**SUMMARY**

* A Ph.D. scientist with formulation and process development experience in a wide variety of dosage forms ( tablets, oral solutions and syrups, buccal thin films, nasal solutions, sterile injectable solutions and suspensions.
* Demonstrated experience in early pharmaceutical development focused on absorption characteristics and preclinical safety evaluation.
* Experience in assessment of NCE’s for pharmaceutical properties (physicochemical and pharmacokinetic) relevant for specialty dosage forms (implants, buccal and nasal dosage forms).

**EDUCATION**

* **Ph.D. Pharmaceutics,** University of Iowa (UI), Thesis Advisor: ***Maureen Donovan*** **2014-2019**
* **M.S Pharmaceutics 2010-2012**

# SKILL SET

* Formulation, in vitro testing of oral solids, liquids and topical dosage forms for small and large molecules
* Solubility and bioavailability enhancement technologies (ASD’s, Implants and Particulate delivery)
* Modelling In-vitro and in-vivo correlation (IVIVC) using GastroPlus®
* IVRT and IVPT testing for various novel delivery systems
* Analytical techniques (UV-VIS, FT-IR, HPLC, LC-MS, fluorescence), particle size characterization (DLS and Microscopy) and functional testing (rheology, osmolality and container integrity)
* Pre-formulation assessment and solid-state characterization (TGA, DSC, PXRD) of NCE’s
* Application of Quality by Design (QbD) initiatives for optimization of formulation and process parameters
* Pharmaceutical unit operations (Wurster Coating/Pan Coating, Blending, Milling, Roller Compaction, Compression)
* Modelling degradation kinetics of small molecules and peptides using AMASTK and R
* Good understanding of biopharmaceutics and pharmacokinetics

# WORK EXPERIENCE

**Formulation Scientist-III, American Regent (Daichi Sankyo Group) March 2020- Present**

***Design and develop formulations and processes for solutions and complex sterile injectables***

* Planned, performed and lead various stages of product development, including pre-formulation, formulation development, process development in optimization of final drug product.
* Designed and performed DOE studies by JMP analysis to construct design space for process parameters
* Development of PSD method development and discriminatory dissolution method development.
* Drafted GMP documentation (manufacturing batch records, study protocols), technical (PD, DOE) reports.

# Merck, West Point, PA June- Aug 2018

## Research Project: Development of In Vitro and In Vivo Relationship (IVIVR) for Long Acting Parenteral Implants

* Assessment and identification of druggable characteristics of NCE’s suitable for the formulation development of LAP implant dosage forms and it’s effect on pharmacokinetic behavior.
* Identification of suitable salt form for LAP implant dosage based on it’s drug release characteristics.
* Studied the effect of various formulation attributes (dose, drug loading, solubility, diffusivity, MW, Log D) on *invivo* input rates in the process of implant dosage form development.
* Formulated and evaluated LAP implants using hot-melt extrusion and direct compression.
* Investigated mechanism of drug release from LAP implants

# AbbVie, North Chicago, IL May-Aug 2017

##  Understanding the Impact of Amorphous-Phase Separation (LLPS and GLPS) to Drive Drug Absorption Ex Vivo

* Developed analytical techniques to characterize invitro precipitation kinetics of ASD’s
* Studied the impact of invitro precipitation kinetics on drug absorption (permeation/perfusion studies).

 ***Awards:*** *Recognized with best intern poster award for the internship work among 50 graduate interns.*

#  Scientist II, Therdose Pharmaceuticals: Hyderabad, TS, India 2012- 2014

 ***Design, development of sterile injectables (solution, suspension and lyophilized products) and manufacturing processes in support of pre-clinical studies as well as support of regulatory filings and technology transfer***

* Evaluated chemical stability, pH solubility, dissociation constants of preclinical compounds.
* Designed, evaluated the functionality of drugs-excipient combinations for liquid and semi solid forms.
* Designed non-infringing bioequivalent generic and 505(b) (2) NDAs products based on QbD principles.
* De-formulation/characterization of RLD of injectables/topicals for the development of generics.
* Performed forced degradation studies for identification of drug degradation products.
* Experience with lyophilization cycle development for small scale and protein therapeutics.
* Wrote stability protocols according to ICH guidelines.
* Performed final dosage form characterization studies (container closure integrity, sterilization studies).
* Authored and reviewed technical reports (product development reports, CMC sections for IND and NDA dossiers).

# University of Iowa, Research Assistant 2014- Present

## Thesis: Bioadhesive Strategies to Optimize Mucosal Retention and Permeability for PreGastric Applications

* Designed, optimized and developed buccal films containing permeation enhancers for a buccal device.
* Investigated the mechanism of permeation enhancers (fatty acids) in buccal absorption using ESR.
* Pre-formulation assessment and identification of CPP and CQA for mucoretentive liquid dosage forms.
* Evaluated the effect of formulation variables of mucoretentive suspension/solution effecting absorption

**Other Projects, Mentoring Activities**

* Studied the effect of drug release and absorption of abuse deterrent (IR/MR) tablet dosage forms.
* Assisted in writing NIH grants (R01 & R21), technical documents, protocols and patent applications.
* Mentored fellow graduate students, supervised Pharm D students in research activities and FPS courses.

***Awards for Ph.D. Research Work:***

* *Best poster Award in PGSRM Conference (2016)* - 1 in 250 graduate students is awarded.
* *Outstanding Research Award in Health Sciences Conference* - 1 in 100 graduate students is recognized.

# PUBLICATIONS

1. Prathima Srinivas, **Chede Laxmi Shanthi\***, M.Sadananam. Microneedle patches in Drug Delivery: A Review. Int J Pharm Tech 2010; 2(3): 329-344.
2. **Chede,L.S**.;\* Jaidev,L.R.;Kandikattu,H.K. Theranostic Nanoparticles for Pancreatic Cancer Treatment. Endocr Metab Immune Disord Drug Targets,21 (2), 203-214.
3. **L**.R.Jaidev, Laxmi Shanthi Chede, and Hemanth Kandikattu. Novel Therapeutic and Diagnostic Approaches in Cancer and Tumorigenesis – Book chapter
4. Laxmi Shanthi Chede; Brett A Wagner; Garry R. Buettner; Maureen D. Donovan. Electron spin resonance evaluation of buccal membrane fluidity alterations by sodium caprylate and l-menthol. *Int. J. Mol. Sci.* 2021, *22*(19), 10708, doi:https://www.mdpi.com/1422-0067/22/19/10708 (2021).
5. Laxmi Shanthi Chede; Maureen D. Donovan. Chemical Enhancement of Buccal Absorption . *Int. J. Mol. Sci.* 2022*.* October Edition.
6. Laxmi Shanthi Chede; Maureen D. Donovan.Novel bioadhesive dosage froms targeting the esophagus for the treatment of eosinophilic esophagitisInt. J. Pharm. 2022- Submitted
7. Laxmi Shanthi Chede; Jaidev, L. R; 3D printing of Pharmaceutics for disease treatment, Frontiers at medical technology.

# RECENT AND SELECTED PRESENTATIONS

* **Laxmi Shanthi Chede*,*** Max T. Baker, **Maureen D. Donovan**. Enhancing Midazolam Permeability across the Buccal Mucosa for Rapid Seizure Treatment. AAPS; 2016; Denver, Colorado.
* **Laxmi Shanthi Chede*,*** Max T. Baker, **Maureen D. Donovan**. Enhancing Midazolam Permeability across the Buccal Mucosa for Rapid Seizure Treatment. 48th Annual Annual Pharmaceutics Graduate Student Research Meeting; June 16-18, 2016; Kansas City, MO- **Best Poster Presentation Award**
* **Laxmi Shanthi Chede*,*** Max T. Baker, **Maureen D. Donovan**. Enhancing Midazolam Permeability across the Buccal Mucosa for Rapid Seizure Treatment. AAPS; 2017; San Diego, California.
* **Laxmi Shanthi Chede*,* Steven Castleberry**, Russ Slade, Tom Borchardt. Understanding the Impact of Liquid-Liquid Phase Separation to Drive Drug Absorption Ex Vivo. AAPS; 2017; SanDiego, California.
* **Laxmi Shanthi Chede, Maureen D. Donovan,** Optimization of Bioadhesive Strategies for treatment of Eosinophilic Esophagitis.Pharm Sci 360, 2018, Washington DC
* **Laxmi Shanthi Chede*,*** Max T. Baker, **Maureen D. Donovan**. Enhancing Midazolam Permeability across the Buccal Mucosa for Rapid Seizure Treatment. AAPS Annual Meeting and Exposition; 2016; Denver, Colorado.
* **Laxmi Shanthi Chede*,*** Max T. Baker, **Maureen D. Donovan**. Enhancing Midazolam Permeability across the Buccal Mucosa for Rapid Seizure Treatment. AAPS Annual Meeting and Exposition; 2017; San Diego, California.
* **Laxmi Shanthi Chede*,* Steven Castleberry**, Russ Slade, Tom Borchardt. Understanding the Impact of Liquid-Liquid Phase Separation to Drive Drug Absorption Ex Vivo. AAPS Annual Meeting and Exposition; 2017; SanDiego, California.
* **Laxmi Shanthi Chede, Maureen D. Donovan,** Optimization of Bioadhesive Strategies for treatment of Eosinophilic Esophagitis. Health Sciences Research, 2018, Iowa City, Iowa- **Best Poster Presentation Award.**
* **Laxmi Shanthi Chede, Maureen D. Donovan,** Optimization of Bioadhesive Strategies for treatment of Eosinophilic Esophagitis. Pharm Sci 360, 2018, Washington DC.
* **Laxmi Shanthi Chede**, Prathima Srinivas. The New Revolution in Pharma Regulatory Affairs-The Know How of e-submission and e-CTD, APTICON Annual Conference. Hyderabad, India, 2010.

# AWARDS & HONORS

* Gold Medal (2012) from Osmania University for Academic Excellence in Master’s Program- Only 3 students in the entire state receive this award.
* All India Best Poster Award in 12th APTI Conference (2010) - 1% of participants receive this award.
* Best poster presentation for ph.D thesis work at PGSRM and Health Sciences Research Conferences.
* J. Keith Guillory Pharmaceutical Fellowship (2014) for academic excellence during 1st year of Ph.D.
* Post-comprehensive and Ballard Sea-shore Dissertation Fellowships (2018-2019) from UI for research excellence.
* Reviewer for Drug Delivery and Industrial Pharmacy (https://publons.com/researcher/1448033/chede-shanthi)- few of the reviews are missing in this page.