

FDA-ISMP Safe Medication Management Fellowship

A Joint One-year Experience in Medication Error Prevention

Overview

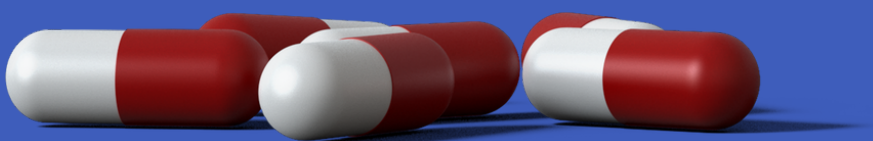
This fellowship program is a joint effort between the Institute for Safe Medication Practices (ISMP) and the U.S. Food and Drug Administration (FDA), Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Office of Medication Error Prevention and Risk Management, Divisions of Medication Error Prevention and Analysis I and II (DMEPA I & II). The fellow will spend 6 months with ISMP, a virtual-hybrid organization with its headquarters located in the suburbs of Philadelphia, PA, and 6 months with the FDA, which is located in Silver Spring, MD.

The fellowship program gives experienced candidates an unparalleled opportunity to learn from and work with some of the nation's top experts in medication safety. The fellow benefits from ISMP's years of experience devoted to medication error prevention and safe medication use. At FDA, valuable regulatory experience is gained by working with the divisions focused on medication error prevention.

Fellowship Benefits

- Competitive monthly stipend
- Supplement to offset the cost of obtaining health insurance coverage
- Vacation & Federal Holidays

***Please NOTE:** Portions of the fellowship may be conducted on a virtual, remote basis. Additional details will be provided by the fellowship mentors.*



The Fellow will have the Opportunity to:

- Assist in investigating errors reported to national error reporting programs
- Follow up with manufacturers and regulators after learning about safety hazards
- Write and review information for columns in journals and ISMP's medication safety newsletters
- Attend meetings relating to medication safety
- Contribute to site visits and safety consultations in different healthcare delivery settings
- Learn how FDA mitigates risk by reviewing proposed proprietary names, labels and packaging, and addressing medication error related issues associated with marketed drug products
- Understand how human factors engineering is integrated into the design of medical products
- Apply the techniques of Failure Mode and Effects Analysis (FMEA)
- Participate in original research and surveys on medication errors and prevention
- Network with pharmaceutical, healthcare, legislative, and regulatory communities
- Recognize worldwide medication-system problems and prevention programs

Qualifications & Application Process

Qualifications

- Applicants must be healthcare professionals who:
 - Received their degree within the last sixty (60) months (5 years), AND
 - Have at least one year of postgraduate experience working in a healthcare setting or completed a residency program.
- Pharmacists, physicians, physician assistants, nurse practitioners, and nurses with risk management, quality improvement, or patient safety experience are welcome to apply.
- FDA and ISMP seek dedicated individuals with a strong commitment to improving medication safety, ability to work in a fast-paced and often-changing environment, and a high comfort level with working independently or in a collaborative process.

How to Apply

- via Zintellect at <https://zintellect.com/>
- Transcripts
 - For details on transcripts, please visit: <https://orise.orau.gov/sepreview/transcripts.html>
- Recommendation Letters
 - 1 educational or professional recommendation
- Resume/CV
 - Should include academic history, employment history, relevant experiences, and publication list

Contact

- For questions about the fellowship information, please email fellowship@ismp.org.
- For questions about the Zintellect website/technical issues, please submit any questions to ORISE.FDA.CDER@orau.org and include the reference code for this opportunity in your email.

FDA

The U.S. Food and Drug Administration (FDA) performs essential public health tasks by making sure that safe and effective drugs are available to improve the health of people in the U.S. Within FDA's Center for Drug Evaluation and Research (CDER), the Office of Surveillance and Epidemiology (OSE), and the Office of Medication Error Prevention and Risk Management (OMEPRM), the Divisions of Medication Error Prevention and Analysis I and II (DMEPA I & DMEPA II) are primarily responsible for the premarket review of proposed proprietary medication names, labels/labeling, packaging, and human factor studies to identify, evaluate, and minimize the potential for medication errors for CDER-regulated products. DMEPA I & DMEPA II serve as the scientific and policy lead for CDER's proprietary naming and human factors programs. DMEPA I & DMEPA II also lead the review of and designate nonproprietary name suffixes for all CDER biological nonproprietary names. Additionally, DMEPA I & DMEPA II work closely with federal partners, patient safety organizations (e.g., Institute for Safe Medication Practices [ISMP]), standard setting organizations and foreign regulators to address broader product safety issues.



FDA - Silver Spring, MD (greater Washington D.C. area)

ISMP

The Institute for Safe Medication Practices (ISMP) is the nation's only 501c(3) nonprofit organization devoted entirely to medication error prevention and safe medication use. ISMP represents more than 30 years of experience in helping healthcare practitioners keep patients safe, and continues to lead efforts to improve the medication-use process. The organization is known and respected worldwide as the premier resource for impartial, timely, and accurate medication safety information.

ISMP's highly effective initiatives, which are built upon a non-punitive approach and system-based solutions, fall into five key areas: knowledge, analysis, education, cooperation, and communication. More than 30 years ago, ISMP started a cornerstone of its medication error prevention efforts—a voluntary practitioner error-reporting program to learn about errors happening across the nation, understand their causes, and share “lessons learned” with the healthcare community. Each year, the National Medication Errors Reporting Program (MERP), operated by ISMP, receives hundreds of error reports from healthcare professionals. The Institute is also an official MedWatch partner with the U.S. Food and Drug Administration.



ISMP - Plymouth Meeting, PA (greater Philadelphia area)

Mentors

FDA



Mishale Mistry currently serves as the mentor for the FDA-ISMP Safe Medication Management Fellowship in the Division of Medication Error Prevention and Analysis I (DMEPA I). She graduated from Northeastern University School of Pharmacy in 2011 and received her Masters in Public Health from University of Maryland School of Medicine in 2012. In 2013, she was a fellow with the Office of Disease Prevention and Health Promotion in the Office of Assistant Secretary for Health, where she completed a one-year fellowship working on adverse drug event prevention before joining FDA/DMEPA. Mishale has been with FDA's DMEPA since 2014, and has served as a Safety Evaluator, Team Leader, DMEPA I's Associate Director for Nomenclature and Labeling, and now serves as the DMEPA I Director.

Mentors

FDA



LCDR Chi-Ming (Alice) Tu currently serves as the mentor for the FDA-ISMP Safe Medication Management Fellowship in the Division of Medication Error Prevention and Analysis II (DMEPA II). She graduated from the University of North Carolina- Chapel Hill Eshelman School of Pharmacy in 2008, completed the PGY1 Managed Care Pharmacy Residency at Medco Health Solutions, Inc. in 2009 and the joint FDA-ISMP Safe Medication Management Fellowship in 2010. LCDR Tu joined FDA's DMEPA after her fellowship and has worked in multiple roles: Safety Evaluator, Team Leader, DMEPA II's Associate Director for Nomenclature and Labeling, and now serves as the DMEPA II Deputy Director.

Mentors

ISMP



Matthew Grissinger, RPh, FISMP, FASCP is the Director of Education at the Institute for Safe Medication Practices (ISMP). He first joined ISMP in 2000 as an ISMP Safe Medication Management Fellow. He has published numerous articles in the pharmacy literature, including regular columns in P&T and is a journal reviewer for a number of publications including the Joint Commission Journal on Quality and Patient Safety, Pharmacoepidemiology, Journal of Managed Care and Specialty Pharmacy, BMJ Quality and Drug Safety, and Annals of Internal Medicine. He is a chapter contributor to a textbook published by McGraw-Hill entitled Pharmacy Management: Essentials for All Practice Settings, Essentials of Nurse Informatics, Remington: The Science and Practice of Pharmacy, and Medication Errors. He is recently completed the Just Culture certification course.

Mr. Grissinger serves as the Chair for the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP), and Co-Chair of the National Quality Form (NQF) Common Formats Expert Panel. He also served on the WHO Focus Group on Measurement Tools for Medication Safety, United States Pharmacopeia's (USP) Safe Medication Use Expert Committee from 2005-2010, the FDA Proprietary Name Review Concept Paper workshop panel in 2008, FDA Naming, Labeling, and Packaging Practices to Minimize Medication Errors workshop panel in 2010 and the Joint Commission Home Care Compounding Pharmacy Technical Advisory Panel in 2013.

He is also an adjunct assistant professor for Temple University School of Pharmacy. Mr. Grissinger received a BS in Pharmacy from the Philadelphia College of Pharmacy and Science and is a fellow of the Institute for Safe Medication Practices as well as the American Society of Consultant Pharmacists.

Current Fellows



Jessica Trinh, PharmD, received her Doctor of Pharmacy degree from Loma Linda University School of Pharmacy in Loma Linda, CA in 2022. She then completed a PGY-1 acute care residency at St. Joseph Medical Center in Tacoma, WA. During her residency, she gained experience revising safety resources such as her hospital's look-alike sound-alike list and chemotherapy sequencing documents, investigating submissions to the Incident Reporting and Improvement System (IRIS), and creating process change alerts to guide safe practices within her institution. Jessica developed a passion for drug safety after navigating a two-week downtime where she felt empowered in her role as a pharmacist and found excitement in ensuring safe clinical practices through proactive measures.

As an FDA/ISMP Medication Safety Management Fellow, Jessica is eager to discover more about developments in drug safety. She aspires to continue evolving her professional growth by working with diverse teams to develop new perspectives, learn how to use various databases and software, and utilize different risk-mitigation strategies. Her long-term professional goal is to become a leader in pharmacovigilance in either a regulatory agency or pharmaceutical sector to positively impact public health outcomes.

Current Fellows



Mariam Gawdat, PharmD, MS, completed her Doctor of Pharmacy and Professional Science Masters in Biomanufacturing and Bioprocessing at Albany College of Pharmacy and Health Sciences in Albany NY, where she also completed an ambulatory care pharmacy residency. In addition, she completed a Bachelor of Science in Biology at Siena College in Albany NY.

She has pharmacy practice experience in community and ambulatory care settings, including chain and independent pharmacy, primary care, outpatient nephrology and rheumatology, and public health services. Throughout her pharmacist experiences in community pharmacy and ambulatory care, Mariam developed a growing interest in medication safety. This interest peaked and was confirmed during her pharmacy residency medication safety rotation at Albany Medical Center in Albany NY. She aimed to focus her residency projects and pharmaceutical industry quality assurance internship on medication safety.

Mariam is pursuing an FDA/ISMP Safe Medication Management fellowship. She aspires to use her medication safety skills in making positive impacts on patients' health by promoting safe and effective medication-use practices and innovative pharmaceuticals.

Past Fellows Spotlight



Ariane O. Conrad, PharmD, BCACP, CDCES
FDA/ISMP Safe Medication Management fellow (2014-2015).

Ariane now works as a Safety Evaluator in the Division of Medication Error Prevention and Analysis I (DMEPA I) in FDA/CDER/OSE/OMEPRM.

Millie Shah, PharmD, BCPS, FISMP
FDA/ISMP Safe Medication Management Fellow (2014-2015).

Millie currently serves as a Human Factors (HF) Reviewer Team Leader in the Division of Medication Error Prevention and Analysis II (DMEPA II) in FDA/CDER/OSE/OMEPRM.



Celeste Karpow, PharmD, MPH, FISMP
FDA/ISMP Safe Medication Management Fellow (2016-2017).

Celeste currently works in the Division of Risk Management (DRM) to focus on Risk Evaluation and Mitigation Strategies (REMS), in FDA/CDER/OSE/OMEPRM.

Sam Suen, PharmD, FISMP
FDA/ISMP Safe Medication Management Fellow (2021-2022).

Sam works as a human factors safety evaluator in the Division of Medication Error Prevention and Analysis II (DMEPA II) in FDA/CDER/OSE/OMEPRM.



Sadik Owolewa, PharmD, FISMP
FDA/ISMP Safe Medication Management Fellow (2022-2023).

Sam currently works as a CVS PBM prior authorization pharmacist.

For a complete listing of past fellows, please visit: <https://www.ismp.org/past-fellows>.