USP Launches New Program to Support Quality in Pharmaceutical Development
Impurities for Development program supports pharmaceutical product development by enabling manufacturers to screen, evaluate and source impurities

Media Contact:
Claudia Costabile
(301) 816-8314
cac@usp.org

Rockville, MD, October 9, 2018 — USP, a world leader in developing quality standards for medicines, foods and dietary supplements, is announcing a new program to assist manufacturers in their drug development efforts—Impurities for Development (IfD). This new program can help pharmaceutical manufacturers meet quality standards and regulatory requirements to control impurities that may be harmful to patients' health.

Characterizing and controlling impurities in drugs under development can present significant challenges to manufacturers because they can occur for several reasons: arising naturally within the source materials, being added as part of a product's synthesis, occurring inadvertently during processing and manufacturing, or forming during the shelf life of the product.

USP's new IfD program aims to help pharmaceutical manufacturers with custom-designed services to identify, isolate, synthesize and characterize impurities in medicines under development, allowing manufacturers to focus on other development processes.

"An accurate and thorough understanding of impurities is essential to produce quality medicines," says Salah Kivlighn, Ph.D., USP's senior vice president of strategic marketing and program operations. "IfD provides real-time expertise in impurity evaluation even at the earliest stages of a product's development cycle."

Prior to its launch, the IfD program was piloted for nine months with several companies, including Orchid Pharma of Chennai, India. Orchid worked with USP to isolate and synthesize an impurity of the cephalosporin antibiotic, cefdinir. According to S. Murugan, Orchid's Head of Analytical Development (API & Formulation), "Under the IfD program, our target impurity was synthesized within the designated time line, making it possible for us to keep our cefdinir project moving forward."

For more information, go to USP Impurities for Development.

About USP

USP is an independent scientific organization that collaborates with the world's top experts in health and science to develop quality standards for medicines, dietary supplements, and food ingredients. Through our standards, advocacy and education, USP helps increase the availability of quality medicines, supplements and food for billions of people world-wide.