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USP Launches *Trust Accelerated* Program to Help Speed Development of Quality COVID-19 Treatments and Vaccines

Free access to USP–NF *for six months now available to new users who need tests, assays and guidelines for quality controls; USP on-demand training and education 75% off*

May 19 complimentary webinar with USP vice president of global biologics to review compendial resources and answer questions from scientists, developers and manufacturers

ROCKVILLE, Md., May 11, 2020 — To accelerate the development of safe and effective COVID-19 vaccines, medicines and other treatments, the U.S. Pharmacopeia (USP) has launched a new program to support scientists, developers and manufacturers worldwide. In response to overwhelming demand, with 2,000 downloads of select COVID-related USP standards made available in March, *Trust Accelerated* offers expanded access to free USP technical expertise and resources to support an efficient path for regulatory predictability, saving developers time and resources. Designed to expedite efforts to bring life-saving vaccines and treatments to market while ensuring quality development, the program builds the confidence and trust of healthcare practitioners and patients necessary for wide-scale adoption.

From discovery research and development through manufacturing and distribution, USP staff can advise on novel vaccines, monoclonal therapies, antiviral and cell therapies, and immunoglobulins or convalescent plasma treatments. Additionally, USP can support scaling up production of approved therapeutics being investigated or used for the treatment of COVID-19.

“Overcoming the COVID-19 pandemic will require rapid development of safe and effective treatments—in particular a vaccine—and ensuring their availability at sufficient scale,” said Jaap Venema, USP executive vice president and chief science officer. “Whether working on a new medicine or scaling up production of an approved therapeutic, recognizing and addressing quality challenges early in the complex research and development process are critical to accelerating any drug development program.”

The program is valuable for:

- Manufacturers and other groups that need assistance qualifying raw materials
- Biopharmaceutical manufacturers (including contract manufacturers) scaling up production of COVID-19-related drugs
- Research organizations and pharmaceutical companies working on analytical methods to characterize or release vaccines or treatments
- Pharmaceutical manufacturers evaluating existing approved drugs for new indications related to COVID-19 treatment (particularly where USP standards exist and can support this exercise)

- Formulations groups that need assistance sourcing or verifying ingredients (excipients) to use in their dosage forms

Testing and compliance to the standards detailed within compendial methods are fundamental requirements for manufacturing release and distribution of vaccines and medicinal treatments around the world. USP compendial tests and methods address common issues, such as suitability, validation, contamination control, stability testing and qualification of raw materials, shared by all drug manufacturers.

Groups ranging from small to midsize organizations—including biotech, university and government labs—to large manufacturers of biopharmaceuticals can leverage USP's expertise as they work quickly to develop COVID-19 therapeutics and obtain regulatory approval.

Available resources include the following:

- New users can **access the *United States Pharmacopeia–National Formulary (USP–NF) Online* free** for six months. USP-NF is the most comprehensive source for medicine quality standards in the world. Get the offer.

- On May 19 at 11 a.m., USP will host a **free live webcast** with Fouad Atouf, USP Global Biologics vice president. Atouf will discuss COVID-19 vaccines and treatments including quality control tools across product classes and technologies, assays and technologies with broad application and impact, compendial tools for injection products and more. He will also answer live audience questions. Register today.

- **On-demand USP training and education** is available at a 75% discount. Courses include analytical method validation and pharmaceutical quality practices. To access, register for a free account.

Additionally, USP scientific staff can help troubleshoot many quality-related challenges commonly encountered during development and scale-up, ultimately supporting manufacturers as they advance their strategies to manage regulatory and compendial expectations.

Our experts have years of experience evaluating a wide range of analytical problems and utilizing validated tests and procedures. These include tests for stability, sterility, extractables and leachables, dissolution, etc. that are required for regulatory approval. We can advise on:

- Regulatory expectations and analytical requirements for system suitability, control for contamination and validation
- Qualification of raw materials to be used in manufacturing
- Safety and qualification of biologically derived/complex materials
- Supplier risk management, including setting expectations based on raw material attributes and process impact

USP is also working to connect companies seeking to collaborate with one another on quality issues and share sourcing of critical reagents. Contact USPBiologics@usp.org for technical assistance or more information.

Visit www.usp.org/covid-19 for more information about USP's COVID-19 response, including supporting front-line workers impacted by shortages of critical drugs and personal protection equipment and helping to build a more resilient global medicines supply chain.

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 worldwide. For more information about USP, visit www.usp.org."