience in both Sterile and Non-Sterile Pharmaceutical Industries. A collaborative team player with a proven track record of successfully implementing Good Documentation Practices (GDP) and Good Laboratory Practices (GLP).To be an efficient performer in all the aspect of my work by optimally utilizing my skills and potentials and fulfilling in the field of Microbiology, that would use my knowledge and experience which would help in the growth of organization. Possess effective communication, and positive result-oriented work attitude.

Experience

Head Of Microbiology

Sands Active (PVT) Ltd *SriLanka*

Feb 2021 - Present

Sands Active (PVT) Ltd, SriLanka working as a Head Of Microbiology from Feb-2021 to till date. Parenteral Division (Formulation-Cephalosporin Dry Powder Injection, Solid dosage and General oral solid dose. [Accredited with NMRA].

- Lead and drive Quality Control Microbiology activities and ensuring products are tested with validated methods in a timely, cost-effective, efficient, and fully compliant manner.
- Review and approve technical documents for regulatory agency submissions and author responses to agency questions as required.
- Planning and Ensure validation activities like MLT, Sterility, BET, Disinfectant, Pass box, DHS, UV Efficacy study, Beta lactamase study, Compressed air and Nitrogen gas etc.,
- Planning and Ensuring Hold Time Study activities like Garments HTS, Media HTS, Culture suspension HTS, Filling Machine parts study, Rubber stopper, UV efficacy study, Disinfectant etc.,
- Implementation of SOP, STP, Specifications and Protocols as per current GMP guidelines and pharmacopeias.
- Being responsible for ensuring EM activities are in place such as Media fill, Autoclave, DHS, Tunnel, Incubator, Water system (PW, WFI, PSG & RW),HVAC qualification etc.,
- Ensuring personnel hygiene and gowning qualification of respective departments.
- Provide guidance on enhancement of sterility assurance and contamination control.
- Proactively identify issues and develop solutions in a collaborative multidisciplinary environment.
- Ensuring that good laboratory practice in microbiology laboratory.
- Supporting and providing technical information pertaining to microbiological tests to lab management on routine basis.
- Participating and co-coordinating in International Audits, System Audits, Audits conducted by external agencies, Regulatory Authorities and take corrective action and preventive action (CAPA) to ensure regulatory compliance.
- Being responsible for the instrument procurement and supplier assessment with create entire new lab facility.
- Being responsible for ensuring Analytical Method Validation (AMV) Sterility (Open & Closed method), BET and MLT.
- Undertaking all aspects of microbiological Risk Assessment Study.
- Conducting investigations regarding out of specifications (OOS) results, OOT results and address and manage deviations, incidents, and change control related to microbiology processes.
- Updating and revision of Microbiology documentation, procedures, work instructions and work sheets.
- Ensure all lab personnel are working safely and in adherence to company health and safety policy and procedures.
- Any other duties as assigned by the General Manager or Director.

Manager Microbiology

Navesta Pharmaceuticals Pvt Ltd, Sri lanka. *Sri Lanka*

Feb-2017 – Jan 2021

Navesta pharmaceutical (P) Ltd Sri Lanka working as a Manager - Lead Microbiologist from Feb-2017 to Jan-2021. Parenteral Division (Formulation-Dry Powder Injection (Cephalosporin) Injectable products and Oral Solid Dosage (OSD)). [Accredited with NMRA and ISO].

- Planning, work allocation, provides periodic training to analyst and Ensure day-to-day running of Microbiology laboratory.
- Support and provide technical information pertaining to microbiological tests to lab management on routine basis.
- Performed meticulous results review into the Laboratory Information Management System (LIMS) and systematically reviewed data entered at the analyst level, ensuring accuracy and completeness within the LIMS platform. (Caliber LIMS).
- Participate/co-ordinate in Internal Audits, System Audits, Audits conducted by external agencies and Regulatory Authorities.
- Reviewer of SOPs, STPs, Specs and Validation protocol.
- Responsible for site aseptic training program.
- Responsible for the instrument procurement and supplier assessment with create entire new lab facility.
- Analytical method validation Sterility, BET and MLT.
- Involve Media fill validation, autoclave validation, HVAC qualification and water system validation.
- Conduct investigations regarding out of specifications (OOS) results, OOT trend results and address and manage deviations related to micro procedures.
- Planning and execution of disinfectant validation, media hold time study, culture suspension hold time study, UV light efficacy study, Sterilized Garment hold time study, Machine parts HTS, CCIT, Anaerobic Environmental monitoring study, Compressed air and Nitrogen gas study.
- Assisting in auditing activities and take corrective action and preventive action (CAPA) to ensure regulatory compliance.
- Responsible for following GDP, GMP, and GLP procedures.
- Participate in cross functional investigation and other relevant forum to represent Microbiology section.

Assistant Manager Microbiology

Biogenomics Ltd *Pondicherry, India.*

Feb 2015 – Jan 2017

Biogenomics Ltd Pondicherry working as a Assistant Manager from Feb-2015 to Jan-2017, Pondicherry. Parenteral Division (Formulation- liquid injections, lyophilized products).

- Preparation and review of SOPs, GTPs, STPs, Specs and Validation protocol.
- Undertaking all aspects of microbiological testing like hold time study samples, In process, Raw materials and Finished products.
- Analytical method validation Sterility, BET and MLT.
- Involve Media fill validation, autoclave validation and water system validation.
- Investigation of quality notification such as OOS and OOT.
- Inventory and Stocktaking, purchase Order of laboratory.
- Updating and revision of Microbiology documentation, procedures, work instructions and work sheets.
- Assisting in auditing activities and take corrective action and preventive action (CAPA) to ensure regulatory compliance.
- Responsible for following GDP, GMP, and GLP procedures.
- Risk assessment study for environmental monitoring and fix alert and action limit.

Senior Executive

Steril-Gene Life Sciences (P) Ltd *Pondicherry, India.*

May 2013 – Jan 2015

Steril-Gene Life Sciences (P) Ltd Pondicherry working as a senior Executive from May -2013 to Jan-2015, Pondicherry. [Formulation- Cephalosporin oral solid dosage, Dry powder injection, Liquid injections, Lyophilized products, General oral solid dose, and Hormones soft gel manufacturer. [Accredited with USFDA, EU-GMP, NDA, MCC, PICS, ISO and INVIMA].

- Preparation and review of SOPs, GTPs, Specs and Validation protocol.
- Development of validation protocol for Sterility, BET, MLT, Antibiotic assay and Vitamin B12 Assay.
- Undertaking all aspects of microbiological testing like hold time study samples, In process, intermediate, Raw Materials and finished products.
- Involve Media fill validation, Performance requalification of autoclave, water system and tunnel validation.
- Investigation of quality notification such as OOS and OOT.
- Inventory and Stocktaking, Purchase Order of laboratory.
- Risk assessment study for environmental monitoring and fix alert and action limit.
- Ensure personnel hygiene and personnel gowning qualification.
- Planning and execution of disinfectant validation, media hold time study, culture suspension hold time study, UV efficacy study, Sterilized Garment hold time study, Compressed air and Nitrogen gas study.
- Responsible for following GDP, GMP, and GLP procedures.

Senior Officer - Microbiology

Sun Pharmaceutical Industries,Gujarat,India. *Dadra and Nagar Haveli*

Mar 2012 - Apr 2013

Sun Pharmaceutical Industries in Dadra worked as a Senior Officer-Microbiology from Mar- 2012 to April-2013 (Formulation tablets and capsules). [Accredited with USFDA,MHRA,TGA, MCC,NDA,PICS, WHO,UKRAIN AND TFDA].

- Raw Data issuance through LIMS (Laboratory Information Management System).
- Environmental Monitoring in production area such as active, passive, surface monitoring and personnel monitoring reports compilation and trend preparation.
- Investigation of quality notification such as OOS and OOT.
- (Laboratory Level Investigation).
- Isolation and identification from Water and EM samples.
- Performance verification of Biological Indictor Qualification.
- Performance verification of autoclave and efficacy for Disinfectant efficacy, UV light efficacy, media hold time study.
- Review test reports log books, data sheets, documentation that are generated in microbiology lab.
- Identification of Microorganisms up to the species using BBL Crystal.
- Bio-burden of Primary Packing material & Water analysis by using membrane filtration method.

Executive-Microbiology

Crescent Therapeutics Ltd *Baddi, Himachal Pradesh.*

Nov 2007 - Feb 2012

Crescent Therapeutics Ltd Baddi (HP), India worked as a Executive Microbiology from Nov 2007 to Feb 2012 (Formulation- Tablets, Capsules and Pre and Probiotics product).[Accredited with ISO and WHO-GMP].

- Preparation of SOP and STP.
- Performed pre and Pro biotic Assay (Eg; Lactic acid bacillus, lactobacillus acidophilus, lactobacillus Rhamnoses, saccharomycesbolardy etc.).
- Analytical method validation MLT, Antibiotic Assay and Vitamin B12 Assay.
- Microbial limit testing of pharmaceutical products.
- Environmental Monitoring aseptic area active, passive, surface monitoring and personnel monitoring reports compilation and trend preparation.
- Receiving and performing growth promotion testing of incoming lots of microbiological media.
- Bio-burden of Primary Packing material & Water analysis by using membrane filtration method.

Microbiologist

MMC Healthcare (P) Ltd *Solan, Himachal Pradesh.*

Jul 2004 - Oct 2007

MMC Healthcare (P) Ltd in Solan(HP), India worked as a Microbiologist from July- 2004 to Oct-2007 (Formulation-Tablet,Capsule&Liquid syrup). [Accredited with ISO and WHO-GMP].

- Microbial limit testing of pharmaceutical products.
- Performing growth promotion testing of incoming lots of microbiological media.
- Water sampling and Analysis for Raw water, RO water & Purified water.
- Environmental Monitoring aseptic area active, passive, surface monitoring and personnel monitoring reports compilation and trend preparation.
- Bio-burden of Primary Packing material & Water analysis by using membrane filtration method.

Education

MPhill (Bio Technology)

Bharathidasan University *Tiruchirappalli*

2005 - 2007

Grade-First Class with Distinction

MSc (Microbiology)

Jamal Mohamed College *Tiruchirappalli*

2002 - 2004

Grade - First Class

Projects

- Microbial Examination of Sterile Pharmaceutical Products.
- Isolation &Identification of Azospirillum,Rhozobium & Phasphobacteria& Compatibility studies of Bio-fertilizer with Bio-pesticide.

Achievements

- Successfully set up the new Advanced Microbiology Laboratory in the organization of Sands Active (Pvt) Ltd. (Sri Lanka).
- Successfully set up the new Moderate Microbiology Laboratory in the organization of Navesta Pharmaceutical (P) Ltd. (Sri Lanka).
- Successfully set up the Microbiology Lab in the organization of Bio Genomics Ltd in Puducherry.

References

PRAKASHBABU M

Plant Head - Vice President (Operations)

Yaden Laboratories (PVT) Ltd,

Plot No.128A,Katunayake EPZ, SriLanka.

prakash@yadenlabs.com

+9714015117676

(Former General Manager at Sterile Gene Lifesciences (P) Ltd, Puducherry)

AMITKUMAR PRAJAPATI,

Head Of Plant,

Navesta Pharmaceuticals (PVT) Ltd,

Millewa, Horana,

SriLanka,

+918790351871,

Amitkumar.P@navesta.com

(Former Plant Head at Navesta pharmaceuticals (P) Ltd, SriLanka)