

200
years of building
trust

Proposed Resolution 7

Education and Training for Industry and Healthcare Practitioners

Resolution white paper developed
by USP staff, with input from the
Council of the Convention

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Education and Training for Industry and Healthcare Practitioners



USP will build and strengthen capabilities fundamental for industry and healthcare practitioners to utilize USP standards through efficient, effective, and measurable education and training programs.

Summary

USP's mission is to improve global health through public standards and related programs that help ensure the quality, safety, and benefit of medicines, dietary supplements, and foods. To fulfill this mission, USP engages with stakeholders—including industry and healthcare practitioners—through educational outreach that helps them learn, integrate, and leverage USP standards into their practices correctly and consistently. USP offers education and training programs through a variety of formats, including in-person and online attendance, as well as a variety of venues, such as universities, USP sites, and stakeholder sites. This Resolution proposes that USP update and expand offerings as needed and in a timely manner. As part

of this Resolution, USP will develop a prospective measurement plan to continually assess registration for and evaluation of its programs. Based on these data, USP will adapt existing programs or create new programs that reflect the evolving needs of industry and healthcare practitioners. To meet these goals, USP already has expanded its pool of instructors, increased the number of trainings available, established module-based courses so they can be tailored to attendee needs, and expanded the ways in which trainings are delivered, such as embedded in university curricula. This proposed Resolution aligns with USP's ambitions to expand impact by providing scalable tools to support capability building across a broader audience than is currently reached.

These efforts will help ensure the intended impact of USP standards through their correct adoption and consistent use. Furthermore, USP education and training provides an opportunity to engage the next generation of stakeholders and volunteers earlier in their careers through university curricula.

Background

The development and production of quality medicines, dietary supplements, and food ingredients depend upon a relentless pursuit of characteristics, systems, and requirements necessary for attaining quality. Standards provide guidelines for consistently reaching these requirements and characteristics through the use of appropriate systems. In other words, standards are the foundation of quality assurance.

In today's rapidly evolving, global medicines supply chain, effective quality assurance requires education and training for current and future professionals in the pharmaceutical industry and healthcare arena. Industry personnel and healthcare practitioners, such as manufacturers and pharmacists, continually need ways to acquire new knowledge and skills in quality assessment. The knowledge and skills are necessary to comply with evolving regulatory standards and align with quality assurance across the medicines supply chain. By doing so, industry and healthcare practitioners are positioned to deliver the quality medicines and care to patients. Furthermore, new scientific approaches and medical products also lead to new training requirements. For example, industries that have traditionally manufactured solid oral dosage forms are moving toward complex generics such as injectables and drug-device combination products. This, too, requires industry and healthcare practitioners to develop new skills in quality assurance.

USP has provided continuing education and training for industry and healthcare practitioners since 2000. Over the past twenty years, more than 63,000 trainees have attended trainings on the effective use of USP standards. In 2019 alone, USP Education offered 155 courses to more than 6,700 trainees.

The content of USP education and training curricula covers a wide range of topics, including pharmaceutical products and active pharmaceutical ingredients, biologics, healthcare quality and safety, dietary supplements and herbal medicines, excipients, current good manufacturing practices, regulatory systems strengthening, and USP's *General Notices*.

Developing and Delivering Education and Training in Quality

USP Education provides courses and training programs year-round about how to effectively interpret and apply USP quality standards. The scientists and other experts who help develop USP standards that are used worldwide also help create the course curricula and materials offered through USP Education. Courses are presented by approved instructors with practical, first-hand knowledge of the subject area and related standards.

The insights shared in the courses not only facilitate implementation and use of USP standards, but also connect trainees to an independent, nonprofit scientific body with the goal of creating a strong foundation for a healthier world.

USP is continually evolving and expanding its training to new sites, new formats, and new topic areas. Courses are presented in classrooms and laboratories at USP sites in the United States, Brazil, China, Ghana, and India, as well as in person at customer sites in more than 37 countries. USP works with manufacturers (including local suppliers) throughout the world, as well as academia and other stakeholders, to increase access to training and education related to medicines quality.

To demonstrate its commitment to support manufacturers in building capabilities to achieve international quality standards and excellence in manufacturing, USP launched the USP Training Institute in Hyderabad, India, in 2018. The Training Institute has offered intensive, application-driven, hands-on training in quality control, quality assurance, and research and development for new pharmaceutical professionals and recent graduates. Additional courses for pharmaceutical professionals across functional disciplines will be offered over time.

As with all USP Education offerings, students at the Hyderabad institute have access to world-class faculty and state-of-the-art facilities and instrumentation. Courses are developed by USP scientists and are based on modern techniques used in industry and their applications, interspersed with current, relevant case studies. The content is delivered using a sophisticated platform to enhance engagement and retention. This platform has pre- and post-class components designed for use on smartphones to expand learning opportunities beyond the classroom.

Beyond the physical classroom at sites around the world, USP Education offers trainings online via webcasts, webinars, and other forms of eLearning. Participants have access to live online programs, such as “Performance Verification Test: Apparatus 1 and Apparatus 2” and “USP Certificate of Pharmacopeial Quality Assessment.” Self-paced online education is available as well, and includes courses on biologics, chemical medicines, dietary supplements and herbal medicines, dietary supplement verification, excipients, food ingredients, regulatory systems strengthening, and healthcare quality standards (HQS).

In the area of HQS eLearning, self-paced courses are offered on handling hazardous drugs and compounding. Role-specific modules are developed for entire hospitals, minimizing staff time away from their duties and allowing training participants to receive training specific to their responsibilities. Existing modules have been designed to meet the needs of institution leaders, compounding professionals, clinical licensed personnel, and general healthcare personnel.

USP Education assesses course content and the delivery of trainings to ascertain the course’s effectiveness and make improvements as needed. USP gathers student feedback after each course and tracks scores for courses and instructors. Overall, students express high rates of

satisfaction with training content and instructors. USP Education will seek ways to capture additional data on the utility and value of its trainings, including whether trainees have implemented what they learned. These findings will guide USP in refining or expanding courses.

Scaling Up Sustainably and Economically

Efforts to expand education and training for industry and healthcare practitioners align with USP’s overall strategy to broaden its impact worldwide. USP will focus on programs that are efficient, effective, and measurable. Expanding its education and training offerings through digital platforms will allow USP to reach many more students with the same investment or a limited increase (e.g., webcasting could triple the reach of courses USP already hosts). USP’s experience in developing and deploying educational content and training will be leveraged across the quality continuum wherever there is a need for capability building and USP can convene the requisite expertise.

Three imperatives support a vision of USP as a world leader in creating and delivering education and training related to the quality of medicines, dietary supplements, and foods within the context of a globalized supply chain. The strategic imperatives are:

Terms of Reference

- **Curricula Expansion:** The enhancement of curricula or course offerings supports customers who are looking to comply with a wide range of practices that improve quality.
- **Content Licensing:** The distribution of educational assets to or through a third party enables wider reach.
- **University Curricula Integration:** This refers to the uniting or meshing of discrete USP courses or modules into a larger university program.

USP Education Facts

- 2000: USP Education launched
- 2000–2019: 63,000 trainees
- 2019: 155 courses; more than 6,700 trainees
- 2025 Goal: 60,000 trainees per year through a scalable, sustainable, global model

- To support standards that impact stakeholders most significantly,
- To expand curricula to encompass a wider range of quality practices and requirements, and
- To integrate content licensing and university curricula.

Support Standards That Impact Stakeholders Most Significantly

The impact of a new or revised standard on stakeholders can vary greatly. USP's support of standards that have far-reaching consequences will enable the effective adoption of the most critical and complex USP standards and engage potential contributors to future standards development.

Education is a powerful tool for those adopting new ways of working. Because USP standards have a significant impact on industry and healthcare providers, educational materials should be developed or revised in conjunction with new or revised standards. Updates of standards for compounding, packaging, reference standards labeling, and residual solvents have already prompted action toward new or revised courseware. Education can also support USP efforts in new areas where public health can be protected through public standards. Innovative learning techniques (e.g., process animation, focused community learning, instructor-led online courses, and blends of live and online formats) appear promising in the effort to support adoption of consequential standards—those standards that can impact many stakeholders or patients, may require significant changes or investment to adopt, or are high profile for various reasons (e.g., regulatory action, litigation, media reports).

Expand Curricula to Encompass a Wider Range of Practices and Requirements That Promote Quality

Expanding curricula will support USP stakeholders who are looking to comply with a wide range of practices that improve quality, including good manufacturing practices (GMP), pharmaceutical continuous manufacturing, and quality by design. This will also help support USP's existing work in activities to sustainably strengthen medical product quality assurance systems in low- and middle-income countries.

Online and blended delivery can dramatically expand reach at a lower cost to participants. Certificate programs in new or foundational areas can meet the needs of growing cohorts of professionals looking to

differentiate themselves. For example, USP recently made available its Certificate of Pharmacopeial Quality Assessment as a comprehensive, online training. The content includes the key USP standards necessary for quality assurance and the knowledge and skills necessary to comply with U.S. regulatory standards and align with GMP. This program was designed and taught by the experts who help establish USP standards.

USP currently has one global education catalog rather than custom courses created at each site. This centralized-portfolio approach allows USP to 1) develop a pool of global instructors able to deliver the full set of courses, 2) ensure that students get the same learning from USP regardless of where they are taught, 3) reduce the expense of course creation by limiting "wheel rebuilding" and by reusing modules across courses, and 4) make it easier for potential students to understand what USP offers by having a consistent curricula, regardless of location. When this expansion requires development of new curricula, USP will recruit consultants with the required expertise to develop and teach new content and to build internal USP capabilities over time.

Integrate Content Licensing and University Curricula

Content licensing and university curricula integration will positively influence those learners who will work toward pharmaceutical quality in the future. Content licensing is the distribution of media assets and intellectual property to any third party. University curricula integration will involve incorporating discrete elements or features of USP Education courses or modules into existing or new academic course curricula, where USP retains the ownership of the intellectual property.¹ These activities aim to prepare incoming professionals for industry expectations.

Many universities are eager to incorporate USP education and training content, as they see the potential for collaborations to expand impact. Already, Northeastern University has hosted USP content for four semesters, and the Massachusetts College of Pharmacy and Health Sciences has licensed USP course content for two semesters. In addition, the University of Maryland, Duquesne University, Chapman University, and the University of Toledo have expressed interest in USP's education content. Enabling in-classroom broadcasts may be one way to fulfill these unmet needs. Meanwhile, industry learning and development departments represent an as-yet unrealized opportunity for growth and expansion of USP Education.

Creating on-demand content, which is increasing in use on a global scale, is another way to efficiently leverage subject matter experts' impact via smaller live interactions. These approaches can help expand the reach and impact of USP's education program through universities and other third parties. Expanding access to USP education and training by leveraging technology (such as webcasting and on-demand services) to enable scalability will widen the use of quality practices by a greater number of industry and healthcare professionals, helping to benefit patients nationally and internationally.

To create on-demand content, however, USP will need to develop a sustainable model for delivery. Tailoring training should be balanced by not overly customizing the content, which will allow a broad model to be rolled out. Reaching the global market necessitates expanding the faculty pool and communicating in a variety of languages; quality will be maintained through careful master course file management practices. Enabling new delivery models at all sites is an innovative way to achieve scale sustainably. Building online delivery capability will expand the reach of live events and enable self-service training. These capabilities also allow USP to provide translated courses for priority languages and support efforts to grow regional instructor pools.

Alignment with USP Mission

By 2025, USP is striving to become the world leader in education and training delivery related to quality

of medicines, dietary supplements, and foods. By offering a wide range of education and training options in a variety of settings, USP aims to promote greater engagement of stakeholders directly affected by USP standards.² USP aspires to reach at least 60,000 students per year through a scalable and sustainable model that is applicable around the globe, leveraging state-of-the-art technology to enable delivery of each training opportunity to a far wider audience. This Resolution will help support standards by enabling the correct adoption of standards and engaging potential contributors to participate in future standards development as USP Volunteers. The Resolution will support advocacy by promoting the value of capacity and demonstrating the value of both USP Education and USP standards. The curricula expansion, content licensing/university curricula integration, and global expansion strategic imperatives all align with USP's strategy to build capability among stakeholders—one of multiple approaches to improve global health.

Resource Assessment

Additional resources required to supplement resources that are currently in place.

This work will build upon the existing USP Education framework but expand to meet the additional needs of stakeholders, through modern training mechanisms, in more regions.

References and Notes

¹ Pearson ML, Hubball HT. Curricular integration in pharmacy education. *Am J Pharm Educ.* 2012 Dec 12;76(10):204. doi: 10.5688/ajpe7610204. PMID: 23275669; PMCID: PMC3530066.

² Ibid.