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Senior Manager (HoD) | 15+ years of success

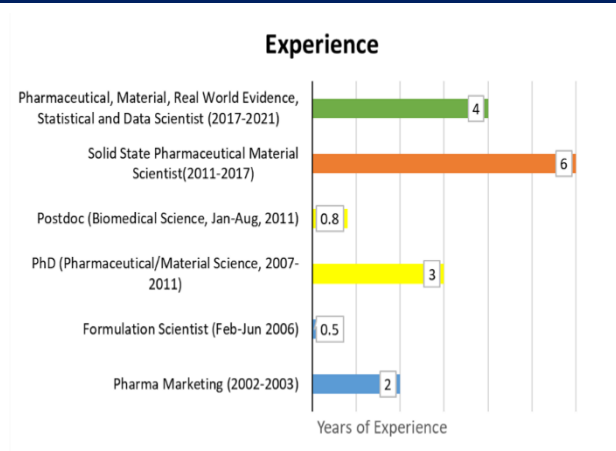
PROFESSIONAL SUMMARY

- >15+ years of pharmaceutical and medical devices industry experience (UK, Malaysia and India) with 5+ years of experience as pharmaceutical data scientist using statistics, ML algorithms and Chemometrics
- Pharmaceutical science, material science, statistics, and data-driven decision making in degradation prediction, regression-clustering for quantitative analysis, non-linear predictive modelling for polymorphs/moisture, quantile regression for particle size
- Through the continuing professional development on advanced statistics, machine learning, physics-based modelling, deep learning and artificial intelligence, current research involves applying big data analytics and first principles modelling to develop a multilateral understanding and correlate the CMAs, CPPs with CQAs of formulated products
- Strong technical skills in physical chemical characterization, formulation, and biopharmaceutics as well as experience in salt, co-crystal, polymorph, particle and powder selection processes.
- Deep subject-matter expertise: Physicochemical characterization, form selection and/or solid-state characterization of organic small molecules and/or drug product formulations using analytical techniques including powder X-ray diffraction, thermal analysis (DSC, TGA), spectroscopic/imaging (Raman, IR, and NIR), microscopy (light and electron) and/or dynamic vapor sorption.
- Late-stage development, including particle API attributes definition, solid-state methods development (particle size, surface area), validation and/or transfer in support of drug substance manufacture, and authoring of relevant sections of regulatory filings.
- Working experience and knowledge in Python libraries such as Scikit Learn, Tensorflow, PyCaret, ppscore, Numpy, Pandas, Matplotlib, Seaborn, Plotly, AutoViz, Sweetviz, Pandas Profiling and Working knowledge of tools like RStudio, Jupyter Notebook, Google Colab
- Academic advisor, pharmaceutical science, material science mentor at International Medical University, KL, Malaysia
- Advanced Data Analytics and Statistics mentor at The Machine Learning Company, Mumbai, India; VIT Chennai, India
- Statistical and ML work Accredited by Journal of Pharmaceutical Science "Virtual Issue: Most Original and Most Significant Scientific Findings" for the article entitled "Quantitative Microscopy: Particle Size/Shape Characterization, Addressing Common Errors Using 'Analytics Continuum' Approach. Journal of Pharmaceutical Sciences. 2021 Feb 1;110(2):833-49."
- Invited Review Paper for Digital Pharmaceutical Development in Pharmaceutics MDPI journal, Manuscript Under Review

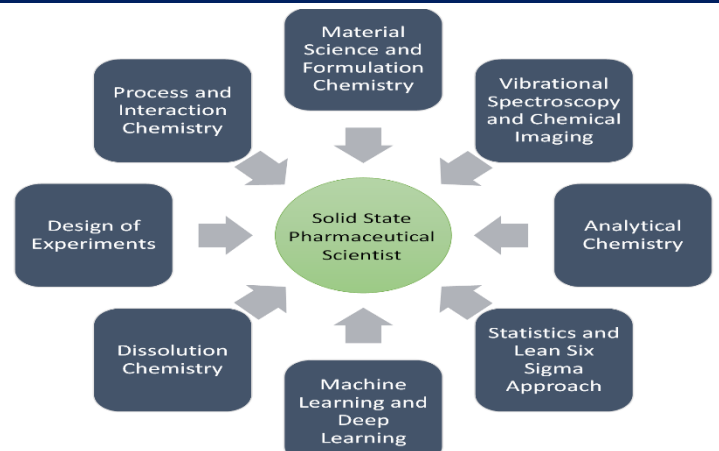
CORE AREAS OF FOCUS

- Solid State Pharmaceutics
- Strategic Technical-Commercial Direction
- Big/Small Data Analytics
- Innovation & Emerging Process Technologies
- Machine Learning and Deep Learning
- Statistics

AREAS OF EXPERTISE and YEARS OF EXPERIENCE



PROFESSIONAL COMPETENCIES



PROFESSIONAL CONTOUR

Oct 2020-At Present **Oncogen Pharma (Malaysia) Sdn. Bhd.** | Senior Manager
 July 2016-Sep 2020 **Sanofi, Goa** | Section Head, Solid

ACADEMIC CREDENTIALS


- **Lean Six Sigma Black Belt (CLSSBB)**, Benchmark Six Sigma, October 2021 (Credential ID: 40353581)
- **PG Program** in Artificial Intelligence and Machine

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| | | |
|--------------------|--|---|
| Dec 2012-June 2016 | State & Biopharma Laboratories Dr. Reddy's Laboratories, IPDO Senior Scientist, Preformulation | Learning, Greatlakes, September 2020-August 2021 ➤ PG Program in Business Analytics and Intelligence, Greatlakes, July 2019-June 2020 |
| Oct 2011-Oct 2012 | Smith&Nephew Research Center, UK Specialist, Surface Analysis | ➤ PhD , Sheffield Hallam University, Sheffield, United Kingdom, 2011. |
| Jan 2011-Sep 2011 | Sheffield Hallam University, Sheffield, UK PDRA | ➤ M.Sc. , Pharmaceutical Analysis, University of Strathclyde, Glasgow, UK, 2007. |
| Jan 2006-Aug 2006 | Strides Shasun Pharma Science Limited Officer | ➤ M.Pharm , SRIPMS, Coimbatore, Tamil Nadu, India, 2006. |
| Dec 2001-Sep 2003 | Wockhardt India Private Limited Territory Manager | ➤ B.Pharm , KMCH College of Pharmacy, Coimbatore, Tamil Nadu, India, 2001 |

Most Recent Research Projects

- **Process and Computational Modelling at Particle Level:** Does particle-level size measurements influence manufacturing/formulation process? Particle size measurements involve dry and wet method. Objective of this work is to correlate the material properties like strength of agglomeration or fragmentation as well as can this particle information be simulated to understand in selecting the manufacturing process. granulation/extrusion/encapsulation/Tabletability/compactibility/compressibility. **Tools:** XRD, PLM, SEM, Statistics, Molecular dynamics, DEM, CFD, PBEs, Machine learning and Deep learning. **Status:** Activities initiated
- **Process and Computational Modelling at Crystal Level:** Does crystal-level properties influence morphology followed by surface wettability and intrinsic dissolution? Objective of this work is to correlate the material properties as well as their surface exposure of atoms in crystals like hydrophilic/hydrophobic with different solvent selection for API crystallisation due to IPR constraints. On a bigger scale does this impact dissolution/surface wetting/granulation/tabletability. **Tools:** XRD, PLM, SEM, Statistics, Molecular dynamics, PBEs, Machine learning and Deep learning. **Status:** Activities initiated
- **Predictive Modelling on Real World Data (Statistical Machine Learning):** Objective of the project is to use the dataset to build a regression model to predict content uniformity collected using near infrared sensor. The data preprocessing requires understanding additive and multiplicative scattering, baseline fluctuations. One of the goal is to overcome the tedious data preprocessing protocols. Instance-based segmentation (clustering approaches) and regression (Regression-Clustering/RC) was employed where no hassles of pretreatment required. Nonetheless, in comparison to conventional approaches "RC" achieved a ten-order-of-magnitude improvement in prediction. Part 2 of this is a validation work using a very low dose API and use of active learning approaches. **Status:** Promising Results and Manuscript under preparation
- **Small Data Analytics on Real World Data (Material Informatics):** This project is a proof-of-concept (PoC) using classification algorithms and ensemble techniques to predict water-solid interactions of pharmaceutical solids (API and Excipients) and its impact on medicinal products' quality using the analytical tools. Deploy machine learning algorithms in effective/rationalized selection of excipients based on stability, compatibility and cost of goods. Various models including Logistic Regression, SVM, Decision Tree, Random Forest etc. and comparison of accuracy across these models will be done to finalise the model for prediction. **Status:** Promising Results and Manuscript under preparation
- **'Analytics Continuum Approach' on Real World Data:** Particle size/shape characterization of active pharmaceutical ingredient (API) is integral to successful product development. Plethora of statistical tests were utilized firstly to understand various errors like a) fundamental error, b) segregation error, c) human error, d) sample randomness, e) sample representativeness etc., followed by selecting appropriate test to infer particle population statistics. Subsequently, attribute-based control chart and bootstrap-based confidence interval developed to monitor product performance. **Status:** Paper published in Journal of Pharmaceutical Sciences and received recognition as "Most Original and Most Significant Scientific Findings"
- **Predictive Modelling Strength of High Performance Concrete (Happenstance Data):** This project involved feature exploration, model selection, and hyperparameter tuning to predict the strength of high-performance concrete. Used Regression models like Decision tree regressors, cross-validation techniques and Grid search to find out the most important features to predict the strength. This project helped in diversifying my skills and tools employed Logistic Regression, kNN, Naive Bayes, Decision Trees, Feature Engineering, Support Vector Machines, Principal Component Analysis, Model Comparison Measures. **Status:** Project report submitted to stakeholders and available for sharing



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CAREER HIGHLIGHTS and CORE EXPERTISE


- **Innovation:** Orchestrated “Innovation Storm”, an open program that captures the ideas of ~60 employees to prioritize future innovation projects in interdisciplinary functions like FD, AD, QA, RA etc) in a fun and competitive manner.
- **Technology Sourcing:** Identification of Sourcing strategy for new, novel and innovative analytical methodologies through academic collaboration and Vendors/Partners
- **Reverse Engineering and Competitor Product Assessment:** Technically conversant towards deformation (Q1/qualitative, Q2/quantitative and Q3/structural deformation) of chemical and physical reverse benchmarking utilizing conventional extraction methods, separation techniques, gravimetric approaches, diffraction, spectroscopic, chemical imaging, thermal, and microscopic techniques.
- **Preformulation and Formulation Chemistry:** Qualified in processing-structure-property correlation, raw material chemistry, granulation, solubility enhancement approaches of drug substance in dosage form design and development
- **Pharmaceutical Material Science:** Developed rational strategies for physical and mechanical property characterization, impact of micronization of drug substance agglomeration of active pharmaceutical ingredients, excipients, and formulations.
- **Physico-chemical and Physico-Technical Characterization:** Established guideline document for physical and chemical characterization procedures using small quantities of drug to support candidate selection and identify dosage form options.
- **Oral Bioperformance Assessment and Dissolution Chemistry:** Acknowledged as expert in developing advanced discriminatory dissolution method for problem solving in bio-study and in dosage form design, API with varying properties and processability, polymorphs, co-crystals.
- **Analytical Chemistry:** Adeptness in characterization to support drug product development at different stages using spectroscopy (NIR, IR, Raman, MS), and microscopy (PLM, SEM), TG/MS/IR, FBRM, diffusion/partitioning, XRD, DSC, TGA, DVS etc
- **Machine Learning and Advanced Data Analytics:** Hands on experience with respect to interpretation of descriptive statistics, data visualization approaches, statistical models (ANOVA, least significant differences etc), multivariate analysis (PCA, clustering, regression modelling, resolution approaches etc.), f2 dissolution similarity, model dependant dissolution studies, etc.

Technical Accomplishments

- Established center of excellence for advanced release testing of API and excipients from drug products that effectively translates 505(j) to 505(b)2, center of excellence for “Solid State and Biopharma Laboratories” to cater innovation, development engine and manufacturing excellence projects from various development centres (India, Brazil, US, Colombia, Turkey).
- Established center of excellence for “Advanced Release Testing” using FTIR imaging
- Successfully reverse engineered immediate release tablets (3), sustain and/or controlled release formulations (2), semisolid dosages and nanoemulsions using a suite of analytical technologies where applicable principles of six sigma and statistics were employed
- Successfully contributed to a total of >150 projects (API's, oral solids, injectables, semisolids) of which following milestones are accomplished- 3 Emerging markets, 14 ANDA's, 5 deficiency, 1 505(b)2, 1 API Patent.

ACCOMPLISHMENTS

- Organizing Committee Member of “NESE Symposium” (NEtwork of Scientific Excellence)-a platform for exchange of science, education, knowledge and collaboration between various development centers (US, India, Brazil, Colombia, and Turkey) of Sanofi, February, 2019.
- Received Sanofi-MD Trophy Award for successfully completing the “Arohaan Project-Conceptualization and completion of Solid State and Biopharma Labs in stipulated time” in July 2016.
- CEO award (2), Innovation-Technical Excellence award (1), Best QbD team (1), monthly SPOT award (2), Team Diversity award (1) in Dec 2012-June 2016, Dr. Reddys Laboratories, Ltd
- Jan 2011-Sep2011, Research Associate, NP mimetic (EU-FP7 grant), Nov 2007-Dec2010, Hallam Research and AstraZeneca PhD studentship, Feb2007-AstraZeneca MSc industrial Studentship



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JOURNAL REVIEWER

- Invited Journal Reviewer for Journal of Pharmaceutical Sciences, Total Papers Reviewed: 9
- Invited Journal Reviewer for European Journal of Pharmaceutics and Biopharmaceutics, Total Papers Reviewed: 5
- Invited Journal Reviewer for Pharmaceutical Development and Technology, Total Paper Reviewed: 2

PUBLICATIONS-FIRST AUTHOR

- Muthudoss et al., 2022. Small Data Analytics Part 1. Protocol Development. Statistical Machine Learning of NIR Spectroscopy Data on Blend Uniformity, Manuscript Under Preparation
- Muthudoss et al., 2022. Small Data Analytics Part 2. Protocol Validation. Statistical Machine Learning of NIR Spectroscopy Data on Blend Uniformity, Manuscript Under Preparation
- Muthudoss et al., 2022. Digital Pharmaceutical Development: Small Data Analytics Tetrahedron (SDAT) and Good Machine Learning Practices (GMLP) in Leveraging Industry 4.0 Revolution, *Submitted to Pharmaceutics (MDPI)*.
- Muthudoss et al., 2022. Topologically Directed Confocal Raman Imaging (TD-CRI): Advanced Raman Imaging Towards Compositional and Micromeritic Profiling of a Commercial Tablet Components, *Journal of Pharmaceutical and Biomedical Analysis*, 210 (20) 114581-114590.

PUBLICATIONS-SECOND AUTHOR

- Muthudoss et al., 2021. Quantitative Microscopy: Particle Size/Shape Characterization-Addressing Common Errors in Microscopy using the 'Analytics Continuum' approach, *Journal of Pharmaceutical Sciences*, 110 (2), 833-849. ("Virtual Issue: Most Original and Most Significant Scientific Findings")
- Muthudoss et al., 2021. Pregelatinized Starch: Variability in Gelatinization and its Influence on Product Performance, *International Journal of Research in Pharmaceutical Sciences*, 12 (1), 141-149.
- Muthudoss et al., 2020. Micronization and Agglomeration: Understanding the Impact of API Particle Properties on Dissolution and Permeability using Solid State and Biopharmaceutical "Toolbox", *Journal of Pharmaceutical Innovation* <https://doi.org/10.1007/s12247-019-09424-1>
- Muthudoss et al., 2019. Vendor qualification: Utilization of solid state characterization "Toolbox" to assess material variability for active pharmaceutical Ingredient. *Journal of Applied Pharmaceutical Science*; 9 (9), 1-9.
- Muthudoss et al., 2017. Iso-structurally Induced Solid Phase Transformations: A Case Study with Lenalidomide. *Crystal Growth & Design*. 17 (2), 612-628.
- Muthudoss et al., 2016. Preliminary studies on unusual polymorphs of thymine: Structural comparison with other nucleobases. *Journal of Molecular Structure*. 1120:86-99.

PUBLICATIONS AND PATENTS AS CO-AUTHOR

- Muthudoss et al., 2017. *In situ* Metastable Form: A Route for the Generation of Hydrate and Anhydrous Forms of Ceritinib. *Crystal Growth & Design*. 17 (12), 6341-6352.
- Muthudoss et al., 2015. Pharmaceutical Supramolecular Complexes, Indian Patent Filed

PROFESSIONAL ASSOCIATIONS

- Member, Royal Society of Chemistry (MRSC)
- Chartered Chemist (CCChem, Direct Admission)
- Member, International Statistical Institute (ISI)
- Member, International Statistical Engineering Association (ISEA)
- Member, Infrared and Raman Discussion Group (IRDG), UK
- Member, Scientific Member WITec GmbH Raman Imaging Instruments