

## CURRICULUM VITAE

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### Professional Summary:

Currently I am Regulatory Affairs Specialist holding about 2 years of **pre-clinical research** experience within an academic (**M.Sc.-Ph.D. from IIT-Bombay**) setting and having Industrial working experience from 2021. Abroad working experience as **Newton-Bhabha Fellow awardee** at Loughborough University, **United Kingdom**. Skilled at preparing regulatory document of **European Union Medical Device Regulation (EU-MDR)**, including reviewing materials, technical data and accuracy of filings. Articulate and personable with exceptional data analysis, report writing and record keeping abilities. Well-organized and diligent Regulatory Affairs Specialist adept at coordinating and tracking regulatory-related actions. Proficient in regulations, standards and best practices. Methodical and objective with good judgment and sound critical thinking and problem-solving abilities.

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### Skills:

#### **Regulatory Affairs Specialized Skills:**

#### **Regulatory Tools:**

- MS Office (Word, Excel, Power Point)
- Endnote application
- PubMed
- Google Scholar
- Embase
- Cochrane
- MSD Manual
- Medscape
- BfArM
- MedWatch
- EUDAMED
- Health Canada
- MHRA

- TGA
- MAUDE
- MS outlook, Share Point, and MS teams

### Regulatory Technical Skills:

- **Systematic literature review (SLR) Document Preparation:** Identifies, selects and critically appraises scientific data in order to prepare SLR document for State of The Art (SOTA) and Subject Device (SD) for medical device assessment. Applying PICO search strategy for comprehensive, transparent search conducted over multiple databases like PubMed, Google Scholar, Embase, MSD Manual, Medscape and Cochrane.
  - **Publication Screening and Data Extraction:** Screening of sorted research publication based on various inclusion and exclusion criteria. Identifies Scientific Data and extract it in order to assessment of Medical device based on EU MDR regulation.
  - **Adverse Event & Clinical trials searches:** Adverse event database searches conducted over multiple databases like BfArM, MedWatch, EUDAMED, Health Canada, MHRA, TGA, and MAUDE. Clinical trials searches has performed on databases like clinicalTrials.gov, WHO-ICTRP, and EU-Clinical Trials Register.
  - **CEP & CER Document Preparation:** Author and conduct medical and technical writing of clinical evaluation plan/reports (CEPs & CERs) in support of compliance to EU MDR for Medical devices across therapeutic areas.
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### Research Specialized Skills:

#### Research Software Skills:

- COMSOL Simulation
- Sigma-Plot
- Chem Draw
- Origin
- Image-J
- GraphPad

#### Research Technical skills:

- **Nanoformulation Development:** Organic, inorganic and nanocomposites nanoparticles synthesis and characterization. Physical, and compositional analysis by various technique like SDS-PAGE, HPLC, immunoblotting, FACS, TG-DTA, X-RD, XPS, ICP-AES, ICP-MS FT-IR, LRS-RAMAN, TEM, SEM, Cryo-SEM, MALDI and etc.
- **Pre-Clinical studies:**
  - In-vitro characterization - Cell culturing and characterization for Biocompatibility or Cell viability studies and internalization studies.
  - In-vivo characterization - Nano formulation efficacy, pharmacokinetics, Biological distribution, renal clearance, toxicity analysis, Photothermal cancer mass ablation studies, and Bioluminescence studies in 4T1 mice model system.

- **Enzyme or Protein Purification & characterization:** Bacterial cells culturing and harvesting. Enzyme and protein isolation by various chromatographic technique and gel technique. Kinetic studies with Oximeter and spectrophotometer. Enzyme assay like plate assay, crude enzyme activity, specific enzyme activity measurement.
- **Genomic DNA isolation from Bacterial cultures:** Genomic DNA isolation; Purification using DNA binding columns. Metagenome analysis; Purification techniques through columns identification or characterization by PCR technique.

#### Research Instrument Operational Skills:

- **Transmission Electron Microscope:** 2 year operational and characterizing experience of different nanomaterials by utilizing TEM (CM200 Philips) at Indian Institute of Technology-Bombay, Mumbai, India. (From 11th Feb, 2015 to 1st March 2017).
- **Cryo-Scanning Electron Microscope:** More than 1 year operational and characterizing experience at Cryo-FEG SEM (JEOL) at Indian Institute of Technology-Bombay, Mumbai (India). (From 20<sup>th</sup> March, 2015 to 30<sup>th</sup> June 2016).
- **Dynamic light scattering and Zeta analyser:** More than 2 year of experience on operation of DLS and Zeta analyser at Indian Institute of Technology-Bombay, Mumbai, India (From 10th March, 2014 to 1<sup>st</sup> August 2016).

## Working Experience:

### Specialist – Medical Electronics at Tata Elxsi (3<sup>rd</sup> March 2022 - Present):

**About Organisation:** Tata Elxsi is amongst the world's leading providers of design and technology services across industries including Automotive, Broadcast, Communications, Healthcare, and Transportation. Tata Elxsi is helping customers reimagine their products and services through design thinking and the application of digital technologies such as IoT (Internet of Things), Cloud, Mobility, Virtual Reality, and Artificial Intelligence.

**Medical Device Design and Engineering:** An ISO 13485:2016 certified medical device engineering practice specializing in consumer research, mechatronics design, industrial design, verification & validation to regulatory compliance for developed & emerging markets.

**Digital Health Engineering:** Innovate and accelerate deployment of digital health products and solutions powered by Tata Elxsi's industry experience and solution accelerators for IoT, cloud computing, big data analytics, AI, automation, and extended reality.

**Medical Device Regulatory Compliance:** Launch and sustain medical devices and pharmaceutical products with Tata Elxsi's team of industry-experienced regulatory compliance specialists and homegrown global regulatory intelligence platform.

**Pharmaceutical & Biotechnology Compliance:** Confidently reduce the risk of regulatory violations, ensure the safety and effectiveness of the products, and protect brand reputation with Tata Elxsi's team of industry experts and its homegrown suite of digital accelerators.

#### Job Done:

##### 1. Authored and Conducted Medical and Technical Writing:

- Accomplished the creation of Clinical Evaluation Plans/Reports (CEPs & CERs) for diverse medical devices, ensuring compliance with European Union Medical Device Regulation (EU MDR- Med Dev 2.7, rev 4).
- Measured success by adherence to regulatory standards and guidelines.

##### 2. Authored Post-Market Clinical Follow-Up (PMCF) Documents:

- Successfully developed PMCF plans and reports, contributing to comprehensive post-market surveillance and risk management practices.
- Achievement measured by the effectiveness of PMCF initiatives in enhancing device safety and performance.

**3. Summarized Postmarketing Surveillance and Risk Management Data:**

- Summarized data from postmarketing surveillance (PMS/PMSR/PMSP) and risk management activities (RMAs & RMRs) for target devices.
- Demonstrated effectiveness in distilling complex information into concise and informative summaries.

**4. Prepared Periodic Safety Update Reports (PSUR) for Medical Devices:**

- Led the preparation of PSURs, ensuring accurate documentation of safety-related information.
- Achievement measured by the quality and compliance of PSURs with regulatory requirements.

**5. Cross-Functional Collaboration and Deadline Adherence:**

- Worked collaboratively across functions to meet submission and company-driven deadlines.
- Success measured by the timely completion of regulatory documents and adherence to project timelines.

**6. Stakeholder Collaboration and Client Support:**

- Collaborated with stakeholders and actively participated in client calls, supporting work stream leaders.
- Demonstrated proficiency in providing product guidance and expertise during client interactions.

**7. Literature Searches and Document Processing:**

- Conducted literature searches on products/product families, providing valuable insights for regulatory documentation.
- Executed proofreading, editing, and document formatting, ensuring document integrity and adherence to standards.

**8. Regulatory Document Preparation:**

- Prepared regulatory documents with a focus on meeting client expectations in terms of content, quality, and presentation.
- Success measured by client satisfaction and positive feedback on the regulatory documents delivered.

**Technical Business Analyst at LABINDIA Instruments (September 2021-February 2022):**

**About Organisation:** Labindia Instruments Pvt. Ltd., established in 1982 has been a pioneer in developing, manufacturing and providing precise solutions for Analytical, laboratory instruments and process measuring systems for the Scientific and Manufacturing community across various verticals like Pharmaceuticals, Life Sciences, Material Characterization, Petroleum etc. Labindia Instruments successfully became the market leaders by providing complete solutions and best quality Instruments from world leaders like Perkin Elmer, Applied Biosystems, Leica, Koehler, Cannon, Renishaw, Nanonics etc.

**Job Done:**

**1. Studied Pharma/Biopharma Processes for Customer Solutions:**

- Accomplished in-depth understanding of various pharmaceutical and biopharmaceutical processes.
- Measured success by the ability to provide tailored solutions to customers, addressing their specific needs.

**2. Conducted Customer Presentations:**

- Visited customers and delivered compelling presentations on diverse product applications.
  - Measured effectiveness through customer feedback and increased engagement.
- 3. Organized Seminars, Symposiums, and Workshops:**
- Successfully organized and executed events such as seminars, symposiums, and workshops.
  - Measured success by event attendance, participant engagement, and positive feedback.
- 4. Collected Market Intelligence:**
- Systematically gathered market intelligence on products, including pricing and competitor analysis.
  - Measured success by the accuracy and relevance of market information collected.
- 5. Kept Abreast with Scientific Developments:**
- Stayed updated with developments in the scientific community.
  - Disseminated technical information to the sales team, enhancing their knowledge and expertise.
- 6. Prepared Strategies, Marketing Plans, and Pricing:**
- Developed comprehensive strategies, marketing plans, and pricing structures.
  - Measured success by the effective placement of products in the market and achievement of sales targets.

### **Research Associateship at IIT-Bombay (October 2019-2021):**

**About Organisation:** Established in 1958, the second of its kind, IIT Bombay was the first to be set up with foreign assistance. The funds from UNESCO came as Roubles from the then Soviet Union. In 1961 Parliament decreed the IITs as 'Institutes of National Importance'. Since then, IITB has grown from strength to strength to emerge as one of the top technical universities in the world.

**Job Role:** Cancer Research at NanoBios Lab BSBE Department, under the supervision of Prof. Rohit Srivastava at IIT-Bombay, Mumbai, India.

### **International Work Experience at Loughborough University, United Kingdom (September 2017- January 2018):**

**About Organization:** In April 1966 Loughborough was awarded its Charter, in recognition of the excellence achieved by Loughborough College of Advanced Technology and its predecessor colleges. Then called Loughborough University of Technology, it was the country's first technological university. It was renamed Loughborough University in 1996. Throughout its history Loughborough University has built upon its distinctive characteristics. Today it is one of the country's leading universities, with a reputation for excellence in teaching and research, strong links with business and industry and unrivalled sporting achievement.

**Job Role:** As a **Newton-Bhabha Fellow Awardee**, I am Visiting Ph.D. Student at Loughborough University, United Kingdom. Work on COMSOL simulation of peristaltic pump for microneedle mediated theophylline delivery in Asthmatic patient.

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## Academic Qualifications:

**M.Sc.-Ph.D. Awarded (2021)** - From Bioscience and Bioengineering Department, **Indian Institute of Technology-Bombay**, Mumbai, Maharashtra, India.

**Ph.D. Thesis (Submitted in 2019)**, titled as “*PPC NanoTorrid<sup>®</sup> Structure for Photothermal Therapy in Breast Cancer*” under the guidance of Prof. Rohit Srivastava, Bioscience and Bioengineering Department, **Indian Institute of Technology-Bombay**, Mumbai, Maharashtra, India.

**M.Sc. Thesis (Submitted in 2013)**, titled as “*Isophthalate Degradation by Acinetobacter lwoffii strain ISP4*”, under the guidance of Prof. Prashant S. Phale, Bioscience and Bioengineering Department, **Indian Institute of Technology-Bombay**, Mumbai, Maharashtra, India.

**B.Sc. (2009- 2011)** - In Biotechnology at **St. Wilfred's PG College**, Affiliated with Rajasthan University, Jaipur, Rajasthan, India.

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## Awards and Fellowships:

- ❖ **Research Associate** (2019-2020): Position at NanoBios Lab, Under the supervision of Prof. Rohit Srivastava at IIT-Bombay, Mumbai, India.
  - ❖ **Newton-Bhabha Fellow Award** (2017-2018): Position at Loughborough University, United Kingdom spend 5 months.
  - ❖ **Senior Research Fellowship** (2015-2019): Gain at BSBE, Indian Institute of Technology-Bombay, Mumbai, Maharashtra, India.
  - ❖ **Junior Research Fellowship** (2013-2015): Gain at BSBE, Indian Institute of Technology-Bombay, Mumbai, Maharashtra, India.
  - ❖ **Master Fellowship** (2011-2013): Gain at BSBE, Indian Institute of Technology Bombay, Mumbai, Maharashtra, India.
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## Short Term Projects:

**September 2017:** 5 Month Newton-Bhabha Project titled as “*Fabrication of Microneedles and modelling of Pumping system in Transdermal Theophylline Delivery*” at Loughborough University, United Kingdom.

**March 2016:** 1-year Project titled as “*Cancer Sensing Device Based On Impedance Measurement*” at Indian Institute of Technology Bombay, Mumbai, Maharashtra, India.

**May 2013:** 6-month project titled as “*Growth Cone Motility and Axon Guidance*” at Indian Institute of Technology Bombay, Mumbai, Maharashtra, India.

**July 2012:** 6-month project of **Bioinformatics** titled as “*Enzyme Degrading Central Metabolic Carbon Compound of Bacteria, Utilizing Aromatic Hydrocarbons*” at Indian Institute of Technology Bombay, Mumbai, Maharashtra, India.

**December 2010:** 2-month dissertation project **during B.Sc. final year** titled as “*Drugs targeting to the Brain*” at Elcon Pharmaceutical Pvt. Limited, Jaipur, Rajasthan, India.

**December 2009:** 1-month dissertation projects **during B.Sc. second year** titled as “*Drugs formulation and Development*” at Elcon Pharmaceutical Pvt. Limited, Jaipur, Rajasthan, India.

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## Trainings:

I have done various certified Trainings or learnings few are listed below. All trainings certificates will be produced on demand.

1. Certified Peer Reviewer-By Elsevier
  2. Six Sigma
  3. Project Management
  4. Product Management
  5. Agile Project Management
  6. Manager & Leadership
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## Workshops:

**February-March 2016:** Workshop on “Patent Searching and Drafting” organised by IPR cell at IIT-Bombay, Mumbai, India.

**November 2015-February 2016:** Workshop on “Intellectual Property Rights Fundamentals” organized by IPR cell at IIT-Bombay, Mumbai, India.

**January 2015:** *Biocompatibility (ISO 10993) training from GLR Laboratories pvt. Ltd.*, at Indian Medical device and diagnostics Conference held at Ahmadabad (Gujrat), India.

**September 2013:** Attended workshop on Matrix-assisted laser desorption/ionization (MALDI) held at IIT-Bombay, Mumbai, India

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## Conference:

**February 2015:** Seminar on “Advanced TEM Techniques” held at IIT-Bombay, Mumbai, India.

**January 2015:** Conference on Medical device and diagnostics held at Ahmadabad (Gujrat), India.

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## Patents and Publications:

1. Jha, A., Ravichandran, G., De, A. et al. NANOTORRID®: Graphene-like properties of a gold/polypropylene nanocomposite and its photothermal application. *Journal of Materials Research of Springer Nature* (2022). <https://doi.org/10.1557/s43578-022-00518-0>
  2. Srivastava Rohit, Jha Ashish. PPC NanoTorrid® for Photothermal therapy in Cancer. **India Patent Office, IPA No. 202121028850**, 2021.
  3. Srivastava Rohit, Jha Ashish. Polymeric NanoCubons® nanofillers for various application. **India Patent Office, IPA No. 202121007979**, 2021.
  4. NANOTORRID®. Class-5. **INDIA Trade Mark No. 4299118**. 2021. Indian Institute of Technology Bombay. Mumbai, India.
  5. NANOCUBONS®. Class-1. **INDIA Trade Mark No. 4296859**. 2021. Indian Institute of Technology Bombay. Mumbai, India.
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