LEAH CUSHING, Ph.D.

Greater Boston, Massachusetts • leah.cushing@medicalmatterssolutions.com • www.linkedin.com/in/leah-cushing

PROFESSIONAL SUMMARY

A published Medical Affairs Manager passionate about helping patients get compliant and high-quality access to care. With both an academic/scientific background and industry experience in large international pharmaceutical companies, I am skilled at directing investigator-initiated studies (IIS), company sponsored studies (CSS) and associated governance processes. I am also experienced with building, testing, and using tools to support clinical and non-clinical studies throughout their lifecycle.

- Work with 60+ countries in a matrixed, multi-cultural environment, regularly using overseas living experience and Portuguese language skills
- Maintain country-specific regulatory and compliance knowledge
- Build and implements databases, User Requirement Specifications, and participate in User Acceptance Testing
- Develop and facilitate trainings, including a behavior-based training for IIS compliance, that received an international award
- Develop metrics and reporting

EXPERIENCE

December 2016 to September 2023

Medical Affairs Manager

Successfully help patients and research through clinical and non-clinical study governance

- Lead cross-functional governance teams throughout the lifecycle of IIS and CSS including strategic fit, study concept, protocol, and change requests, including protocol amendments, and study reports. Create and present metrics and perform strategic study level assessments of risks to compliance, patients, and programs. Further demonstrate strong leadership by actively steering, managing, and streamlining the governance process; foster cross-functional consensus, and ensure rigorous quality and compliance throughout.
    - Result: successful governance oversight of hundreds of studies, helping inform strategy, benefit patients, and advance research.
- Established and managed governance boards, including with alliance partners Pfizer and GSK. Served as subject matter expert in governance, compliance, IIS, and CSS. Developed cross-functional trainings and addressed queries proactively to prevent issues and maintain timelines.
    - Result: successful and efficient governance board operation and collaborations with alliance partners.
- Developed an innovative behavioral compliance training for ISS taken by 1000+ colleagues, which received an international e-learning association award.
    - Result: a lasting positive impact on colleagues handling ISS, contributing to company success and ultimate benefit to patients in the trials the company supports.

Assist patients with no alternative options to receive approved medication for an unapproved use.

- Set up and manage process and training for handling global ad hoc approved medication for unapproved use requests, including country-specific requirements; provide data and metrics for ethics advisory board presentations and Access To Medicine index reports.
    - Result: the company rose to number 5 in the Access To Medicine index report ranking in 2022, and over 100 individual patients with serious, life-threatening diseases received free medication they would otherwise have no access to in 2022.

Help patients by creating, maintaining, and continuously updating a platform tool to streamline and optimize the clinical and non-clinical study process.

- Major role in building and implementing a state-of-the-art technical solution platform that supports company-sponsored, collaborative research, and investigator-initiated studies throughout their lifecycle and enables accountability, continuous improvements, and good decision-making with transparency and compliance at the forefront. Act as a subject matter expert and business administrator for the platform and assist in creating User Requirement Specifications and participate in User Acceptance Testing.
    - Result: This platform tool reduced live governance meetings - studies are now approved virtually via the platform. It also reduced errors, compliance risks, and non-value adding work. Due to its success, the tool was expanded to be adapted and utilized in other company programs and processes.

- Played a pivotal role in the data migration of studies from SharePoint and older platforms into a new platform.
    - Result: consolidated all ongoing study information across programs into one centralized location, enhancing study availability and accessibility, and facilitating the efficient generation of metrics.
- Spearhead training, change management, and continuous improvement initiatives, developing and updating platform and process training materials for both internal and external users. Efforts included the creation of an interactive PowerPoint "sandbox" for external Investigators, creating and maintaining templates and guides on the platform's "Information Page," managing platform Q&A channel, and providing ad hoc training and support.
    - Result: colleague acceptance and efficient use of the platform, along with appreciation of the benefits of the platform.

April 2015 to December 2016

Senior Scientist

- Worked closely with multiple drug discovery project teams to manage cell-based assay development, validation and screening for small and large molecule therapeutic targets being developed for projects in immunology and immuno-oncology.
    - Result: Created a new assay using natural killer cells and live cell imaging, as well as streamlined established assays utilizing whole blood and peripheral blood mononuclear cells to make them more high-throughput.
- Led effort to find, evaluate and establish partnerships with CROs, including conducting site visits, working with procurement, and organizing externalized assays for the group.
    - Result: multiple routine assays were externalized, allowing the dedication of more time and effort to optimize existing assays for higher throughput while concurrently developing novel assays for rigorous validation and ultimately screening purposes.
- Participated in Discovery Technologies departmental strategy planning (must wins scoping), presented to leadership team, and managed action items.

June 2012 to April 2015

Postdoctoral Fellow

- Research focused on determining the regulation of TLR/IL-1R-induced downstream signaling by the protein kinase IRAK4. Worked on a large interdisciplinary project team that together pushed a small molecule therapeutic to first in human safety trials.
    - Results are documented in publications below.
- Helped evaluate potential new therapeutic targets as part of the exploratory biology group. This included collecting knowledge from the literature, initiating, and participating in international collaborations, networking at conferences, and sharing with the group in the form of presentations and small group discussions.
    - Result: multiple potential targets were identified and brought for discussion and further evaluation.

TRAININGS

- Association for Talent Development (ATD) Master Trainer Course - 2021
- Change Management - 2021
- GCP training - 2023 and annually
- Conflict Resolution - 2020
- Unconscious Bias - 2020
- Strengthen Your Resilience - 2019
- Leadership Effectiveness - 2017

EDUCATION

BOSTON UNIVERSITY SCHOOL OF MEDICINE

Postdoctoral Fellow, Pulmonary Department

Expanded Ph.D. research in the Pulmonary Department to establish new collaborations in academia and publish in vivo effects of loss of miR-29 in transgenic knockout mice (See Publications). In addition, trained medical fellows (pulmonologists) and Ph.D. students in the laboratory.

BOSTON UNIVERSITY SCHOOL OF MEDICINE
Ph.D., Department of Medicine, Molecular Medicine
Thesis: The Role of miR-29 in Pulmonary Fibrosis
Completed all courses and research requirements including publishing in a peer-reviewed journal (See publications). Completed whole genome and miRNA array profiling and data analysis. Presented research regularly to project teams, in small group meetings, and at internal and external conferences.

PUBLICATIONS

Primiano MJ, Lefker BA, Bowman MR, Bree AG, Hubeau C, Bonin PD, Mangan M, Dower K, Monks BG, Cushing L, Wang S, Guzova J, Jiao A, Lin LL, Latz E, Hepworth D, Hall JP. Efficacy and Pharmacology of the NLRP3 Inflammasome Inhibitor CP-456,773 (CRID3) in Murine Models of Dermal and Pulmonary Inflammation. J Immunol. 2016 Aug 12. [Epub ahead of print]

Cushing L, Costinean S, Xu W, Jiang Z, Madden L, Kuang P, Huang J, Weisman A, Hata A, Croce CM, Lu J. Disruption of miR-29 Leads to Aberrant Differentiation of Smooth Muscle Cells Selectively Associated with Distal Lung Vasculature. PLoS Genet. 2015 May 28;11(5).

Cushing L, Stochaj W, Siegel M, Czerwinski R, Dower K, Wright Q, Hirschfield M, Casanova JL, Picard C, Puel A, Lin LL, Rao V. Interleukin 1/Toll-Like Receptor-Induced Autophosphorylation Activates Interleukin 1 Receptor-Associated Kinase 4 and Controls Cytokine Induction in a Cell Type-Specific Manner. J Biol Chem. 2014 Apr 11;289(15):10865-75 – Highlighted in Global Medical Discovery Journal, October 11, 2014. https://globalmedicaldiscovery.com/

Cushing L, Kuang P, Lu, J. The role of miR-29 in pulmonary fibrosis. Biochem Cell Biol. 2015 Apr;93(2):109-18.

Cushing L, Jiang Z, Kuang P, Lu J. The Roles of miRNAs and Protein Components of the miRNA Pathway in Lung Development and Diseases. Am J Respir Cell Mol Biol. 2015 Apr;52(4):397-408

Jiang Z, Cushing L, Ai X, Lu J. miR-326 is Downstream of Sonic Hedgehog Signaling and Regulates the Expression of Gli2 and Smoothened. Am J Respir Cell Mol Biol. 2014 Aug;51(2):273-83.

Cushing L, Stochaj W, Siegel M, Czerwinski R, Dower K, Wright Q, Hirschfield M, Casanova JL, Picard C, Puel A, Lin LL, Rao V. Interleukin 1/Toll-Like Receptor-Induced Autophosphorylation Activates Interleukin 1 Receptor-Associated Kinase 4 and Controls Cytokine Induction in a Cell Type-Specific Manner. J Biol Chem. 2014 Apr 11;289(15):10865-75.

Varma S, Mahavadi P, Sasikumar S, Cushing L, Hyland T, Rosser AE, Riccardi D, Lu J, Kalin TV, Kalinichenko VV, Guenther A, Ramirez MI, Pardo A, Selman M, Warburton D. Grainyhead-like 2 (GRHL2) Distribution Reveals Novel Pathophysiological Differences Between Human Idiopathic Pulmonary Fibrosis and Mouse Models of Pulmonary Fibrosis. Am J Physiol Lun Cell Mol Physiol. 2014 Mar 1;306(5):L405-19.

Cushing L, Kuang P, Qian J, Shao F, Wu J, Little F, Thannickal V, Cardoso W, Lu J. miR-29 is a Major Regulator of Genes Associated with Pulmonary Fibrosis. Am J Respir Cell Mol Biol. 2011 Aug;45(2):287-94.