

# Request for Applications

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**Fellowship in Quality of Medical Products  
at the University of California, San Francisco  
sponsored by the Quality Institute of the U.S. Pharmacopeial Convention (USP)**

The University of California, San Francisco (UCSF) and the U.S. Pharmacopeial Convention (USP) Quality Institute have partnered to establish a fellowship program for early career scientists and researchers who wish to contribute to the evidence base for quality medical products. This Request for Applications (RFA) seeks qualified candidates with advanced degrees who wish to conduct novel research and receive specialized training in medicine quality, with a specific focus on the *quality of excipients*.

The USP Quality Institute defines *medicine quality* as a balanced, risk-based set of pre-specified characteristics, systems, and requirements that consistently ensure a medicine's delivery of stated and implied clinical outcomes for patients. This definition encompasses all aspects of a medical product's lifecycle, including design, manufacture, supply chain, storage and distribution, and falsification. Excluded from this definition is the quality or appropriateness of treatment guidelines and practices.

Product quality can be designed into, improved, and reinforced all along the medicine continuum, from initial drug research all the way through to the dispensing of the medicines. These interventions differ for different products, product classes, and geographies, and have varying costs, feasibility, and outcomes. Assessing which interventions are most actionable and potentially effective is of critical importance to promote judicious policies and investment aimed at promoting medicine quality. USP has strong, trust-based relationships with quality professionals and healthcare policy makers globally, as well as several well-established offices and training centers in regions throughout the world. These global sites strengthen USP's understanding of local priorities and specificities, as well as its ability to effectively disseminate robust evidence and recommendations.

## **Framing the Issue: Quality of Excipients for Medical Products**

Excipients are essential to most, if not all, therapeutic and diagnostic medical products. Excipients are intentionally added ingredients that serve many purposes, including improving the delivery of the active pharmaceutical ingredient (API) in a patient. Excipients may be derived from plants, animals, minerals, or synthetic substances. Examples of excipients include fillers, extenders, diluents, wetting agents, solvents, emulsifiers, preservatives, flavors, absorption enhancers, sustained-release matrices, and coloring agents.

In general, excipients are not intended to have a therapeutic effect; however, they are not necessarily inert. Excipients may have some activity and should be evaluated for their benefits or risks in the context of their use. In the United States, the safety of an excipient is evaluated by regulators at the Food and Drug Administration as part of the approval process for a finished drug and there is no independent regulatory pathway for excipients. Worldwide, regulation of excipients varies by country. Adding to this complexity are risks to medical product approval introduced by unevaluated excipients. Furthermore, most excipients are commodity products sold to diverse industries. In fact, only a small fraction of these products are used in medicines. Because excipient

manufacturers do not know necessarily which commodity their substance will become a component of, they do not always adhere to the same Good Manufacturing Practices (GMPs) required of pharmaceutical, biological, or diagnostic product makers.

## Problem Statement

*The diversity and variability of excipients, the lack of harmonized global regulatory framework for excipients, and the fragmented supply chain for products used as excipients allows for potential risks to the quality of these products and the medicines in which they are used.*

## Research

### *Quality of Excipients*

- ▶ Characterizing the burden, in terms of poor health outcomes or economic consequences, from poor-quality medicines due to poor-quality excipients
- ▶ Understanding where and when vulnerabilities exist in the excipient supply chain and how they impact medical product quality
- ▶ Examining varying global regulatory pathways for excipients and defining a harmonized guideline within the ICH Q Series describing all steps for GMPs of excipient manufacturing
- ▶ Other ideas related to quality of excipients, and its impact will be considered

### *Novel Excipients*

- ▶ Identifying regulatory and market approaches to promote the development of novel excipients, including those suited to continuous manufacturing
- ▶ Quantifying the need for novel excipients to support medical product development for special patient populations (e.g., pediatrics) or conditions (e.g., neurodegenerative diseases), as well as specific product classes and emerging formulations (e.g., biologics)
- ▶ Identifying specific existing medicines or classes of medicines where quality could be advanced with the use of novel excipients

### *Testing Excipients*

- ▶ Understanding the specific functional and quality impact of excipients on medical products

Fellows formulate research projects they will carry out over 1- to 2-year timeframes. Projects will be milestone-driven and will identify actionable solutions to one or more of these evidence gaps. Actionable solutions may be appropriate for policy makers, medical product manufacturers, shippers, procurers, or other stakeholders. Fellows will be expected to analyze data and report findings in peer-reviewed publications and to the broader scientific community through international conferences. The USP Quality Institute will also promote research findings to inform and guide healthcare decision makers.



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## **Mentorship**

The Fellowship in Quality of Medical Products provides a research opportunity that includes co-mentors from the academic partner, experts at USP engaged in related research, and members of the USP Quality Institute Advisory Group or Steering Committee. In the first several weeks of the fellowship, research projects will be refined and conducted based on mutual interests and competencies of the fellows and co-mentors. Co-mentors will commit to the full duration of the fellowship; they will collaborate in the supervision and guidance of each fellow's research project as well as meaningful outcomes.

## **Fellowship Activities**

The fellows will work with mentors to advance medicines quality; key activities include the following:

- Initiate and independently conduct at least one research project on issues relevant to medicines quality, incorporating guidance from mentors as described above
- Develop a comprehensive understanding of the value of quality medical products, its applications to public health, and key evidentiary gaps in the demonstration of that value
- Collaborate with faculty and scientists from UCSF and USP on research initiatives
- Attend scientific meetings and summarize the process and outcomes of such meetings
- Present on selected medicine quality topics at meetings or in a written format
- Experience learning opportunities with USP (e.g., direct interactions with staff, giving or attending presentations, attendance at select meetings)

## **Candidate Qualifications**

Ideal candidates will demonstrate a strong interest in medicine quality through their professional and educational backgrounds. Candidates should be enthusiastic, self-motivated individuals who have a deep desire to develop their careers at the intersection of academia, industry, and government.

Candidates should possess the following qualifications:

- Advanced degree in a related scientific field (e.g., MD, PhD, PharmD, or equivalent)
- Ability to write and communicate clearly and thoughtfully
- Experience and comfort working in a research setting
- Demonstrated capacity to work independently and collaboratively
- U.S. citizenship or permanent residency, or a visa granted by the U.S. Department of State granting permission to work in the United States

## **Criteria for Review and Selection**

Applications will be reviewed by a committee comprising USP staff and UCSF faculty advisors for the following criteria:

- Fulfillment of candidate qualifications and application criteria
- Quality of the research proposal, and alignment of proposal to the USP Quality Institute's research area of focus, scientific review score, personal statement, and demonstrated ability to independent thinking

Finalists will be invited to UCSF for an in-person interview (tentatively scheduled for May 10, 2019)

### **Location, Duration, and Benefits**

Fellow/s will work full time at UCSF in San Francisco, CA, USA. Fellow/s will be awarded an initial one-year term, with the possibility of a one-year extension upon successful completion of the first year. Success will be defined by pre-specified milestones and deliverables, which the fellow/s will establish with co-mentors and program directors from UCSF and USP Quality Institute. The anticipated start date of the first year will be on or around July 1, 2019

Fellow/s will be offered the following:

- Competitive salary (up to \$70,000, commensurate with education and experience)
- Comprehensive benefits including medical, dental, vision, and others
- Funds for travel to professional conferences, at the discretion of fellowship mentors
- Support for research and publications costs

### **Conditions**

This fellowship is supported by the USP Quality Institute and administered by UCSF. The awardee will be appointed as an academic fellow to an appropriate department, depending on educational background and prior training. Upon appointment, UCSF will require the fellow to complete annual disclosure forms listing financial and other interests that they, their spouses or minor children, or organizations in which they are involved (as a partner, employee, board member, etc.), have a financial interest that may give rise to real or apparent conflicts with the work of the fellowship. Please note: the USP Quality Institute does not allow Indirect Costs.

### **Submitting an Application**

Submit items 1-6 of the materials listed **as a single PDF in the order listed on page 5** via email to [Maria.Friciello@ucsf.edu](mailto:Maria.Friciello@ucsf.edu) by **April 12, 2019**. The PDF filename should follow this format: ApplicantLastName\_USPQI Fellowship Application.pdf. Letters of recommendation to be submitted separately via email to [Maria.Friciello@ucsf.edu](mailto:Maria.Friciello@ucsf.edu), directly from the authors, and must be received by the application deadline.

### **Contact Information**

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## Application Criteria & Key Dates

### March 29, 2019 – Letter of Intent

Applicants are required to submit an email letter of intent (LOI) and strongly encouraged to do so by the date listed above. *LOIs sent after the date above, and before the application deadline, will be accepted.*

LOIs should include the applicant's name, highest degree and conferring institution, and contact information (i.e., email address, mailing address, and phone number), as well as a copy of the applicant's resume or CV. Applicants should indicate their status to work in the United States (i.e., US citizen or permanent resident, holder of a visa permitting work. Non-resident/non-visa holder will NOT be accepted). The LOI should be sent via email to [Maria.Friciello@ucsf.edu](mailto:Maria.Friciello@ucsf.edu).

### April 12, 2019 – Application

1. **Cover Page (template sent to you upon receipt of the LOI; see above)**
2. **Curriculum Vitae** (5 page maximum)
3. **Personal Statement** (500 words maximum) describing professional background, interest in medicines quality, and how the fellowship aligns with long-term career goals.
4. **Research Proposal** (5 pages maximum in Times 11pt font, excluding references) describing a research project to undertake during the fellowship (see "Research" section above). The proposal is intended to gauge the interests, thoughts, and competence of fellows rather than constitute a fully formed research plan. Proposals should include the following:
  - Title, objective, aim(s), methodologic and analytic approaches
  - Data Sources: Data may be accessed from public sources or newly generated. USP resources referenced above can be made available to fellows in support of their research projects. If existing data will be utilized, source(s) should be cited.
  - Challenges or Limitations: The proposal should identify possible challenges or limitations to the feasibility of the research.
  - Milestones: The proposal should identify specific, meaningful milestones that will help to close the evidence gap (as discussed in the "Research" section above) and are feasible to accomplish in each year of a possible two-year fellowship.
  - Mentorship Plan: The proposal should also indicate how the applicant expects mentorship (as described above) to benefit the proposed research.
5. **Quad Chart (template sent to you upon receipt of the LOI; see above)** providing a single-page summary of the proposal, should only include information taken directly from the research proposal.
6. **Scientific Publications or Other Writing Samples** (submit only 2 publications). Applicant should indicate authorship role in the samples provided (i.e., primary drafter or other role). Publications are intended to gauge the research and writing capability of applicants and do not necessarily need to be on the topic of medicines quality or excipients.
7. **Letters of Recommendation.** Two professional letters of recommendation are required. Letters of recommendations to be submitted separately via email to [Maria.Friciello@ucsf.edu](mailto:Maria.Friciello@ucsf.edu), directly by the authors, and must be received by the application deadline.



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### Partner Organizations

- UCSF Schools of Pharmacy and Medicine perform high-quality basic, translational, and clinical research in the fields of drug development sciences, pharmacogenomics, therapeutic bioengineering, and computational biology. In partnership with foundations, non-profit organizations, commercial entities, and government, the schools provide modern technologies, and tools that help evaluate medical products for quality, safety, efficacy, and performance.
- The Quality Institute is an objective, independent institute based at the U.S. Pharmacopeial Convention (USP), a scientific non-profit organization whose mission is to improve global health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods. The Quality Institute taps into global health, policy, scientific, and technical expertise to assess the benefits, costs, and feasibility of improving medicine quality. The Quality Institute will build a robust evidence base to facilitate evidence-based decisions that can help increase the availability of quality medicines everywhere, helping to build a foundation for a healthier world.



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