Resolution Proposal Submissions

200 usp The standard of trust

Convention
The 2020 Meeting

Key to Submissions

Name, Organization	Submission Number(s)
Gregory Amidon, University of Michigan, College of Pharmacy*	41
Demetra Antimisiaris, University of Louisville*	1
Tiffany Chan, USP staff	4
Grady Chism, Indiana University Purdue University Indianapolis**	25
Roger Clemens, USC School of Pharmacy (USP, FIEC Member)	8, 27
John Clos, The Coca-Cola Company	26
Megan Coder, Digital Therapeutics Alliance*	5, 11, 12
Hany Demian, U.S. Food and Drug Administration*	20, 23
Jonathan DeVries, DeVries & Associates	24
Barbara Ferguson, New Jersey Pharmaceutical Quality Control Association*	6, 9, 13, 21, 37, 40
Ryan Forrey, Becton Dickinson and Company	33
Michael Ganio, ASHP**	30, 31
Scott Haber, American Academy of Ophthalmology**	42
Ronna Hauser, National Community Pharmacists Association*	29
James Hoffman, Clinical Pharmacogenetics Implementation Consortium	10
Joseph Laning, International Society Cell & Gene Therapy*	2
Tina Morris, Parenteral Drug Association*	7, 14, 15, 19, 22, 38
Mark Neuenschwander, THRIV	32, 35, 36
Robert Rankin, International Food Additives Council*	28
Ralph Schmeltz, Pennsylvania Medical Society*	39
Shelly Spiro, Pharmacy HIT Collaborative	3
Dharati Szymanski, American Veterinary Medical Association (AVMA)	34
James Wooten, University of Missouri, Kansas City School of Medicine*	16
Priscilla Zawislak, IPEC-Americas*	17, 18

* Submitted by the Delegate of the USP Convention Member

** Submitted on behalf of the USP Convention Member

200 years of building trust

Submission 1

Special Rubrics for Biological Agent Drug Monographs

Resolution Proposal Submissions

200 usp The standard of trust | Convention The 2020 Meeting

Submission 1:

Special Rubrics for Biological Agent Drug Monographs

Summary:

The proliferation of biologic agents to market paired with the conventional small molecule standards of new drug testing can result in sub-optimal ADME characterization of biologic agents. Clinicians look to FDA drug monographs to understand a medication's expected physiological "behavior". The complex ADME of biologics paired with current standards result in drug monograph data is often an inadequate clinical resource. USP might consider leading improved reference data on biologic agents.

Statement of the Challenge:

Biologic agents are brought to market with similar standards for new drug testing as conventional small molecule drugs. However, atypical biologic activity of these drugs poses a challenge for clinicians, especially pharmacodynamic effect. Often clinicians use the traditional guideline that 5X t1/2 is adequate hold time to eliminate a drug from the body, especially when toxicity is detected. But with biologicals, sometimes the hold does nothing to halt the pharmacodynamic effect.

Desired Outcome:

USP might provide an important service by advocating for expanded drug monograph data for biologicals; to include topics like- PD effect after halting administration (example omalizumab's t1/2 is 28 days and its IgE suppression has been observed up to 3+ years post drug DC), expanded half life of elimination, complex distribution (biologicals absorption such as pinocytosis, etc), and immunogenicity. Drug information standards for biologicals should have a new rubric to provide meaningful data.

Resolution Alignment

How does the proposal align with USP's mission and vision?

USP's mission to help protect and improve the quality of medicines around the world as mentioned requires embracing disruptors. The challenge for biologicals in delivering easy access to meaningful information for consumers and clinicians requires disruption. (Meaningful information requires a new rubric for biologics as a class compared to standard historical small molecule drug information formats) Evidence of the need for disruption is that there is awareness that biologicals behave differently at the biomolecular level and as such need to be managed differently than clinicians are taught via standard professional education modalities. But that awareness is only elucidated within silos and pockets of curious stake holders ranging from FDA scientists and basic scientists, to specialist clinicians working with a single drug for which they observed atypical outcomes (i.e. stopping omalizumab treatment and observing suppression of IgE levels years after discontinuation). There is no one stake holder calling for the synthesis of this information in one convening resource such as the drug monograph. The drug monograph does a pretty good job of synthesizing the basic science with the clinical implications. Therefore USP leading the call for distinct biological drug monograph rubrics is disruptive but in alignment with the USP mission, and furthermore, USP convenes the siloed stake holders and might be the only entity that can achieve action to disrupt the current application of small molecule standards to biologicals in terms of drug monograph and drug information easy access resources.

A sample review of the challenges of biologic agents' ADME compared to small molecule traditional ADME can be found at: Shi S. Biologics: an update and challenge of their pharmacokinetics. Curr Drug Metab. 2014 Mar; 15(3): 271-90.

Which of the three essential components of "Standards", "Advocacy", and "Capability Building" does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why:

This proposal to explore implementation of a new rubric for biologic agent drug monographs aligns with all aspects of the 2025 strategy: First and foremost, quality standards regarding new emerging therapy classes.

Developing a biologic specific rubric for drug information can fill a gap in quality of use for emerging therapies (biologics). Also, this proposed resolution helps fulfill our advocacy mission because while there is bench and clinical science signals about this problem, little policy or quality improvement leadership is underway, and frankly the only force that can lead this proposed concept of perhaps a different rubric for biologicals is USP.

Lastly, the strategy of capacity building by working with industry and practitioners on the SAFE adaption of new technology is an important one. Proliferation of drug development is not dissimilar from proliferation of computer technology; it is happening so exponentially fast, that the users/clinicians are having difficulty with ethical, and safe use. You may have seen that suddenly JAK inhibitors are under scrutiny for a link to serious cardiac complications. This problem was not expected, moreover the question is when the drug is stopped due to cardiac arrest, how does the clinician have awareness of hidden potential for long term pharmacodynamic effect due to complex pharmacokinetics and bio-signaling? Moreover, many biologicals place patients at risk for infection and cancers due to immunosuppressant mechanisms, therefore, it is important to advocate for easy to access ADME and pharmacodynamic drug data for this class of drugs.

It will require all stakeholders to determine standard rubrics for biologicals that will shine light on safe use, because the gap in knowledge between the basic scientist who create these drugs and clinicians is wide. Closing this gap is a challenge that if successfully done will benefit the Pharma drug developers, consumers, and clinicians alike.

USP is the perfect convener of stakeholders to help solve this challenge, and this challenge aligns perfectly with both 2025 strategy and our mission of leveraging USP's robust history to impact public health by helping to mitigate potential hidden threats of the widespread use of biologicals. These drugs are game changers and we need to help the risk-benefit of use keep in line, otherwise they will either cause inadvertent, avoidable harm or be pulled needlessly off the market.

200 years of building trust

Submission 2

Driving Cell and Gene Therapy Development Through Standards Development

Resolution Proposal Submissions

200 usp The standard of trust | Convention The 2020 Meeting

Submission 2:

Driving Cell and Gene Therapy Development Through Standards Development

Summary:

The USP will actively devote resources to evaluate, modify, or otherwise create monographs and/or standards to help accelerate guidance and quality tools for the burgeoning cell and gene therapy (CGT) industry.

Statement of the Challenge:

The pace of change for biologic medicines is unprecedented. In order for USP to maintain a leadership position throughout the breadth of the biologics field, an active and coordinated effort within cell and gene therapy should be a USP priority. Issues facing the CGT industry range from raw material quality, to controls and monitoring methods for particulates, to ensuring effective testing for product characterization. This resolution would solidify joint advocacy and expertise to advance CGT.

Desired Outcome:

Increase the breadth of testing and standards for new or cutting-edge cell and gene therapy products by expanding technological expertise in cell and molecular analysis methods. Utilizing this expanded expertise, provide input and expertise for the CGT industry to regulators and pharmacopeias worldwide. In addition, ISCT is uniquely positioned to contribute to this resolution based on significant experience working with other global standards and accrediting organizations.

Resolution Alignment

How does the proposal align with USP's mission and vision?

The call for a USP resolution specifically tailored to cell and gene therapies aligns with all three structural pillars of the USP 2025 strategy triangle: standards, advocacy and capability building. Specifically, direct involvement in advanced therapeutic fields like cell and gene therapy enable mission impactful progress towards the development of standards to address new and emerging therapy classes, and keep USP not only up-to-date but at the forefront. It also drives capability building that will be the cornerstone for the facilitation and acceleration of new technologies enabling meaningful progress for regulatory agencies and product providers alike. ISCT is also committed to capability building through our commitment to training the next generation of health/science/regulatory professionals, as a key and complimentary aspect of driving the development of standards. Finally it will play an integral role in further combining USP standards into frameworks for biomedical innovations and emerging areas of medicine, with this being especially true by being a partner and collaborator with regulators. All of these facets provide the overarching structure for continuing to be the global leader in ensuring the quality and safety of medicines around the world. By leveraging USPs collaborative history in a CGT-focused resolution we are more likely to see meaningful dialogue and action on topics that have an positive enabling effect on the advancement of CGT products.

Which of the three essential components of "Standards", "Advocacy", and "Capability Building" does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why:

The call for a resolution specifically targeting cell and gene therapy touches on all three essential components as follows;

(1) The resolution advocates for development of standards for increasingly diverse product portfolios which are often comprised of highly complex or mixed component structures. Providing standards for analytical testing methods and having a voice in the types of assays these standards are used for, positions USP well for the future. (Clarke et. Al, ISCT PPD Committee, Cytotherapy 2016). These standards could include stand-alone genetic materials, gene-modified cell standards or modified cellular assay targets expressing panels of surface or secreted proteins, which are able to be used for mutliple assay controls. USP involvement in assay or standard development for cell and gene therapy helps shape the product characterization for the entire industry. It also creates a direct link between product innovators and regulators that USP can proactively develop to further its position as a CGT resource. (Bravery et. Al, ISCT PPD Committee, Cytotherapy 2013). As previously noted, ISCT has extensive experience working with other global standards and accrediting organizations as a Category A Liaison to the International Standards Organization (ISO), Board Member of the Standards Coordinating Body (SCB) and co-founder/parent organization of the Foundation for the Accreditation of Cellular Therapy (FACT).

(2) Advocacy and communication across regulatory agencies with a specific focus on cell and gene therapy will be incredibly helpful for the overall standardization of the industry. Leveraging the relationships that USP has with regulatory bodies and other pharmacopeias to drive informed and accurate science that is practical and reproducible across labs is vitally important. Incorporating industry input at the expert committee level ensures continuity of thought and process which aligns the needs of product innovators with regulator expectations. ISCT, as a translational Society, brings input and consideration on how these factors affect the end therapy. Advocacy for responsible development of cell and gene therapies is a core value of ISCT, embodied by the ISCT Presidential Task Force on the Use of Unproven and/or Unethical Cell and Gene Therapy as it strives to promote the role of rigorous research and appropriate investigation and application of cell based therapies.

(3) Probably most pressing for USP would be the motivation to maintain the world class scientific capabilities that USP has been known for in a time where the pace of change can be dizzying. Maintaining USP leadership through the use of advanced technologies and methods is a natural by-product of developing strategic competencies that will be critical in the testing of cell and gene therapy products. Building out capabilities that support detailed protein, cell population, and genetic variability testing (among others) for complex cellular products requires a new and forward-thinking mindset as well as a commitment to the field as a whole.

200 years of building trust

Submission 3

Health IT Expert Panel on Allergy and Intolerance

Resolution Proposal Submissions

200 usp The standard of trust | Convention The 2020 Meeting

Submission 3:
Health IT Expert Panel on Allergy and Intolerance

Summary:

This resolution is requesting the development of standardized terminology for medication allergies and clinical manifestations of intolerance with associated codes to promote interoperability and information sharing. Standardization of this information would result in a "value set" of medications and clinical manifestations of intolerance that would be made publicly available through the Value Set Authority Center (VSAC) at NLM. http://pharmacyhit.org/pdfs/USPRes2020.pdf

Statement of the Challenge:

Drug allergy "classes" and clinical manifestations of intolerance are determined and maintained by proprietary vendors or built and maintained by individual health systems. Creating and maintaining a publicly accessible single standard that is developed and endorsed through public standard-setting processes could be a significant contribution to improving patient safety and enhancing public health. http://pharmacyhit.org/pdfs/USPRes2020.pdf

Desired Outcome:

The Expert Panel would (1) Address the timely public health need for allergy â€˜classes' standard to support ONC USCDI. (2) Increase collaboration with governmental partners RxNorm, CMS, and ONC. (3) Modernize USP partnerships provide valuable therapeutic digital information for practitioner-stakeholders. (4) Develop synergistic approaches support codification with FDA on SPL indexing and harmonization of drug classes. http://pharmacyhit.org/pdfs/USPRes2020.pdf

Resolution Alignment

How does the proposal align with USP's mission and vision?

The United States Pharmacopeia 2025 strategy recognizes that digitalization of healthcare is a disruptor in the healthcare space, specifically noting that "increasing access to big data and digital health frameworks challenge stakeholders to rethink their patient engagement and delivery of care." USP's ambition is to be a leading provider of services that are essential to improving medicine quality by facilitating adoption of new technologies. http://pharmacyhit.org/pdfs/USPRes2020.pdf

Which of the three essential components of "Standards", "Advocacy", and "Capability Building" does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why:

Standards in the form of harmonization with health IT standards organizations related to terminology for allergy and intolerance with health systems (e.g. HL7 and ONC). For more detailed information follow this link http://pharmacyhit.org/pdfs/USPRes2020.pdf.

200 years of building trust

Submission 4

Electronic Medical Record Standardization for Diverse Populations

Resolution Proposal Submissions

200 usp The standard of trust | Convention The 2020 Meeting

Submission 4:

Electronic Medical Record Standardization for Diverse Populations

Summary:

USP is a steward of empowering diversity, inclusion, and public health, and seeks to raise the bar in innovation and digital technology. An ever growing tool in both public health and digital technology is the use of electronic medical records (EMR), for which there is little to no standardization catering to diverse populations of patients. In particular, the LGBTQ+ community which is also advancing in unique treatments that EMRs are not transparent in, leading to great consequences.

Statement of the Challenge:

The 2015 US Transgender Survey demonstrated 33% had a negative experience because of their gender identity within the past year when interacting with a health care practitioner; 24% reported that their health care providers knew "almost nothing" about transgender health care; 23% delayed seeking necessary care in the past year out of fear of discrimination based on their gender identity. Gupta et al. affirmed that EMRs do not document gender identity or provide lab ranges for this population.

Desired Outcome:

Standardizing information included in EMRs, particularly for the LGBTQ+ population, will improve:

- Provider-patient relationship
- Incomplete medical history
- Missed routine exams (ex. PSA, pregnancy)
- Incomplete medication lists (ex. Hormones)
- Missed diagnoses in a vulnerable population
- Increased rates of unemployment, mood and psychological disorders, suicide risk, substance abuse, and HIV

USP would also align with multiple organizations (e.g, USHHS, Epic, WPATH, Endo. Soc).

Resolution Alignment

How does the proposal align with USP's mission and vision?

USP is a steward of improving global health through public standards for the quality and safety of medicines. An ever growing tool in public health to foster safety and quality of care is the use of electronic medical records (EMR), for which there is little to no standardization catering to diverse populations of patients. The LGBTQ+ community has a growing population of transgender patients estimated to be 390 adults per 100,000, or almost 1 million adults nationally (Am J Public Health. 2017;107(2):e1–e8). This population is advancing in unique treatments that EMRs lack transparency in, leading to impactful consequences.

The 2015 US Transgender Survey noted that 33% had a negative experience because of their gender identity within the past year when interacting with a health care practitioner; 24% reported that their health care providers knew "almost nothing" about transgender health care; and 23% delayed seeking necessary care in the past year out of fear of discrimination based on their gender identity (Eur Psychiatry. 2015;30(6):807-15; ustranssurvey.org). When encountering a healthcare professional, this population experiences inflexibility of EMRs in documenting affirmed gender, lack of apparent reference ranges for unique laboratory tests, unclear guidelines regarding gender classification for blood donation eligibility criteria, and poor handling and interpretation of surgical and cytologic specimens on a routine basis (Lab Med. 2016;47(3):180-8). Additionally, from a practitioner's perspective, there are challenges associated with inter-communicability of patient information to the retail or outpatient space, incorporating features in the EMR

may require specific builds or purchase of additional unstandardized "packages," and providers may simply not be trained to ask for relevant information (e.g., cultural adjustment).

Ultimately it is the patient that suffers. These issues aggregate to strain provider-patient relationships, and impart incomplete or inaccurate medical histories. Patients miss routine exams that could otherwise prevent life-changing medical diagnoses (e.g., PSA, cancer, pregnancy). Ultimately, due to inadequate quality and safety of patient care, this already vulnerable population of patients may experience increased rates of unemployment, mood and psychological disorders, suicide risk, substance abuse, and HIV (Clin Biochem. 2014;47(10-11):983-7).

Fortunately, recognition of this problem and ongoing efforts have been initiated. Meaningful Use per US Health and Human Services identified that there needs to be a designated area for information in the EHR highlighting social, psychological, and behaviorial data per demographics; improved medical verbiage (SNOMED); and standardized ways to ask appropriate questions for this population. The EMR working group convened by a World Professional Association for Transgender Health (WPATH) Executive Committee recommended that the demographic variables of an EMR should include preferred name, assigned sex at birth, gender identity, and pronoun preference. The Affordable Care Act requires access to essential preventative procedures and treatments (e.g., mammograms, pap smears) if deemed necessary by a medical provider. Epic, a leading EMR company, incorporated preferred names and sex versus gender information as an optional EMR build. The Endocrine Society produces the only guideline on how to address transgender care, however this is relatively obscure to practitioners, has a narrow scope, and is rarely integrated into existing EMRs (J Clin Endocrinol Metab. 2009;94(9):3132-54). These efforts are limited by lack of enforcement, utility, and unity. USP, a leading standard-setting organization with prestige in quality and trust, can fill this gap by bringing expert volunteers together to create a concerted and standardized effort addressing the various facets of each of these organizations, creating a unified approach to improving patient care for this vulnerable population. In fact, USP is a leader in bringing passionate people like the above together to have important conversations.

The need for higher quality transgender health care is growing, especially standardization of basic health care components (EMRs). Standardization of healthcare for the transgender population will deter serious safety events and improve detection of illnesses for preventative care. USP must be a steward of diversity and public health in this digital age.

Which of the three essential components of "Standards", "Advocacy", and "Capability Building" does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why:

Standards: The need for standards in EMRs, especially for vulnerable diverse populations of patients, is overdue. Although there are various organizations tackling specific facets pertaining to the larger issue of standardizing EMRs for LGBTQ+ communities, there is no concerted and standardized document to unify these efforts. USP can lead the momentum in producing new and definitive standards for all medicines, including the safety and quality of those very systems which direct providers in the practice of medicine.

Advocacy: The growing population of transgender patients in the United States is exponential. USP has demonstrated a strong voice advocating for patient safety and quality of care over the past 200 years, and recently has raised a flag advocating for Pride. In addition to the effort to have a strong voice in the digital age, USP can unify these three different voices into a strong stance to lead diversity and public health in this growing age of innovation.

Capability Building: There is currently governmental support for stronger recognition of the LGBTQ+ community in patient care, as evident by the efforts of the US Health and Human Services in Meaningful Use. Leading EMR companies (Epic) are also looking into building the capability of elevating patient care for this population within their very own systems. USP can unite these efforts into a usable standard that can be equipped by many EMRs and can be considered for adoption into Meaningful Use, or other medication/patient safety initiatives, while bringing in the quality and expertise that this movement desperately needs.

200 years of building trust

Submission 5

International Collaboration

Resolution Proposal Submissions

The standard of trust

Convention
The 2020 Meeting

Submission 5:
International Collaboration

Summary:

USP will collaborate with other national pharmacopeia to promote universal applicability and implementation of quality standards for digital health technologies.

Statement of the Challenge:

Digital therapeutics and similar technologies are used across multiple regulatory jurisdictions. While different requirements apply to these products related to market authorization and access, there should be consistency in the way these products are designed, manufactured, validated, and support clinical claims. USP should work with other pharmacopeia to develop, promote, and implement robust quality standards to ensure reliability and safety across regulatory boundaries.

Desired Outcome:

A focus on international harmonization of quality standards for digital health products is crucial. The development of consistent standards for DTx products will support current efforts being made by regulatory and notified bodies globally. Manufacturers, clinicians, and patients will benefit from the use of products that meet this set of harmonized standards, regardless of the product's country of origin and/or use.

Resolution Alignment

How does the proposal align with USP's mission and vision?

The USP "continually work[s] to build and reinforce a foundation that draws us closer to a world where everyone can be confident of quality in health and healthcare." The key word that directly relates to this resolution is "world." National standards are beneficial, but applicability internationally is crucial. This resolution both supports and insists upon "working collaboratively with key stakeholders across the globe".

Which of the three essential components of "Standards", "Advocacy", and "Capability Building" does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why:

An international effort to develop and harmonize quality standards for digital health technologies supports the "Advocacy" idea that "USP will be the global institutional leader advancing medicine quality". This resolution requires the "develop[ment] and assembl[ing of] evidence" to "expand awareness, urgency, and political will" and "integrate USP standards into frameworks for biomedical innovations and emerging areas of medicine".

"Capability Building" is also tied to this resolution, as USP will need to build on international perspectives to best "equip stakeholders to use our standards". More precisely, this resolution also calls for simultaneous collaboration with regulatory and notified bodies.

200 years of building trust

Submission 6

Harmonization with Other Pharmacopeias

Resolution Proposal Submissions

200 usp The standard of trust | Convention The 2020 Meeting

Submission 6:

Harmonization with Other Pharmacopeias

Summary:

USP is encouraged to expand its efforts on harmonization of pharmacopeial standards, partnering with pharmacopeias around the world including the World Health Organization's (WHO's) International Pharmacopoeia and relevant International Conference on Harmonization (ICH) topics.

Statement of the Challenge:

This resolution addresses the need to consolidate the multitude of pharmacopeial standards in the various compendia, including those pharmacopeias outside of the Pharmacopeial Discussion Group (PDG). Divergent public standards do not result in any benefit to the patient.

Desired Outcome:

To ensure that materials and chapters that are most commonly used in the industry are harmonized, eliminating redundancy in testing and reducing the regulatory burden of divergent standards globally. There are many aspects to harmonization, and USP could also work toward the concept of mutual acceptance of the content in other pharmacopeias and vice versa, with the approval of the relevant regulatory authorities.

Resolution Alignment

How does the proposal align with USP's mission and vision?

Harmonization is an essential factor in providing greater access to quality medicines.

Which of the three essential components of "Standards", "Advocacy", and "Capability Building" does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why:

USP can demonstrate that they are the "Global institutional leader advancing medicine quality" by bringing together the various pharmacopeias to harmonize standards. This resolution supports "Standards" by allowing for a "more flexible, agile, and iterative approach to standards development".

200 years of building trust

Submission 7

Globally Harmonized Standards

Resolution Proposal Submissions

200 usp The standard of trust | Convention The 2020 Meeting

Submission 7:
Globally Harmonized Standards

Summary:

USP will expand its commitment to harmonization of compendial standards by working with pharmacopoeias, the World Health Organization, and other stakeholders to determine optimal ways to advance and sustain globally harmonized standards.

1. Harmonization process improvement—
USP will continue to champion a leaner and nimbler harmonization process, and will promote the fundamental reform of historically established harmonization work plans to be more reflective of issues that are critical and current to stakeholders rather than working through legacy items

2. Harmonization scope—
USP will encourage broader harmonization dialog that fosters alignment of the pharmacopeias from relevant emerging markets and mirrors the growing circle of ICH engagement. USP also will encourage greater convergence and dialog between ICH and WHO to narrow gaps and reduce disagreement in requirements between ICH and non-ICH countries

Statement of the Challenge:

Current harmonization mechanisms are not capable of supporting a global supply chain of increasing complexity and rapidly accelerating development pace.

Desired Outcome:

Establish and maintain mechanisms to create modern, globally relevant standards.

Resolution Alignment

How does the proposal align with USP's mission and vision?

USP's core mandate is to create standards that support global public health. This resolution proposal is a re-commitment to Resolution III from the 2015 Convention—Globally Harmonized Standards.

Which of the three essential components of "Standards", "Advocacy", and "Capability Building" does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why:

Standards and advocacy. This proposed resolution maps to the 2020 Resolution Concept "Harmonization".

200 years of building trust

Submission 8

Share USP Knowledge, Experience, Skills and Successes with the World

Resolution Proposal Submissions

200 usp The standard of trust | Convention The 2020 Meeting

Submission 8:

Share USP Knowledge, Experience, Skills and Successes with the World

Summary:

Key individuals of USP or associated with therewith will communicate on USP knowledge, experience, skills and successes in key national and international forums.

Statement of the Challenge:

The work of the FIEC is not as familiar to national and international organizations as it should. By utilizing the professional networks of our FIEC members, the important expertise of USP can be readily shared. FIEC members have contacts in numerous countries and among respected organizations. For example, Dr. Clemens will address a) CRISPR and b) ultra-processed foods during the 2020 IUFoST meeting in New Zealand. He, along with USP's Dr. Xie, facilitated a food color session at IFT19.

Desired Outcome:

1. Worldwide education of USP's knowledge, experience, skills and successes to gain professional and scientific organization support for the use of USP standards and the *FCC* specifications.

2. Extend the concepts of food quality and integrity beyond classic toxicology and traditional microbiology.

Resolution Alignment

How does the proposal align with USP's mission and vision?

This proposed resolution promotes USP's mission and vision by strengthening the organization's connection among and communication with like-minded domestic and international organizations and regulatory agencies that develop and establish standards, methods, and specifications for foods and food ingredients. These efforts will enhance USP's image and the value of the *FCC* among these scientific allies.

Which of the three essential components of "Standards", "Advocacy", and "Capability Building" does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why:

USP's communication of its 2025 strategy among key domestic and international organizations as well as regulatory agencies will enhance its efforts and capabilities to promote its expertise. Communications efforts among these organizations will contribute to USP's visibility and its critical contributions to the food industry, sharing with regulatory agencies, and important NGOs. This efforts will elevate the value of *FCC* and its importance in promoting food safety, integrity and quality.

200 years of building trust

Submission 9

Promote Greater Engagement of Stakeholders Directly Impacted by USP Standards

Resolution Proposal Submissions

200 usp The standard of trust | Convention The 2020 Meeting

Submission 9:

Promote Greater Engagement of Stakeholders Directly Impacted by USP Standards

Summary:

USP is encouraged to reevaluate the USP volunteer model to determine if a different, more forward-looking approach for USP's standard-setting body would better suit USP's purpose. Expert Committees should be more reflective of users of USP, which would result in more robust standards. We also encourage continued engagement of stakeholders at Stakeholder Forums and on Project Teams as this provides an equally important avenue for USP to engage with stakeholders, including industry and regulators.

Statement of the Challenge:

The development of unnecessary (i.e., out-of-scope) or confusing standards and implementation timeframes that are unrealistic.

Desired Outcome:

Including qualified candidates (i.e., those with expertise in Compendial Affairs, Quality Assurance/Control, Regulatory Affairs or in the technical areas that utilize USP on a regular basis) on USP Expert Committees, Expert Panels, and/or Working Groups will help develop necessary USP standards with realistic implementation timeframes, and enhance stakeholders' timely implementation of new and revised USP standards.

Resolution Alignment

How does the proposal align with USP's mission and vision?

Developing quality standards with the collaboration of stakeholders who are actual users of the USP with the ultimate goal of setting quality public standards for medicines.

Which of the three essential components of "Standards", "Advocacy", and "Capability Building" does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why:

USP will be a "definitive source of medicine quality standards" by collaborating with key stakeholders to establish the standards and timeframes. If Expert Committees were more reflective of the users of the USP, it would provide for more diversity in education, and in technical, quality, regulatory and compendial experience, and would result in more robust standards. In this way, USP would promote the engagement of stakeholders who routinely use USP standards and/or who understand the business processes that may be impacted by these standards, especially for USP standards that cut across many aspects of USP such as General Notices and General Chapters, and it would include engagement at all steps of the USP standard-setting process. This effort would also provide USP's acknowledgement and recognition that this experience is of value to the USP standards-setting process, and not solely from a commenter perspective. This resolution supports "Standards" by ensuring a more "flexible approach to standards development", and supports "Advocacy" by building "trust in USP standards".

years of building trust

Submission 10

Implementation of Pharmacogenetics as a Patient Safety Strategy

Resolution Proposal Submissions

The standard of trust

Convention
The 2020 Meeting

Submission 10:

Implementation of Pharmacogenetics as a Patient Safety Strategy

Summary:

USP will collaborate with stakeholders to improve the quality and safety of medication use by facilitating the implementation of personalized medicine strategies such as pharmacogenetics. USP's standards setting expertise can encourage greater use of pharmacogenetics across various subjects, such as laboratory testing, standardized terms, drug information, and integration into the electronic health record. USP is uniquely positioned to amplify the ongoing work of organizations such as CPIC.

Statement of the Challenge:

Pharmacogenetics is a leading personalized medicine strategy. Limited standardization and inconsistent use of established evidence are barriers to wider use. CPIC has generated consensus and standardized aspects of pharmacogenetics. More opportunities for standardization and interoperability remain, including test selection and ordering, standardized approaches and terminology in laboratory processes, and reporting of results into the electronic health record with clinical decision support.

Desired Outcome:

By connecting stakeholders, advocating, and developing standards USP can enable greater use of pharmacogenetics as a personalized medicine strategy. Developing new standards and disseminating existing standards will make implementation of pharmacogenetics into routine practice more efficient. An immediate focus can be to include pharmacogenetics in USP's HealthIT work as other opportunities are prioritized. Other outcomes may be to include pharmacogenetic information into USP monographs.

Resolution Alignment

How does the proposal align with USP's mission and vision?

Advancing the use of pharmacogenetics as a leading strategy within personalized medicine is directly aligned with the USP mission to "ensure the quality, safety, and benefit of medicines" Greater use of pharmacogenetics will facilitate the USP vision of "access to high quality, safe, and beneficial medicines" USP is positioned to help take pharmacogenetics from an underused medication safety strategy to a foundational strategy used to proactively promote patient safety.

USP's mission is to create public standards, and further standardization is needed to enable the implementation of pharmacogenetics. USP can collaborate and leverage the work of established groups with deep expertise in pharmacogenetics but limited capacity to produce formal public standards. The Clinical Pharmacogenetics Implementation Consortium (CPIC www.cpicpgx.org) is an international consortium of individual volunteers and a small dedicated staff who are interested in facilitating use of pharmacogenetic tests for patient care. One barrier to implementation of pharmacogenetic testing in the clinic is the difficulty in translating genetic laboratory test results into actionable prescribing decisions for affected drugs. CPIC's goal is to address this barrier to clinical implementation of pharmacogenetic tests by creating, curating, and posting freely available, peer-reviewed, evidence-based, updatable, and detailed gene/drug clinical practice guidelines (See here for all CPIC publications https://cpicpgx.org/publications/).

CPIC guidelines follow standardized formats, include systematic grading of evidence and clinical recommendations, use standardized terminology, are peer-reviewed, and are published in a leading journal. While CPIC has developed standardized terms for pharmacogenetics (see Caudle KE et al. Genet Med. 2017 Feb;19(2):215-223.), many other opportunities to provide standards for pharmacogenetics remain.

Creation of new standards and further dissemination of existing standards to integrate pharmacogenetics into the electronic health record will provide a strong foundation to enable wider implementation. Interoperability and digitalization will be key components to maximizing the value of the standards, tools and dissemination techniques USP would utilize. Increasing the use of pharmacogenetics into routine clinical care is in complete alignment with USP's mission to ensure the quality, safety and benefit of medicines. Enabling the implementation of pharmacogenetics in routine clinical care will help ensure the full value of personalized medicine reaches the ultimate end user, the patient.

Which of the three essential components of "Standards", "Advocacy", and "Capability Building" does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why:

Expanding the use of pharmacogenetics as a leading personalized medicine strategy supports USP's impact across "standards", "advocacy" and "capability building". Standards: As already noted, some standards exist for pharmacogenetics, but CPIC leaders have recently summarized how standardization can accelerate the adoption of pharmacogenetics (Caudle KE, et al. Pharmacogenomics. 2018 Jul 1;19(10):847-860.). In this paper, standardization opportunities were summarized in three categories 1) within clinical laboratory processes, 2) test ordering, and 3) results reporting. Some progress has been made through the efforts of CPIC and others, particularly with standard terms that are now recognized by both LOINC and SNOMED-CT. Building from this foundation, the public standard setting capabilities and influence of USP will propel standardization for pharmacogenetics forward. Pharmacogenetics is a dynamic field where standards development is occurring at the same time as deployment and implementation. This requires standards be developed in an agile and iterative process, making pharmacogenetics a great use case for USP's standards expertise and ambitions. Advocacy: Within the patient safety community, pharmacogenetics is not always appreciated as a strategy that can improve medication safety. Given the USP's mission to ensure the quality, safety, and benefit of medicines, USP is well positioned to advocate for greater use of pharmacogenetics and use of the accompanying standards that USP could produce to enable use of medications. As advocates for the use of pharmacogenetics, USP will need to carefully reference the available evidence. In the current environment, some stakeholders advocate for broad use of pharmacogenetic tests where the evidence does not yet support use, but other influential stakeholders have inappropriately narrow view of the use of pharmacogenetics. USP has the opportunity to advocate in a neutral and unbiased manner and use the best available evidence to promote safe medication use, thus ensuring responsible use of the latest scientific breakthrough in personalized medicine. Further standardization and incorporation of pharmacogenetic information into practice can improve appropriate prescribing across a range of therapeutic areas, such as pain, oncology, cardiovascular disease, and depression. (https://cpicpgx.org/genes-drugs/) USP's involvement and advocacy can illustrate the wide applicability of pharmacogenetics. Capability Building: A growing number of health-systems, professional organizations, NIH-funded consortiums, clinical laboratories, and health IT entities are working to build the capability for health-systems to implement pharmacogenetics into routine patient care. As USP advances standards for pharmacogenetics in collaboration with groups such as CPIC, this community will be readily equipped to evaluate, use, and disseminate these standards. USP may also be well positioned to convene and equip the pharmacogenetics community interested in implementation. Ultimately, all of these activities will enhance interoperability of pharmacogenetic data and increase the likelihood a patient will receive maximum benefit from personalized medicine. In summary, new standards for implementation of pharmacogenetics into the electronic health record as part of routine patient care is directly aligned with the USP strategic goal to be the definitive source of medicine quality standards.

200 years of building trust

Submission 11

Digital Therapeutic Quality Standards

Resolution Proposal Submissions

200 usp The standard of trust | Convention The 2020 Meeting

Submission 11:
Digital Therapeutic Quality Standards

Summary:

USP will develop quality standards that address digital therapeutic (DTx) product design, manufacture, and verification, and make them available to product manufacturers, regulators, clinicians, and end users as they work to develop, evaluate, and/or deploy digital health technologies.

Statement of the Challenge:

Quality standards do not currently exist for digital therapeutics â€“ products that deliver medical-grade interventions. It is therefore important to develop standards for DTx products to ensure that all categories of medicine, regardless of their mechanism of delivery, are held to robust design, manufacture, and quality measures. This will not only prevent the development of sub-standard products, but also ensure ongoing patient safety and benefit.

Desired Outcome:

The development of standards for digital therapeutic products will enable further innovation, quality, sustainability, and trustworthiness across this quickly evolving industry.

Resolution Alignment

How does the proposal align with USP's mission and vision?

USP is dedicated to ensuring and protecting medicine quality, which this resolution will achieve in the expanding field of digital medicine. Per the USP 2025 Strategy, there is an "explosion of new medicine modalities: The rapid introduction of new classes of medicines and increasing breadth of what is considered medicine requires new types of quality standards."

Digital-specific quality standards will, among other things, specifically relate to the nuances of digital tools (a "new medicine modality") to enable industry cohesion, in addition to the eventual identification of counterfeit and/or adulterated products.

Which of the three essential components of "Standards", "Advocacy", and "Capability Building" does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why:

This resolution most supports and advances the "Standards" of the 2025 Strategy. Using a "flexible and iterative approach" to develop "modernized standards" for digital health tools ensures the USP, "remain[s] up-to-date" and "addresses new and emerging therapy classes, including biologics and biosimilars".

In addition, a specific set of digital product quality standards will facilitate the "Advocacy" topic of "integrate USP standards into frameworks for biomedical innovations and emerging areas of medicine", as well as the "Capability Building" section on "facilitat[ing] adoption of new technologies" by insisting on concrete, quantifiable measures of quality. As with Resolution #1, these standards will emphasize the USP's commitment to "rais[ing] our voice to continue to advocate for quality".

200 years of building trust

Submission 12

Equitable Recognition of Medical-Grade Interventions

Resolution Proposal Submissions

200 usp The standard of trust | Convention The 2020 Meeting

Submission 12:
Equitable Recognition of Medical-Grade Interventions

Summary:

USP will develop quality standards for all medical-grade therapeutic interventions, regardless of the intervention's mode of delivery (i.e., chemical, digital).

Statement of the Challenge:

All medical-grade therapeutic interventions should adhere to the same rigor of quality standards regardless of the intervention's mode of delivery (i.e., chemical, digital, etc.) to ensure patient safety and product efficacy. As digital therapeutics (DTx) are increasingly recognized as medical therapies on par with other evidence-based clinical treatments in national frameworks, it is necessary for USP to develop robust quality standards for this new category of medicine.

Desired Outcome:

All medical-grade therapeutics should be subject to rigorous quality standards in order to: a) establish credibility and trustworthiness for patients, clinicians, healthcare organizations, and payers; b) demonstrate purity, consistency, and clinical reliability; and c) complement current regulatory frameworks.

Resolution Alignment

How does the proposal align with USP's mission and vision?

This resolution aligns with USP's mission to "improve global health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods". Quality standards should be developed for all medical-grade therapies regardless of their mode of delivery to ensure consistency product design, manufacture, and verification.

Which of the three essential components of "Standards", "Advocacy", and "Capability Building" does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why:

USP states, "We begin our third century ready to make a greater impact on public health than ever before by leveraging our history, integrity and strength along with a renewed commitment to advance the quality of medicine."

This resolution directly supports and advances the "Standards" ambition of the 2025 Plan, which aims to "make USP the global leader in advancing medicine quality, and establish a culture of accountability and continuous improvement where the bar for quality is set higher for ourselves".

In addition, this resolution upholds the "Advocacy" ambition of "raising our voice to continue to advocate for quality", as it promotes adherence to high levels of rigor of quality for all types of medicine.

200 years of building trust

Submission 13

Enhance USP's Quality Systems

Resolution Proposal Submissions

200 usp The standard of trust | Convention The 2020 Meeting

Submission 13:
Enhance USP's Quality Systems

Summary:

USP is encouraged to continuously improve its Quality Systems to ensure that USP standards are right-first-time. This will not only ensure quality, but will also build stakeholder trust in USP and its standards. Part of enhancing USP's Quality Systems is ensuring appropriate communication and transparency. Robust public review and publication processes and two-way communication are essential to reviewing and resolving feedback from stakeholders, and publishing correct information.

Statement of the Challenge:

Addresses issues with incorrect/erroneous USP standards as well as those that contain publication errors, and those that need to be published multiple times and in multiple ways to correct these problems. Also addresses transparency of these processes to ensure all changes to USP standards are visible and available to stakeholders. This is especially important with USP online changes, which although they can be made in a timely manner, these changes still need to be transparent to stakeholders.

Desired Outcome:

The goal is to ensure an error-free USP that instills confidence in the product and USP itself. When errors need to be corrected, or stakeholders' issues need to be addressed, all changes would need to be transparent to stakeholders.

Resolution Alignment

How does the proposal align with USP's mission and vision?

This is directly related to USP's mission to ensure the quality of medicines.

Which of the three essential components of "Standards", "Advocacy", and "Capability Building" does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why:

This is directly related to building trust in USP standards, and ensuring the integrity of USP standards. This resolution supports Standards and Advocacy in that it will "build trust in USP standard" and "establish a culture of accountability and continuous improvement where the bar for quality is set higher for ourselves".

200 years of building trust

Submission 14

USP Standards Quality

Resolution Proposal Submissions

200 usp The standard of trust | Convention The 2020 Meeting

Submission 14:
USP Standards Quality

Summary:

USP will continue strengthening its quality systems to ensure the timely and accurate delivery of public standards. USP will maintain and strengthen its commitment to implementing a fully integrated, global approach to quality and will monitor its progress against clearly specified metrics and objectives to achieve continuous improvement as measured by USP performance.

1. Council of Experts and associated groups: USP commits to fostering more cross-functional collaboration for greater consistency across expert body deliberations to improve the management of chapter/monograph dependencies and avoid conflicting requirements
2. Revision process and standards quality:
   a. High impact revisions: USP commits to timelier stakeholder dialog and to expanding its communication and outreach about proposed changes beyond the PF route.
   b. Early and throughout the standards development process, USP will consider implementation challenges that industry will face, and will consider flexible timing for the introduction of new or significantly changed requirements.
   c. Revision process: USP will assure that the quality of the commentary is consistently reflective of the revision input received.

Statement of the Challenge:

Despite improvements in the 2015–2020 Revision Cycle, there is a continuing need for USP to improve and adapt its processes and quality systems to stay abreast of stakeholder needs.

Desired Outcome:

Ensure the timely and accurate delivery of public standards.

Resolution Alignment

How does the proposal align with USP's mission and vision?

USP's core mandate is to create standards that support global public health. This resolution proposal is a re-commitment to Resolution IV from the 2015 Convention that speaks to USP's Quality Systems. It expands upon this by including a more proactive and more generally interactive stakeholder dialog during the standards development process.

Which of the three essential components of "Standards", "Advocacy", and "Capability Building" does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why:

Standards and capability building. This proposed resolution maps to the 2020 Resolution Concept "Culture of Quality".

200 years of building trust

Submission 15

Global Health Impact

Resolution Proposal Submissions

200 usp The standard of trust | Convention The 2020 Meeting

Submission 15:
Global Health Impact

Summary:

USP will work with regulators around the world to combat counterfeit, falsified, and substandard medicines to secure the global supply chain of life-saving medicines.

Statement of the Challenge:

To effectively combat global public health issues, USP has to effectively work with regulators, industry, and other pharmacopeias around the world to advance innovative solutions to unmet medicines quality needs.

Desired Outcome:

Increased medicines quality and availability in the global supply chain.

Resolution Alignment

How does the proposal align with USP's mission and vision?

USP's core mandate is to create standards that support global public health. This resolution is a recommitment and update to Resolution XI of the 2015 Convention — Global Health Impact. It sharpens the focus on combating counterfeit, falsified, and substandard medicines, an area where compendial standards can most effectively support the global stakeholder community.

Which of the three essential components of "Standards", "Advocacy", and "Capability Building" does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why:

Standards and Advocacy. This proposed resolution maps to the 2020 Resolution Concept "Regulatory Systems Strengthening".

200 years of building trust

Submission 16

Polypharmacy and Medication Use in the Elderly

Resolution Proposal Submissions

200 usp The standard of trust

Convention The 2020 Meeting

Submission 16:

Polypharmacy and Medication Use in the Elderly

Summary:

The USP should address the problem of “Polypharmacy.” The elderly population in the United States is growing. Medication use in this age group is quite high. The USP should develop criteria on how medications should be used and monitored in elderly patients. In addition, all monographs should include specific information on using medications in the elderly.

Statement of the Challenge:

The USP should adopt specific standards regarding medication utilization in elderly patients. These standards must address the "polypharmacy" problem. Unfortunately many older medications (e.g. digoxin) can be a problem in the elderly. Considerations must be addressed regarding polypharmacy and use i in the elderly for these older medications. Older monographs must be edited to include a "Use in the Elderly" section.

Desired Outcome:

By listing specific criteria regarding polypharmacy and medication use in the elderly, the USP can be at the forefront in combating the polypharmacy problem.

Resolution Alignment

How does the proposal align with USP’s mission and vision?

The USP's mission is to "improve global health through public standards" related to medication use. Polypharmacy (especially in elderly patients) is a major issue today and this problem will be much greater as our elderly population grows. By addressing this problem now, the USP can be at the forefront in helping this growing age group.

Which of the three essential components of “Standards”, “Advocacy”, and “Capability Building” does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why:

The polypharmacy issue is directly related to the USP’s “Advocacy” component. The “Advocacy” section includes a desire to provide “quality medication use.” Besides the “quality” of the medication being used, the USP should advance recommendations on the quality of how specific medications are used in various age groups. By combatting “polypharmacy” in the elderly the USP can improve the quality of medication utilized in our aging population.

200 years of building trust

Submission 17

Quality Standards for Dietary Supplements and Their Ingredients

Resolution Proposal Submissions

200 usp The standard of trust

Convention
The 2020 Meeting

Submission 17:

Quality Standards for Dietary Supplements and Their Ingredients

Summary:

USP will ensure alignment of the standards for dietary supplements and ingredients with US FDA regulations and guidance. Dietary supplement regulations currently include both dietary ingredients and non-dietary ingredients.

Statement of the Challenge:

The *USP–NF* standards, policies, and USP Verification Services programs are not currently aligned with all dietary supplement regulations and guidance as outlined in DSHEA and FSMA.

Desired Outcome:

USP–NF and *FCC* standards will be fully aligned with U.S. FDA regulations and requirements for dietary supplements and ingredients. This will ensure USP standards for non-dietary ingredients in dietary supplements are aligned with FDA food compliance requirements.

Resolution Alignment

How does the proposal align with USP's mission and vision?

This resolution will ensure that the quality and safety of non-dietary ingredients in dietary supplements meet and support the appropriate food standards as established by the FDA. Additionally, it will ensure consumers have access to high quality, safe, and beneficial foods and dietary supplements.

Which of the three essential components of "Standards", "Advocacy", and "Capability Building" does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why:

This resolution will bring the *USP–NF* standards into alignment with FDA regulations and requirements for food. Additionally, it will enhance the collaboration among the USP, FDA, and stakeholders on dietary supplement matters. This Resolution supports "Capability Building" from the USP 2025 strategy by enabling collaboration between the USP and Regulatory authorities through the development of appropriate standards for dietary supplements.

200 years of building trust

Submission 18

Develop a Framework for Non-Standard Excipient Monographs

Resolution Proposal Submissions

200 usp The standard of trust | Convention The 2020 Meeting

Submission 18:

Develop a Framework for Non-Standard Excipient Monographs

Summary:

USP will collaborate with industry and regulatory stakeholders to develop a framework for addressing ingredients and/or technologies that are typically not covered by current USP processes.

Statement of the Challenge:

No process currently exists for proactively developing and establishing standards for materials where a regulatory pathway has not been established. Some examples might include Atypical Actives, Novel Excipients, 3D Printing and Combination Products.

Desired Outcome:

For USP to partner with FDA to develop a process for the development of standards and regulations for materials currently excluded from the regulatory process.

Resolution Alignment

How does the proposal align with USP's mission and vision?

This Resolution would enable USP to take a proactive approach in creating standards that ensure quality and safety for innovative products.

Which of the three essential components of "Standards", "Advocacy", and "Capability Building" does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why:

This Resolution will enhance the collaboration with regulators and stakeholders to ensure standard setting for innovation remains current as new excipients, regulations, and technologies develop. This Resolution supports Capability Building by anticipating the need for standards to support the control of innovative novel excipients and atypical actives.

200 years of building trust

Submission 19

Modern Standards

Resolution Proposal Submissions

200 usp The standard of trust

Convention
The 2020 Meeting

Submission 19:
Modern Standards

Summary:

USP will meet the needs of the U.S. Food and Drug Administration (FDA), industry, and other stakeholders for modern quality standards. USP will work with industry and FDA to explore new strategies for developing and sharing analytical approaches needed to create and maintain modern, relevant standards.

Compendial and Scientific Focus areas:

1. To improve the applicability and relevance of key tests, USP will invest in the development and validation of multi-source or universal procedures to replace methods that favor specific reagents or were provided by a single manufacturer.
2. USP will continue the systematic modernization of key standards that align with FDA's and other stakeholders' needs.
3. USP will explore where USP public standards represent or provide a clear link to patient safety and clinical relevance. USP will further aim to articulate the clinical relevance and applicability of those standards as appropriate.

Reference standard quality and science:

1. USP will invest in the quality and relevance of the USP reference standard portfolio by improving scientific and quality oversight of reference standards development, value assignment, and release.
2. USP will continue to advance reference standard science by utilizing modern measurement and metrology approaches to the development of reference materials whenever possible.

Statement of the Challenge:

Ensure the creation of modern and relevant standards that are at pace with the development of modern medicines and fulfill the needs of all stakeholders.

Desired Outcome:

Ensure the continued relevance and sound science for USP standards.

Resolution Alignment

How does the proposal align with USP's mission and vision?

USP's core mandate is to create standards that support global public health. This resolution is a recommitment and update to Resolution II of the 2015 Convention — *USP–NF* Monograph Modernization. It expands beyond monograph modernization to a more comprehensive and cross-cutting look at modernizing standardization approaches and science.

Which of the three essential components of "Standards", "Advocacy", and "Capability Building" does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why:

Standards and capability building. This proposed resolution maps to the 2020 Resolution Concept "Quality Standards".

200 years of building trust

Submission 20

Collaborate with the U.S. Food and Drug Administration (FDA)

Resolution Proposal Submissions

200 usp The standard of trust | Convention The 2020 Meeting

Submission 20:

Collaborate with the U.S. Food and Drug Administration (FDA)

Summary:

USP resolves to increase collaboration with the FDA throughout the standards development process and involve FDA in the early stages of planning a standards to promote alignment with FDA's regulatory and scientific policies and priorities. USP will seek FDA and industry input prior to and through the development of high impact proposals to clearly understand the regulatory impact of standards proposals, and develop appropriate implementation timelines and training material.

Statement of the Challenge:

High impact new or revised USP standards, implemented without understanding of regulatory implications and assessment of training needs, lead to confusion for *USP* users and pose challenges with compendial compliance. Additionally, a large number of standards proposals, and multiple cycles of proposals for the same standards have placed an enormous burden on limited agency resources.

Desired Outcome:

In requesting adoption of this resolution, FDA asks USP to assess the impact of new requirements and burden to FDA and industry in the prioritization of standards and deciding on implementation timelines. FDA also asks USP to align standards development activities with FDA's policies and regulatory expectations for small molecule human and animal drugs.

Resolution Alignment

How does the proposal align with USP's mission and vision?

The proposal directly aligns with USP's mission to improve global health through public standards that enhance quality of drug products. This proposal augments long-standing USP and FDA collaborative efforts to provide the public with compendial standards that reflect the Agency's approval standards/recommendations, safety concerns, and sound scientific principles.

Which of the three essential components of "Standards", "Advocacy", and "Capability Building" does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why:

The proposed resolution aligns with elements of the "Standards" and "Capacity Building" components in USP 2020 strategy which include effective collaboration with regulators, and, educating industry.

200 years of building trust

Submission 21

Collaboration with U.S. Food and Drug Administration

Resolution Proposal Submissions

200 usp The standard of trust | Convention The 2020 Meeting

Submission 21:

Collaboration with U.S. Food and Drug Administration

Summary:

USP is encouraged to continue its collaboration with the U.S. Food and Drug Administration (FDA) to ensure appropriate standards are developed and adopted with appropriate implementation timeframes that allow for FDA review of the necessary changes to drug applications.

Statement of the Challenge:

Standards that are developed and/or adopted without sufficient FDA input and alignment resulting in stakeholder confusion regarding implementation of the standard and/or the implementation timeframe.

Desired Outcome:

Ensure that appropriate standards with appropriate timeframes are developed and adopted with FDA input and alignment so that stakeholders are able to implement standards by the official implementation date.

Resolution Alignment

How does the proposal align with USP's mission and vision?

Ensures that USP standards actually benefit medicines, and that USP collaborates with all stakeholders, including regulators.

Which of the three essential components of "Standards", "Advocacy", and "Capability Building" does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why:

USP will strengthen its collaboration with regulators to produce standards that will improve the quality of medicine. This resolution supports "Standards" and "Capability Building" to "collaborate with regulators", especially the FDA.

200 years of building trust

Submission 22

Working with US FDA

Resolution Proposal Submissions

200 usp The standard of trust | Convention The 2020 Meeting

Submission 22:
Working with US FDA

Summary:

USP commits to a substantial and meaningful dialog with the FDA that strengthens the complementary roles of both organizations to improve access to high quality medicines.

Key focus areas for this dialog will include:

a. Modernization of standards for high priority generic medicines.

b. Modernization of key general tests to modern expectations (e.g. rapid microbial testing).

c. USP's role and contribution to standardization for biological medicines and the applicability of those standards.

d. Gap analysis and identification of overlap or redundancy, particularly as it relates to biological medicines.

Statement of the Challenge:

Ensure a more seamless and collaborative working relationship between the organizations that recognizes and leverages their respective complementary roles in the overall safety net for medicines quality.

Desired Outcome:

Increased efficiency in the delivery of standards and guidance that support medicines quality and patient safety.

Resolution Alignment

How does the proposal align with USP's mission and vision?

USP's legal mandate is to create the official compendium for the United States. This resolution is a recommitment and update to Resolution I of the 2015 Convention — Collaboration with the U.S. Food and Drug Administration.

Which of the three essential components of "Standards", "Advocacy", and "Capability Building" does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why:

Standards and Advocacy. This proposed resolution maps to the 2020 Resolution Concept "U.S. FDA".

200 years of building trust

Submission 23

Enhanced Process for *USP–NF* Monograph Modernization

Resolution Proposal Submissions

200 usp The standard of trust | Convention The 2020 Meeting

Submission 23:

Enhanced Process for *USP–NF* Monograph Modernization

Summary:

USP is encouraged to continue its collaboration with the U.S. Food and Drug Administration (FDA) to ensure appropriate standards are developed and adopted with appropriate implementation timeframes that allow for FDA review of the necessary changes to drug applications.

Statement of the Challenge:

Standards that are developed and/or adopted without sufficient FDA input and alignment resulting in stakeholder confusion regarding implementation of the standard and/or the implementation timeframe.

Desired Outcome:

Ensure that appropriate standards with appropriate timeframes are developed and adopted with FDA input and alignment so that stakeholders are able to implement standards by the official implementation date.

Resolution Alignment

How does the proposal align with USP's mission and vision?

Ensures that USP standards actually benefit medicines, and that USP collaborates with all stakeholders, including regulators.

Which of the three essential components of "Standards", "Advocacy", and "Capability Building" does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why:

USP will strengthen its collaboration with regulators to produce standards that will improve the quality of medicine. This resolution supports "Standards" and "Capability Building" to "collaborate with regulators", especially the FDA.

200 years of building trust

Submission 24

Become a Global Health Ambassador of WHO for Food Safety, Quality and Integrity

Resolution Proposal Submissions

200 usp The standard of trust | Convention The 2020 Meeting

Submission 24:

Become a Global Health Ambassador of WHO for Food Safety, Quality and Integrity

Summary:

Summary: WHO has just appointed several global health ambassadors. https://mailchi.mp/who.int/new-who-goodwill-ambassadors-for-promoting-health?e=839a3a53f5 USP could serve as a WHO global ambassador for food safety, food quality, and food integrity? Could USP collaborate with this organization via its office in Singapore?

Statement of the Challenge:

Sharing the immense knowledge of USP and the FIEC in particular, across the world will reduce the risk of food fraud and improve food safety, quality, and integrity. The World Health Organization, by its charter is responsible for improving the health of all. By incorporating the expertise of USP's FIEC this charter can be advanced.

Desired Outcome:

Share the USP's FIEC expertise globally via a WHO ambassadorship, properly titled.

Resolution Alignment

How does the proposal align with USP's mission and vision?

Global Health

Which of the three essential components of "Standards", "Advocacy", and "Capability Building" does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why:

Standards and Advocacy

200 years of building trust

Submission 25

Harmonizing US Standards for Food Safety and Quality

Resolution Proposal Submissions

200 usp The standard of trust | Convention The 2020 Meeting

Submission 25:
Harmonizing US Standards for Food Safety and Quality

Summary:

Reduce the overwhelming workloads in the USFDA, USDA and 5 other federal agencies that have responsibility for Food safety by providing harmonized specifications and testing protocols for food and dietary supplement additives and ingredients.

Statement of the Challenge:

While progress has been made in harmonization among U.S. food safety organizations, they are still overwhelmed with respect to the identity, quality, and safety of ingredients and additives in foods and dietary supplements. By supplying harmonized specifications and testing protocols, *FCC* can reduce that workload, enhance safety for consumers and reduce burdens on manufacturers providing providing additives and ingredients for products regulated by different agencies.

Desired Outcome:

Harmonized specifications for food and dietary supplement additives and ingredients across US food regulatory bodies.

Resolution Alignment

How does the proposal align with USP's mission and vision?

Lead in Harmonizing US Standards for Food Safety and Quality Through Specifications and Testing Protocols for Food Ingredients and Additives Aligns directly with USP's Mission: To improve global health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods and Vision: USP envisions a world in which all have access to high quality, safe, and beneficial medicines and foods.

Which of the three essential components of "Standards", "Advocacy", and "Capability Building" does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why:

Standards. The whole focus of this resolution is Standards that impact foodmsafety.

200 years of building trust

Submission 26

Communication Between FIEC and Key International Organizations

Resolution Proposal Submissions

200 usp The standard of trust | Convention The 2020 Meeting

Submission 26:

Communication Between FIEC and Key International Organizations

Summary:

Key individuals of key national and international organizations will be communicated with on the merits and importance of *FCC* and the specifications and methods contained therein.

Statement of the Challenge:

The *FCC* is not as familiar to national and international organizations of relevance to food quality and integrity. By networking on the FIEC members' personal contacts, a collaborative network amongst key parties can be established with FAO/WHO and EFSA, Health Canada (Ottawa), the Mexican Bureau of Standards, the State Food and Drug Administration of China, and Japan's Ministry of Health, Labor and Welfare. FIEC members can be key to making this happen.

Desired Outcome:

Establishment of a network of individuals relevant to the food and dietary supplement quality and integrity efforts across a broad international base to encourage full utilization of the *FCC*.

Resolution Alignment

How does the proposal align with USP's mission and vision?

The resolution promotes USP's mission and vison by strengthening the connection among the various national and international regulators and organizations that set standards, methods and specifications for food and food ingredients. By doing this, organizations will have a clearer picture of what USP does and the value of the *FCC*.

Which of the three essential components of "Standards", "Advocacy", and "Capability Building" does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why:

By promoting collaborations with regulators and other standard-setting organizations, this resolution supports the capability building component of USP's 2025 Strategy. This will in turn increase the visibility of USP and its contributions to the food industry. In connecting with these key, leading experts in government agencies and NGOs, USP can increase the profile of *FCC* and the value it has in promoting food safety, integrity and quality.

200 years of building trust

Submission 27

USP Global Health Impact via Food Quality and Integrity

Resolution Proposal Submissions

2020 usp The standard of trust | Convention The 2020 Meeting

Submission 27:

USP Global Health Impact via Food Quality and Integrity

Summary:

Build bridges with key international partners regarding food quality and integrity.

Statement of the Challenge:

There is a lack of international harmonization in combating food fraud and adulteration. When harmonization of standards exist, the opportunities for rogue operators to take advantage of differences in standards is eliminated.

Desired Outcome:

Reducing the risk of food fraud and consequent threats to public health.

Resolution Alignment

How does the proposal align with USP's mission and vision?

USP is committed to global health through public standards that contribute to the safety and quality of foods and their ingredients. This proposed resolution reinforces these attributes on an international basis through the collaboration of like-minded organizations and agencies. Those organizations include the International Union of Food Science and Technology and its Academy of esteemed fellows committed to the global safety of foods and consistent communication of their safety and health benefits. Another exceptional potential partnership is the international food safety program, particularly the National Center for Food Protection & Defense at University of Minnesota. This expertise from these kinds of organizations and institutions includes comprehensive understanding safety and health from crop to cell...impacting the health of the global community through critical agricultural management, food processing, and health delivery through safe foods.

Which of the three essential components of "Standards", "Advocacy", and "Capability Building" does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why:

The fundamentals of the USP 2025 strategy are standards, capability building and advocacy. This proposed resolution advocates international harmonization of food quality and integrity, which, in turn, would elevate USP's position as a global leader in food and food ingredient quality. This global leadership is critical as food and food ingredients are international, and their safety, nutritional value, availability and affordability are key factors in having a significant impact on health. The global food supply chain is complex. The digitization of that supply chain and the implementation of the Food Safety Modernization Act are critical, proactive food safety efforts to assure all aspects of foods and food ingredients meet emerging standards. USP, in collaboration with other domestic and international like-minded organizations can develop and promote positions and policies directed to mitigate efforts intended disrupt the food supply chain. We are reminded that Hippocrates is attributed to "Let food be thy medicine, and medicine be thy food" is the emerging path of the food and dietary supplements industries. Research, Communication and Innovation are critical and foundational modalities to assure food safety, public health and common sense policies. Thus, it remains critical for USP to have a greater impact in food quality and its safety while leveraging tools designed to disrupt the food supply system.

200 years of building trust

Submission 28

Alignment and Streamlining Processes–CODEX and FDA

Resolution Proposal Submissions

200 usp The standard of trust | Convention The 2020 Meeting

Submission 28:

Alignment and Streamlining Processes–CODEX and FDA

Summary:

USP will better align *Food Chemicals Codex* (*FCC*) standards for food additives with Codex Standards, food standards outlined in Chapter 1, Title 21 of the U.S. Code of Federal Regulations (CFR) and/or other globally accepted standards developed by scientific and regulatory authorities.

Statement of the Challenge:

Currently, not all *FCC* monographs and *FCC* General Chapters are aligned with existing standards laid out by the Joint FAO/WHO Food Standards Programme (i.e., Codex Alimentarius) and/or set forth in regulation by the U.S. Food and Drug Administration (FDA) and other globally recognized food additive standards. Given the global nature of the food additive industry, lack of alignment could inadvertently create barriers to entry and marketing restrictions in international markets.

Desired Outcome:

USP will align *FCC* monographs and applicable General Chapters with Codex and other globally-accepted standards developed by scientific and regulatory authorities (e.g., Joint FAO/WHO Expert Committee on Food Additives, U.S. FDA, European Food Safety Authority, Food Standards Australia New Zealand).

Resolution Alignment

How does the proposal align with USP's mission and vision?

This resolution will ensure *FCC* monographs align with Codex standards and/or U.S. FDA requirements, which manufacturers turn to for guidance and to ensure compliance with relevant regulations, in order to "improve global health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods" are met.

Which of the three essential components of "Standards", "Advocacy", and "Capability Building" does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why:

This Resolution addresses both "Standards" to align with Codex and U.S. FDA, a request to remain up-to-date as standards evolve, and adopt a more flexible and interactive approach to standards development. The resolution also addresses "Capacity Building" for firms or stakeholders to more easily use USP standards, continue collaboration with regulators, and continue to educate industry on quality.

The USP strategy includes "modernized standards" and "increasingly global and connected staff." Alignment of *FCC* standards with Codex and/or U.S. FDA ensures the functional equivalency of those standards, thereby supporting manufacturers' ability to comply with the standards while improving consumer understanding. As most manufacturers monitor and follow Codex, USP can continue its "global" presence and relevance to the food and food additive industries only if it is aligned with Codex and/or U.S. FDA.

200 years of building trust

Submission 29

Beyond-Use Date Guidance

Resolution Proposal Submissions

200 usp The standard of trust

Convention The 2020 Meeting

Submission 29:
Beyond-Use Date Guidance

Summary:

USP should work proactively to create an Informational General Chapter to provide consistent interpretations of scientific rationale that compounders can utilize to extend beyond use dates on compounded sterile and nonsterile products (CSP and CNSP). A separate Informational General Chapter would improve global health, as stated in USP's mission, as it would help maintain a safe supply of CSPs and CNSPs for patients who have benefited from compounded medications.

Statement of the Challenge:

USP finalized Chapters and but did not provide resources allowing compounders to extend BUDs for CSPs, thereby impeding patient access to medically necessary compounded products.

Desired Outcome:

Increased patient access to safe compounded preparations.

Resolution Alignment

How does the proposal align with USP's mission and vision?

USP's mission and vision is to improve global health and to use science-based standards to achieve that goal. By creating a separate chapter for BUDs, USP will be able to further the availability of safe compounded products by providing specific thresholds for compounders to meet when extending BUDs.

Which of the three essential components of "Standards", "Advocacy", and "Capability Building" does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why:

One of USP's missions, capability building, is to equip stakeholders to use their standards. By creating a resource to allow compounders to extend BUDs, USP will be furthering its goal to engage with practitioners to further patient access.

200 years of building trust

Submission 30

CSTD Protocol to Evaluate Beyond-Use Date Extension

Resolution Proposal Submissions

200 usp The standard of trust | Convention The 2020 Meeting

Submission 30:

CSTD Protocol to Evaluate Beyond-Use Date Extension

Summary:

A 2016 study estimated that the U.S. may spend close to $2 billion on oncology drug products that are discarded because they come in single-dose vials in which the volume of drug product exceeds what is needed for most doses. A growing number of studies have generated data that indicate specific closed-system transfer devices (CSTDs) may of maintain sterility and allow extension of in-use time when used under sterile conditions defined by United States Pharmacopeia Chapter.

Statement of the Challenge:

In 2018, ASHP passed a policy statement to foster additional research on and develop standards and best practices for use of CSTDs for this practice, known as drug-vial optimization (DVO). Published data are from studies performed in various pharmacies around the country. However, these studies have evaluated the practice using a specific CSTD under conditions specific to each site. The variability in sites and practices and small study sizes have limited the acceptance and adoption of DVO.

Desired Outcome:

The desired outcome of this Resolution is to address the variability in published data by developing a uniform protocol designed to test the ability of all CSTDs to prevent microbial ingress and extend the in-use time of single-dose vials. The development of a standard for use of CSTDs in extending beyond-use dates should also be considered.

Resolution Alignment

How does the proposal align with USP's mission and vision?

This Resolution aligns with USP's mission and vision of improving global health by ensuring access to high quality and safe medications. The developed standard will ensure compounded sterile preparations made using the practice of DVO are safe from microbial contamination. Preventing waste helps reduce drug costs and can improve patient access to medications.

Which of the three essential components of "Standards", "Advocacy", and "Capability Building" does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why:

This Resolution advances USP's priorities in the "Standards" component of its 2025 strategy. By developing a standard protocol addressing the practice of DVO, USP will ensure its compounding standards remain up to date and support innovative techniques. This resolution also supports the "Capability Building" component of USP's 2025 strategy by facilitating the adoption of new compounding technologies and engaging practitioners and professional organizations.

200 years of building trust

Submission 31

Technology-Assisted Workflows in Compounded Preparations

Resolution Proposal Submissions

200 usp The standard of trust | Convention The 2020 Meeting

Submission 31:

Technology-Assisted Workflows in Compounded Preparations

Summary:

USP compounding chapters offer a framework of administrative and engineering controls to ensure the safety and quality of compounded preparations. The chapters do not address technology that can prevent incorrect ingredients from being used on compounded preparations. Despite available technologies, wrong-ingredient errors continue to occur and cause harm. Both Pew and the Institute for Safe Medication Practices (ISMP) have reported wrong-ingredient errors.

Statement of the Challenge:

The current versions of General Chapters and do not adequately address verification of ingredient selection and measurement, stating "The CSP must be visually inspected to confirm that the CSP and its labeling match the prescription or medication order." As reported by Pew and ISMP and addressed in ASHP policy, visual inspection of physical appearance is not adequate to prevent and stop compounding errors. This resolution addresses potential compounding errors.

Desired Outcome:

The desired outcome of this resolution are:

1. The formation of an expert committee or expert panel to evaluate best practices related to technology-assisted workflows and establish standards for their use.
2. Incorporation of the established standards in compounding chapters, and any other relevant compounding chapter.

Resolution Alignment

How does the proposal align with USP's mission and vision?

This Resolution aligns with USP's mission and vision of improving global health by ensuring access to high quality and safe medications. Technology-assisted workflows in compounding have demonstrated reduced error rates which improves patient access to safe compounded preparations.

Which of the three essential components of "Standards", "Advocacy", and "Capability Building" does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why:

This Resolution advances USP's priorities in the "Standards" component of its 2025 strategy. By addressing the technology-assisted workflows, USP will ensure its compounding standards remain up to date and support innovative technologies. This resolution also supports the "Capability Building" component of USP's 2025 strategy by facilitating the adoption of new compounding technologies and engaging practitioners and professional organizations.

200 years of building trust

Submission 32

Documentation of Lot Numbers and Expiration Dates for all CSPs

Resolution Proposal Submissions

200 usp The standard of trust | Convention The 2020 Meeting

Submission 32:

Documentation of Lot Numbers and Expiration Dates for all CSPs

Summary:

2018 *USP* <797> requires that "Compounding Records must include...vendor, lot number, and expiration date for each component for CSPs prepared for more than 1 patient, and for CSPs prepared from nonsterile ingredient(s), and for each component of Individual Allergenic Extract Prescription Sets." We argue that whatever rationale applies for requirements in these later categories should apply equally to CSPs for individual patients.

This Resolution requests that USP extend standards and requirements for documenting component lot numbers and expiration dates to all compounded sterile preparations.

Statement of the Challenge:

Presumably, exempting individual patient CSPs from the requirement to document each component's lot numbers and expiration dates was made in the interest of efficiency. However, we argue that quality and safety are of greater importance than efficiency. The need for identifying and responding to recalls and outdates is as critical for ingredients in individual CSPs as for batch preparations and preparations with nonsterile components and allergenic extracts.

Desired Outcome:

That USP would continue to improve quality by extending the same documentation requirements of component lot numbers and expiration dates used for compounding all individual patient CSPs as it currently requires for batch preparations and individual CSPs that utilize non-sterile components and allergenic extracts.

Resolution Alignment

How does the proposal align with USP's mission and vision?

USP's Mission is "to ensure the quality, safety, and benefit of medicines."

Compounding with expired and/or recalled components compromises USPs quality and safety standards.

Prospectively, requiring documentation of component expiration dates serves as a forcing function that will promote compounders' faithfulness in verifying that the components they are about to use have indeed not expired.

Retrospectively, aggregated lot number and expiration data may be parsed for quality improvement to identify where/how things go wrong, enabling providers to "rethink their delivery of care." This is analogous to the airline industry utilizing black-box data to rethink and improve its delivery of safe aviation. Without documentation, essential data does not exist.

Our Resolution furthers USP's commitment to "Establish a culture of accountability, continuous improvement, and setting a higher bar."

years of building trust

Submission 33

Hazardous Drug Environmental Monitoring General Chapter

Resolution Proposal Submissions

200 usp The standard of trust | Convention The 2020 Meeting

Submission 33:

Hazardous Drug Environmental Monitoring General Chapter

Summary:

This Resolution is to create an informational chapter modeled after but focused on hazardous drug (HD) environmental monitoring and control. General Chapter Section 6 describes environmental quality and control as a component of safe handling of HDs, however it is lacking in the information, detail, and recommendations required to establish an effective HD environmental monitoring program. This proposed chapter would provide those details to the healthcare community.

Statement of the Challenge:

This Resolution is intended to address the challenge of establishing an effective HD environmental monitoring program for controlled HD aseptic processing environments. This will help facilities with monitoring the effectiveness of controls in place to reduce exposure of healthcare workers, patients, and others to HDs.

Desired Outcome:

The desired outcome of this resolution is the development of a new informational general chapter for hazardous drug contamination monitoring of aseptic processing environments.

Resolution Alignment

How does the proposal align with USP's mission and vision?

This proposal aligned with USP's mission and vision because it seeks to develop a standard to improve the quality medicines prepared in hazardous drug (HD) aseptic processing environments and improve global health overall. This new proposed informational chapter would build upon the standards outlined in USP and incorporate the concepts of general chapter related to establishing a state of control and ongoing monitoring of the aseptic processing environment. Development of such a chapter enhances the vision of USP to ensure high quality and safe medicines. A controlled environment where HD contamination is monitored and minimized helps to ensure that adulterated or contaminated medicines are not reaching patients. In the FDA guidance on insanitary conditions, cross contamination with highly potent or hazardous drugs is identified as an insanitary condition that may cause patient harm. This informational chapter will assist in high production that without such an insanitary condition.

Which of the three essential components of "Standards", "Advocacy", and "Capability Building" does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why:

This proposed Resolution supports the "Standards" component of the USP 2025 Strategy. Development of a standard for HD contamination environmental monitoring in aseptic processing environments will ensure that USP is up to date with technology for detection and quantification of contamination. It will also allow USP to inform users on the appropriate processes for an effective environmental monitoring program, building off of the capabilities established by USP in the most recent cycle (2015-2020) with revisions to USP and the release of USP. Additionally, this standard may incorporate new technologies available after the release of which may provide additional safety and quality for handling of HDs.

An informational chapter on HD contamination environmental monitoring would also allow USP to expand in the "Capability Building" component of its strategy. This chapter, if developed, could serve as the basis for educational programs and content for healthcare workers handling HDs. As is stated in there are no standards for acceptable limits of HD surface contamination and there are no studies demonstrating the effectiveness of a specific number or size of wipe samples in determining levels of HD contamination. A chapter such as this would establish informational standards that could serve as the basis of design for studies to address these gaps in knowledge. This would engage practitioners in ensuring compliance with USP and monitoring the effectiveness of the controls established in that chapter. It may also facilitate the adoption of new technologies aimed at detection of HD surface contamination for a more broad array of drugs, including gas chromatography (GC), high-performance liquid chromatography (HPLC), ultra high-performance liquid chromatography (UHPLC) in combination with mass spectrometry (MS) or tandem mass spectrometry (MS/MS) LC-MS/MS, and lateral flow immunoassay (LFIA). USP will be able to also address the "Advocacy" Strategy by developing and assembling evidence to support this standard which may also support FDA with insanitary conditions determinations among other interpretive guidelines.

200 years of building trust

Submission 34

Veterinary-Specific Standards for Compounds

Resolution Proposal Submissions

2020 usp The standard of trust | Convention The 2020 Meeting

Submission 34:
Veterinary-Specific Standards for Compounds

Summary:

The standards in *USP* GC <795> and *USP* GC <797> were developed to ensure quality in compounded products. However, such standards for animals must be developed with deliberate consideration for the unique needs of veterinary patients. Veterinarians care for an incredibly species- and type-diverse population, formulate for patient use within veterinarian-client-patient relationships, and practice in a wide range of settings (e.g., hospitals, mobile practices, farms, racetracks, zoos/aquaria).

Statement of the Challenge:

USP GC <795> and *USP* GC <797> are based on assumptions applicable to compounding for humans and practices that cannot all be translationally applied to veterinary patients. Among other considerations, veterinary care is unique in that patients are considered to be property, have a market value, and can be consumed as food. With this resolution, in addition to ensuring quality, the authors' perspective would include attention to the unique attributes of veterinary medical care.

Desired Outcome:

The AVMA seeks the development of comprehensive standards for compounding activities for animal patients that are conducted by veterinarians within the context of a veterinarian-client-patient relationship and that can be practically implemented by practitioners in a variety of veterinary practice settings. While ensuring quality in compounded products, we simultaneously seek to avoid unintended economic impacts that would compromise accessibility of quality medications for animal patients.

Resolution Alignment

How does the proposal align with USP's mission and vision?

The USP Mission indicates a commitment to "ensure the quality, safety and benefit of medicines and food." This resolution to develop veterinary-specific compounding Standards would result in more patients benefitting from quality medications provided by veterinarians. Currently, when veterinary practitioners are required to comply with the existing provisions of *USP* <795> and <797>, the needs of veterinary patients will not be met because the diversity of veterinary practice settings within which veterinary care (including necessary compounding) is delivered have not been adequately considered. Development of veterinary-specific compounding standards applied to the medical management of food animal patients would also support USP's effort to ensure the quality, safety, and benefit of food intended for humans.

The USP Vision indicates that USP is committed to "working collaboratively with key stakeholders across the globe." While it comes together as a profession, the veterinary community includes multiple stakeholders because veterinary practitioners providing services for particular species and/or types of animals face novel challenges when working to ensure access to safe and efficacious compounded products for their patients. Accordingly, the development of a veterinary-specific compounding chapter that appropriately and adequately addresses the challenges unique to particular practice types, as well as those challenges faced by the profession as a whole, would make great strides in

support of USP's efforts to build relationships with key stakeholders. With respect to the geographic distribution of stakeholders, it is worth noting that veterinarians are also considered public health officials because they are often the frontline observers detecting public health threats at both domestic and international levels. Actively engaging the veterinary community further aligns USP and relevant stakeholders in support of better animal and public health globally.

Which of the three essential components of "Standards", "Advocacy", and "Capability Building" does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why:

Under Advocacy within its strategic plan, the USP has indicated that, "Access to quality medicines is essential for addressing the world's top public health priorities, yet all too frequently these priorities get overlooked because (of) policy reform..." Currently, the policy that requires application of USP GC <795> and USP GC <797> to veterinary practitioners presents an unnecessary obstacle in ensuring veterinary patients' access to quality medicines. The veterinary profession applauds the USP for the progress it has made toward its goal of creating standards that guide the formulation of high-quality products. However, additional work is necessary to ensure that USP guidance appropriately and realistically meets the needs of veterinary patients and veterinary practitioners. USP has also indicated its intention to develop "evidence-based" standards "to support the case for quality." The AVMA recognizes and echoes the importance of creating evidence-based standards so that practitioners can be confident that when they follow those standards the result will be high-quality medications. We also believe it important that those same standards be evaluated and substantiated with respect to whether they are practically achievable and to assure that the actions needed to implement them deliver the appropriate return-on-investment.

Under "Capacity Building" within its strategic plan, the USP has indicated that it wishes to become "a leading provider of training and other services to manufacturers, government agencies, and other interested stakeholders." While we recognize the expertise of the individuals traditionally tapped by the USP to create its guidance and deliver associated training, it is critical that both guidance and training be audience- and situation-appropriate. Correspondingly, a veterinary-specific compounding chapter that includes contributions from boots-on-the-ground practitioners from across the veterinary profession is likely to be better understood, with greater potential to proactively consider and creatively address any barriers to implementation and be more enthusiastically embraced by veterinarians. The USP has also indicated that it will "meet stakeholders where they are in their quality journey and help them move towards a shared vision for quality medicines." The AVMA shares this goal of continual improvement and we believe the creation of a veterinary-specific compounding chapter will best bridge the gap between the USP's current approach to ensuring safe and efficacious compounded products and the practical implementation of quality control standards by veterinary practitioners.

200 years of building trust

Submission 35

Use of Workflow Management Systems During Compounding

Resolution Proposal Submissions

200 usp The standard of trust | Convention The 2020 Meeting

Submission 35:

Use of Workflow Management Systems During Compounding

Summary:

Because compounded preparations (CP) quality necessitates sterility and accuracy, this Resolution calls on USP to address accuracy with the same attention and expertise as it has sterility by articulating "requirements that must be followed to minimize harm, including death, which could result from... 3) variability from the intended strength of the correct ingredients."

Specifically, we ask USP to define standards and requirements for independent in-process verification measures that include the use of workflow management systems (WMS) to ensure CP accuracy.

Statement of the Challenge:

1 in 9 compounded sterile preparations may involve errors (e.g., wrong ingredients and/or volumes, etc.); too many of which cause patient harm and death. CP processes are subject to human error (e.g. inattentional blindness, distractions, confirmation bias, etc.), and to high-risk methods employed in pharmacists checking technicians' work (e.g., syringe pullback method, etc.). While confirming preparations with two sets of eyes is better than with one, the person checking another's work can miss errors as easily as the person who made them. This is not unlike documents being proofread by multiple people and all parties miss some of the same errors. WMS technologies detect and intercept errors that humans alone may make and fail to catch, making it harder for CP personnel to get things wrong and easier to get things right.

USP has not articulated requirements for accuracy to the extent it has for sterility. It has neither required independent in-process ingredient/volume verification nor WMS the CP production.

Though WMS have been shown to minimize CP errors, adoption of these systems is sluggish and is utilized for a limited percentage of preparations in hospitals that have them installed, . Universal adoption and utilization of these patient-safety tools is unlikely unless/until they are required by USP standards.

As evidenced by slow adoption of CP sterility practices by pharmacists prior to USP's current Chapter<797>, we need a similar stimulus from USP that requires compounding parties to adopt modern workflow verification methods to ensure CPs are made accurately.

Desired Outcome:

That USP leadership would commission an expert committee in the Healthcare Quality and Safety Collaborative group to address CP accuracy. Experts would be charged with developing standards and requirements that articulate CP product/volume verification steps for ensuring there is no "variability from the intended strength of the correct ingredients" ordered and expect compounding personnel to utilize WMS. It is expected that said requirements will result in "reducing harm, including death to patients." It can be demonstrated that the use of such systems would have prevented past sentinel events (e.g., Emily Jerry, Loretta McPhearson, Corpus Christi infants receiving Heparin overdoses, to name few).

Resolution Alignment

How does the proposal align with USP's mission and vision?

Phrases in quotes below are from "USP 2025 Strategy."

Under "Our Mission," USP articulates its overarching commitment "to ensure the quality, safety, and benefit of medicines." (This Resolution focuses on the first two, quality and safety.)

As its Mission statement becomes more granular, USP commits to remain "Disruptors in the Healthcare Space" encouraging the, 1. "Digitalization of healthcare" and promotion of 2. "Innovative manufacturing technologies."

1. "Digitization of Healthcare: Increasing access to big data and digital health frameworks challenges stakeholders to re-think their patient engagement and delivery of care."

WMS proposed in this Resolution are *digitalized* workflow systems—technologies that guide compounders step-by-step through CP recipes, forcing the use of technology-assisted ingredient-and-volume verification tools, while digitally autodocumenting each step.

Aggregated WMS data may be parsed for quality improvement to identify where/how things go wrong, enabling providers to "rethink their delivery of care." This is analogous to the airline industry utilizing black-box data to rethink and improve their delivery of safe aviation.

2. "Innovative manufacturing technologies: Powerful, potentially disruptive, analytical technologies (see above) and production methods."

Unlike manufacturers, healthcare providers are not required to comply with cGMPs to safeguard CP processes, nor do they do this voluntarily. Seminal research involving a five-hospital observational study on the accuracy of preparing small and large volume injectables, chemotherapy solutions, and parenteral nutrition showed a mean error rate of 9%, meaning almost 1 in 10 products was prepared incorrectly prior to dispensing.

A five-hospital observational study on the accuracy of preparing small and large volume injectables, chemotherapy solutions, and parenteral nutrition showed a mean error rate of 9%, meaning almost 1 in 10 products was prepared incorrectly prior to dispensing.

WMS have been proven to "powerfully disrupt" unsafe CP production methods and actually move compounding practices closer to conventional manufacturing practices. Data from the most widely utilized CP WMS have demonstrated an error-interception rate of 4.9% (through Feb 2019, 7.1MM errors were intercepted out of 142.4MM CPs). The most repeated intercepts involved wrong ingredients and/or volumes, preventing what may have harmed patients or caused death. Some WMS users have shown even better results. One study concluded that the use of WMS in CP was associated with the detection (interception) of 14 times more errors than systems not assisted with the technology and also led to faster preparation times and lower preparation costs.

Ideally, all CPs ordered by prescribers and administered to patients would be conventionally manufactured in cGMP facilities and arrive at points of administration without having been manipulated. Such products are the most likely to be sterile and contain "the intended strength(s) of the correct ingredients."

While dispensing and administering ready-for-use cGMP-produced CPs whenever possible may be wise, preparing CPs in healthcare settings is not going away. It is more likely to increase as a plethora of new drugs comes to market. Also, given the potential for more personalized dosing (based on increased genomic and outcomes data) we may expect CP production in healthcare and compounding facilities to increase moving forward.

In support of USP's stated intent, WMS introduces "innovative production technologies" to CP practices.

While WMS are neither suggested nor required in 2019 <797>, the Chapter's glossary includes "Workflow Management Systems (WMS)" and defines it as "Technology comprised of hardware and software that allows for automation to assist in the verification of components of, and preparation of, CSPs and to document components and processes."

Before requiring compounding personnel to use the "innovative production technologies," USP experts must articulate minimal specifications (features and functions) that said WMS systems *shall* possess. These systems must include but not limited to:

A. CP workflow management software, on screens, in prep areas, that includes: Order queuing, "recipe" checklists, and autodocumenting of each step.

B. Bar-code scanning—verifying ingredient and diluent identities.

C. Volume verification—using one or more of the following tools as appropriate for given orders:
   1) Image capture or live video—for requiring a second set of physical eyes to review.
   2) Optical recognition—using technological eyes to auto-verify syringe draws.
   3) Gravimetrics—using balances.
   4) Flow-metrics—using technologies that automatically release, measure, and verify completed volumes.

D. Final patient and/or product-specific bar-code label production (or) verification and activation of process labels *only after all previous steps have been accurately completed.*

E. Concurrent autodocumentation of each preparation step.

Which of the three essential components of "Standards", "Advocacy", and "Capability Building" does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why:

In regard to "USP 2025 Strategy," this Resolution supports two components of its "Mission Impact" triangle in particular: 1) "Standards" and 2) "Capability Building." And it supports component 3) "Advocacy" in general.

1. Under "Standards," USP promises that it will continue to "Be a definitive source of medicine quality standards," and while "Remaining up-to-date."

CP quality requires accuracy and sterility. By embracing this Resolution, USP would "produce new and definitive standards" that supply what is currently lacking on the accuracy side of the CP quality equation, while fulfilling its commitment to "Remain Up-to-Date."

Today's CP preparation processes are well behind other industries that manufacture solutions. For example, for decades, Kodak has used similar workflow systems for chemical admixing. Technicians, led through automated checklists, are required to scan and weigh each ingredient to verify the accuracy of selections, pours, and completed products. The company can't afford to produce photo-developing solutions that don't work. Why should there be any less care taken in CP production?

2. Under "Capability Building," USP commits to "Equip stakeholders to use our standards," by being "a leading provider of services that are essential to improving medicine quality," which includes (among other things) "Facilitating adoption of new technologies."

WMS equips stakeholders to use USP standards by directing compounding personnel through each preparation step and preventing them from moving to next steps until previous steps are verified, all the while autodocumenting each step. WMS may also include USP sterility-process and SOP prompts.

Notably, WMS digitalization equips users for compliance with current "USPs Master Formulation Records" and "Compounding Records" requirements and standards (see p. 20 in 2019 *USP* General Chapter <797>).

Requiring AWS de facto "facilitates the adoption of new technologies," which, if not new to the rest of the world, are missing in most facilities where CP preparation occurs.

It would be the end of Amazon if 1 of 9 orders were fulfilled incorrectly or the downfall of Delta if 1 of 9 checked bags checked were lost. Using workflow technology similar to WMS, Amazon fulfillment-center error rates are below .001%, while Delta's bag-loss rate is below .002%,—both considerably below previously referenced 11% for CP. We must facilitate the crossover of similar technologies to ensure CP accuracy.

It is difficult to find a pharmacy department that doesn't believe in the value of WMS. Yet, nearly 70% of respondents to the the 2018 "ASHP national survey of pharmacy practice in hospital settings" cited budget as the number one barrier to entry, though WMS costs a small fraction of what is it takes to comply with current <797> sterility requirements. Furthermore, in addition to best-of-breed systems, most major EHR vendor platforms include WMS modules with no additional software charges or service fees to customers.

We argue that by establishing standards and requirements for WMS, USP will provide pharmacists with the necessary justification and support required to obtain funds and IT support to implement the same.

3. Advocacy: USP remains steadfast to "Raise our voice to continue to advocate for quality."

It is possible, even with best intentions and concentrated focus, for technicians to produce and pharmacists to confirm doses, which though sterile, are lethal.

USP has excelled in advocating for CP sterility by articulating detailed "requirements that must be followed to minimize harm, including death, which could result from 1) microbial contamination, 2) excessive bacterial endotoxins, 4) physical and chemical incompatibilities, 5) physical and chemical contaminants, and 6) use of ingredients of inappropriate quality."

This Resolution asks USP to continue its same good work by advocating for CP accuracy and articulating detailed standards and requirements for in-process ingredient-and-volume verification that include the use of WMS as "requirements that must be followed to minimize harm, including death, which could result from 3) variability from the intended strength of the correct ingredients."

To neglect standards/requirements development in either sterility or accuracy is tantamount to developing one wing of an airplane and not the other.

200 years of building trust

Submission 36

Bar Code Labeling Standards

Resolution Proposal Submissions

2020 usp The standard of trust | Convention The 2020 Meeting

Submission 36:
Bar Code Labeling Standards

Summary:

This Resolution requests USP to establish clear labeling standards requiring that manufacturers include lot numbers and expiration dates in bar codes on all immediate drug container labels (in addition to NDC numbers already required by the current FDA Bar Code Rule).

Statement of the Challenge:

Several USP standards and requirements already exist related to lot numbers and expiration dates. *USP <7> Labeling*, and *USP <1178> Good Repackaging Practices* included the requirement that this information be prominently displayed on drug packaging.

USP also clearly recognizes the value in having readily retrievable lot numbers and expiration dates for all drug products as evidenced by the most recent revisions of *USP* <795> and *USP* <797> requiring that vendor, lot number, and expiration date of each component be documented in compounding records.

Unfortunately, a carveout in <797> drops this documentation requirement for compounded preparations made for individual patients. Presumably, this exception was driven by the fact that current FDA-compliant bar codes are insufficient for capturing this information by scanning bar codes on components. Requiring bar codes to include lot numbers and expiration dates would allow compounders to capture and record this valuable information more efficiently and accurately than with current manual practices.

The 2004 FDA Bar Code Rule requires, with rare exceptions, that labels on immediate drug packages, including conventionally manufactured premixes, must include linear bar codes that contain National Drug Code (NDC) numbers.

During the public-comment period preceding the finalization of this rule, many healthcare stakeholders asked the FDA to add lot numbers and expiration dates to its bar code requirement. The administration was faced with two problems. 1) While new 2-D bar codes were capable of holding enough data to include NDC, lot, and expiration data, nearly all hospital scanners could read only linear or one-dimensional bar codes. And 2) Linear codes were and still are not capable of carrying NDC numbers along with lot number and expiration data without resulting in symbols that were longer than could fit on reasonably sized packaging.

In the end, the FDA ruled to require just NDC numbers in linear bar codes but promised that the rule would be reviewed for possible updating in five years.

True to its promise, in May of 2011, the FDA posted notice calling for comment regarding "Updating regulations in recognition of changing technology." "The goal of the review," its memo stated, "will be to assess the costs and benefits and to determine if the rule should be modified to take into account changes in technology that have occurred since the rule went into effect."

In fact, the time was right, as the technology had matured. Since then, GS1 has standardization DataMatrix (2-D) codes capable of carrying more than enough data to hold NDCs as well as lot and expiration data. Likewise, since the rule went into effect, in the routine process of replacing bar code scanners, hospitals had been universally selecting imagers that were capable of reading 2-D as well as linear symbols. The safety community was encouraged.

Soon thereafter, the process was mysteriously dropped. We eventually learned this was in deference to the Congressional drafting of the Drug Supply Chain Security Act (DSCSA), which became law on November 27, 2013.

DSCSA requires that bar codes contain serialized numbers to prevent drug counterfeiting, retain NDC numbers, and must also include lot numbers and expiration dates as well.

However, DSCSA labeling requirements only apply to the lowest sellable unit, not to each immediate drug package. For example, consider Heparin 5000 units/mL

vials. While the bar code on a 25-vial box must include serial and NDC numbers as well as lot numbers and expiration dates, bar codes on the box's 25 individual vials (immediate containers) continue to be regulated by the 2004 FDA rule and contain only NDC numbers, not lot numbers, expiration dates, or serial numbers.

While we agree that all immediate drug containers do not need to be serialized, we argue that each immediate drug container must contain its lot number and expiration date in machine readable format, which by default would call for a 2-D bar code. Today, scanners capable of ready 2-D bar codes are ubiquitous.

There is no evidence that the FDA has plans to amend the 2004 rule or to start the process of crafting a new bar code rule.

Desired Outcome:

That USP would establish clear labeling standards requiring that manufacturers include lot numbers and expiration dates in bar codes on all immediate drug container labels (in addition to NDC numbers already required by the current FDA Bar Code Rule).

Resolution Alignment

How does the proposal align with USP's mission and vision?

In USP vision language, this resolution would result in "capability building" by "equipping stakeholders to use USP standards, facilitating adoption of new technologies" and "enabling the use of (bar code) technology" for efficient and accurate capture of lot and expiration data.

The resulting benefits would be enormous and invaluable. Scanning can prevent pharmacy technicians, drug compounders, and nurses from using out-of-date medications; help intercept recalled medications before they are dispensed, compounded, or administered to patients, and "facilitate the use of technology" that enables more faithful and accurate documentation, which assists in identifying patients who have received medications and compounds with suspected or known quality issues for appropriate action.

This would facilitate readily available scan-to-stock technologies for intercepting recalled and outdated medications from being placed in patient cassettes, drug storage bins, automated dispensing machines, and other drug storage-and-retrieval systems, thus preventing product selection errors.

While some hospitals are committed to manually entering lot and expiration data with touch keys, such data-entry methods are prone to human error, which compromises "data" value. Additionally, because key-in-data entry is time consuming, this step is often neglected.

Of particular interest to USP, the inclusion of lot numbers and expiration dates in bar codes on all immediate drug packages will assist in intercepting out-of-date and recalled components during compounding. It also will enable more efficient and accurate compounding documentation already required by *USP* Chapters <795> and <797>.

The action requested in this Resolution would advance USP's missional commitments of continuing to be a "Disrupter in the healthcare space by disrupting errors; facilitating adoption of new technologies; and promoting the "Digitization of Healthcare: (as) increasing access to big data and digital health frameworks challenges stakeholders to rethink their patient engagement and delivery of care."

More thorough and accurate data collection will contribute to quality improvement by helping healthcare providers identify where/how things go wrong, enabling them to "rethink their delivery of care." This is analogous to the airline industry utilizing black-box data to rethink and improve its delivery of safe aviation.

Adopting this Resolution will result in making the medication-use process safer during dispensing, preparation, administration, and documentation activities.

200 years of building trust

Submission 37

USP Convention Membership

Resolution Proposal Submissions

200 usp The standard of trust | Convention The 2020 Meeting

Submission 37:
USP Convention Membership

Summary:

USP is encouraged to review the composition of the USP Convention Membership to ensure members are engaged in USP processes and activities during the entire 5-year cycle. There are several ways to accomplished this: 1) alter the composition, 2) engage Convention Membership throughout the 5-year cycle, and 3) separate Convention Membership into groups based on their area(s) of interest.

Statement of the Challenge:

USP Convention Membership that votes on USP Resolutions and other matters currently includes groups that are not fully aware of USP standards and their impact, and are not engaged throughout the entire 5-year cycle. This is a result of the design of the USP Convention which has not been substantially changed for the last 200 years. USP is challenged to review the last 200 years with regard to medicines (i.e., who makes them and is regulated by FDA), and realign the membership accordingly.

Desired Outcome:

To ensure that USP Convention Members are engaged in the USP throughout the entire 5-year cycle, and are not just attendees at the Convention every five years. A reevaluation and redesign of the USP Convention Membership would enhance engagement of the members throughout the cycle, and enable them to be more active participants at the USP Convention.

Resolution Alignment

How does the proposal align with USP's mission and vision?

This resolution ensures that USP works "collaboratively with key stakeholders" from the initiation to completion of resolutions and other aspects that set USP policies and practices.

Which of the three essential components of "Standards", "Advocacy", and "Capability Building" does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why:

This resolution will allow USP to assemble the best cadre of people to advise USP in order to achieve its ambition be a "global institutional leader of advancing medicine quality", not only in its standards-setting processes but in all areas of USP.

This resolution supports "Advocacy" by allowing USP to "expand awareness, urgency and political will". USP Convention Members that are better informed about USP processes and practices can provide more appropriate direction to shape USP resolutions and policies. This can be accomplished by several means: 1. altering the composition to ensure that it includes more stakeholder groups, 2. engaging the Convention Membership throughout the 5-year cycle to provide more awareness as to USP standards and processes, and 3. separating the Convention Membership into groups that would review, discuss and consider those aspects and activities of USP that are more closely related to their area(s) of interest.

200 years of building trust

Submission 38

Sustainability, Relevance, and Reach

Resolution Proposal Submissions

200 usp The standard of trust | Convention The 2020 Meeting

Submission 38:
Sustainability, Relevance, and Reach

Summary:

1. USP commits to protecting the organization's future by strengthening revenue sources beyond the required reference standard model, as future medicines are expected to rely less and less on broadly applicable physical reference materials.

2. USP commits to making physical reference standards available at special pricing in the context of public health emergencies and to non-profit NGOs engaged in the manufacture of products for the treatment of communicable diseases intended for use in underserved regions or populations.

3. USP will expand its outreach and collaboration into academia to build a stakeholder base in the most innovative scientific and medical fields that will support USP's innovation and relevance moving forward.

Statement of the Challenge:

Protecting the organization's future in an environment that requires less and less broadly applicable reference standard materials.

Desired Outcome:

Establish and maintain scientific, regulatory, and operational sustainability models for new types of standards concepts.

Resolution Alignment

How does the proposal align with USP's mission and vision?

USP's core mandate is to create standards that support global public health. This resolution proposal is a re-commitment to Resolution V from the 2015 Convention that speaks to Research and Innovation. It expands upon this by including reach and impact expansion, as well as the commitment to a sustainability model not primarily grounded in physical reference materials.

Which of the three essential components of "Standards", "Advocacy", and "Capability Building" does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why:

Standards and capability building. This proposed resolution maps to the 2020 Resolution Concept "Impact Expansion".

200 years of building trust

Submission 39

Resolution on Resolutions

Resolution Proposal Submissions

200 usp The standard of trust | Convention The 2020 Meeting

Submission 39:
Resolution on Resolutions

Summary:

To widen input from the Convention in determining USP's future direction.

Statement of the Challenge:

Current process doesn't provide resolutions submitted to the delegates. No transparency of the proposals submitted; Need to know how many resolutions, who submitted & the reasons for submission; Background & financial information; Resolutions could be modified in a way not reflective of the intention of the proposer; CoC has diverse membership whose representatives may not be delegates to the convention. Intent of the resolutions may not be understood by the CoC. No input before CoC revision.

Desired Outcome:

Process be revised to provide the delegates with the maker of each resolution submitted, the rationale, the current status of the issue, the financial implications of the actions proposed and the opportunity to hear the pros and cons of adopting. Each resolution, either singly or in combination with similar ones, be voted upon by the delegates in Convention assembled. Adopted resolutions should incorporated into USP's strategic planning process.

Resolution Alignment

How does the proposal align with USP's mission and vision?

According to the USP website, they are to be "instrumental in guiding USP's work during each five-year cycle". They are to provide a formal and institutionalized channel for 'member organizations, delegates, and other interested stakeholders to influence USP's strategic direction" Resolutions are the result of issues which affect specific segments of the membership, though they often have wider applicability. They are the issues which are bothersome in the day to day exercise of business and the issues which keep one up at night. With the resolutions going to the Council of the Convention for vetting as a first step, the only resolutions that get to the floor for discussion are those which the CoC deem worthy. That decision is made without the benefit of hearing the perspective of the maker of the resolution or the collective wisdom of the Convention as a whole. Does the submitter of the resolution leave with the feeling that their particular issue or point of contention has been heard? We need some mechanism where all of the resolutions submitted, can be seen and evaluated by the entire Convention. Recognizing that that is may not feasible for the Convention sitting as a committee of the whole, there are a number of possible avenues to do this.

1. Create Reference Committees: These would be representative groups of the delegates which would hear testimony with regard to the individual resolutions (grouped by topic, pehaps by one or more expert areas), and create a report making recommendation to the Convention on each resolutionâ€¦adopt, not adopt, or refer to the Board for study or decision. Time should be allotted during the convention for this to take place. The Reference Committee's recommendations would be presented to the Convention as a "consent calendar", where there recommendations could be accepted as presented or any individual item extracted for discussion on the floor of the convention, where it could be amended, accepted or rejected as an individual item.

2. Create an Online Forum: As the Resolutions are received, they could be categorized and placed in a secure online "chat room" where any interested party could make a comment supporting, opposing or adding perspective. These forums could guide the "Resolutions Committee in allowing the more contentious items to come to the floor for discussion or to make a recommendation to adopt, not adopt or refer each item. The consent calendar process as described above could then be followed. Both of these processes have the advantage of allowing the entire Convention to see the issues as perceived by its component parts, and permit each member to recognize that its issue has been addressed. Even if rejected, it has at least been heard.

Which of the three essential components of "Standards", "Advocacy", and "Capability Building" does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why:

Modernized standards, Increasingly global and connected staff , New quality medicine educational and advocacy programs Even optimally manufactured medicines are of little value if they are not used appropriately. USP has not done enough to this point in outreach to the end-users to assure that pharmaceuticals are properly used. The collective wisdom of the Convention is great. Issues brought up through a resolution may strike a responsive chord in many other organizations and lead to recognition by USP that it should be adopted as an arm of its future. Explosion of new medicine modalities: The rapid introduction of new classes of medicines and increasing breadth of what is considered medicine requires new types of quality standards.

Digitalization of healthcare: Increasing access to big data and digital health frameworks challenge stakeholders to re-think their patient engagement and delivery of care. Agree wholeheartedly. USP does not have the expertise to do this and must reach out to the stakeholders to help them appreciate the potential implications of the new medications so that use be optimized.

We Choose to Act Now.

While change in the global drug manufacturing system occurs slowly, acting now is key to make the most of our enduring strengths and keep USP sustainable for the long-term. We begin our third century ready to make a greater impact on public health than ever before by leveraging our history, integrity and strength along with a renewed commitment to advance the quality of medicine

If not us, who? If not now, when?.

Widening the input from the Convention will help keep USP in its frontrunner position.

200 years of building trust

Submission 40

Expand USP's Commitment to Transparency and Stakeholder Engagement

Resolution Proposal Submissions

2020 usp The standard of trust | Convention The 2020 Meeting

Submission 40:

Expand USP's Commitment to Transparency and Stakeholder Engagement

Summary:

USP is encouraged to expand its commitment to transparency and stakeholder engagement throughout the public review process. Good communication is fundamental in the USP standards-development process, and good communication will drive good standards. USP is encouraged to publish all comments received during the *Pharmacopeial Forum* (*PF*) review process on the USP website, and to respond to comments directly to the stakeholder/commenter.

Statement of the Challenge:

USP does not currently publish all comments it receives on proposals, and does not routinely provide communication back to stakeholders who commented (i.e., two-way communication).

Desired Outcome:

Publication of all comments received would allow for a more transparent standard-setting process. Responding directly to stakeholder/commenter ensures that the stakeholder is aware of USP's position and can better interpret the standard to prepare for implementation. This two-way communication also facilitates USP's understanding of the stakeholder/commenter's perspective.

Resolution Alignment

How does the proposal align with USP's mission and vision?

Ensures the quality of medicines through collaboration with stakeholders.

Which of the three essential components of "Standards", "Advocacy", and "Capability Building" does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why:

Allows USP to be more transparent in how it "develops and assembles evidence" for setting standards. Publication of comments received currently extends only to comments on the final version of the Standard adopted for publication, with a succinct response to the comment from the Expert Committee. Comments from stakeholders during earlier versions of the proposed Standard that are not adopted by the Expert Committee are not published on the website, and visibility of such comments, with responses from the Expert Committee are not available to stakeholders, not even to the commenter. Consideration would be given to confidential information consistent with the USP Document Disclosure Policy. USP is also encouraged to publish all comments received on USP web postings, such as Intent to Revise, Revision Bulletins, and Interim Revision Announcements, since these comments are not currently published. In addition, USP is encouraged to respond to comments directly to the stakeholder/commenter, especially if the standard will be re-proposed in PF, and especially if the commenter has indicated that this comment is critical to their product/process. This would ensure that the stakeholder is aware of USP's position and can better interpret the standard to prepare for implementation. This two-way communication also facilitates USP's understanding of the stakeholder/commenter's perspective.

This resolution supports "Standards" by ensuring that the standards are "up-to-date" and not necessarily out-of-step with industry practices and requirements. Being more transparent also enables USP's digital ambitions by "improving efficiency and transforming our impact".

200 years of building trust

Submission 41

Quality and Safety Related to Cannabis and Related Cannabinoids

Resolution Proposal Submissions

200 usp The standard of trust | Convention The 2020 Meeting

Submission 41:

Quality and Safety Related to Cannabis and Related Cannabinoids

Summary:

USP will collaborate with stakeholders to develop, strengthen, revise, and promote adoption of healthcare quality standards that address quality and safety related to cannabis and related cannabinoids including tetrahydrocannabinol and cannabidiol that are of value to patients and practitioners.

Statement of the Challenge:

Legal use of medical cannabis and related products including THC and CBD is rapidly expanding throughout the United States thereby providing access to millions of individuals. Without quality standards to assure strength, purity, identity and quality, individuals are at risk of substandard, ineffective, and potentially dangerous products.

Desired Outcome:

The desired outcome is an established set of quality standards that can be applied to cannabis related products and utilized by state organizations and other regulatory agencies to assure access to safe medicines.

Resolution Alignment

How does the proposal align with USP's mission and vision?

With the rapid growth in medical cannabis and related products in the United States there is an urgent need for quality standards for cannabis related products. This proposal aligns with the USP vision of a world "in which all have access to high quality, safe, and beneficial medicines". It also aligns with USP's mission to improve global health through public standards that help ensure the quality, safety, and benefit of medicines.

Which of the three essential components of "Standards", "Advocacy", and "Capability Building" does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why:

This proposal aligns with USP's Standards goal to "produce new and definitive standards for all medicines". USP's strategic plan calls on USP to be a definitive source of medicine quality standards. It also aligns with USP' Capability Building goal to equip stakeholders.

to use USP standards and to be a leading provider of services that are essential to improving medicines quality in the United States and around the world.

200 years of building trust

Submission 42

Addition of Products Administered by Ophthalmic Route to <232> Exclusion List

Resolution Proposal Submissions

200 usp The standard of trust | Convention The 2020 Meeting

Submission 42:

Addition of Products Administered by Ophthalmic Route to <232> Exclusion List

Summary:

USP monograph added the requirement to monitor elemental impurities, while identifying various classes of drugs and biologics for exclusion. Missing from the exclusion list is products administered by ophthalmic routes of administration. Ophthalmic drug products are administered by ophthalmic routes that are not sufficient to raise significant safety concerns.Typically, only 1-2 percent of ophthalmic drops are systemically absorbed.

Statement of the Challenge:

Because of the need to monitor elemental impurities of ophthalmic products, new ophthalmic products are delayed in coming to market. This is detrimental to ophthalmology patients who could benefit from new drugs and biologics. This requirement adds time, expense, and promotes the wasting of resources for those developing and producing new ophthalmic drug products.

Desired Outcome:

The desired outcome is that the exclusion list be amended to include products administered by an ophthalmic route of administration.

Resolution Alignment

How does the proposal align with USP's mission and vision?

The resolution promotes USP's vision and mission to drive access to safe, high-quality, and beneficial medicines. This resolution will reduce barriers to innovative ophthalmic drug products being brought to market and ensure that ophthalmology patients have timely access to new high quality drugs and biologics.

Which of the three essential components of "Standards", "Advocacy", and "Capability Building" does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why:

This resolution has strong alignment with all three essential components of USP's 2025 strategy, including standards, advocacy, and capacity building. Standards: The ambitions of USP's 2025 Strategy include the adoption of more flexible, agile, and iterative approaches to standards development and delivery. A critical component of ensuring the success of such a strategy is to ensure that current standards are aligned with scientific evidence and don't foster unnecessary barriers to new therapies. The resolution to add drug products administered by the ophthalmic route to the exclusion list would reflect alignment with USP's 2025 strategy by showing flexibility in standards delivery, promoting the idea that new evidence or information can ensure that USP standards aren't rigid and in a constant state of review.

Advocacy: This resolution aligns with this key component in that it seeks to promote collaboration between USP and ophthalmology experts. A priority for USP should be to promote engagement with different areas of medicine, including ophthalmology, that are impacted by the development and delivery of their standards. This helps build trust between USP and the medical community, their patients, and the broader public.

Capability Building: Adoption of this resolution would show a key willingness by USP to engage with the ophthalmic community to drive appropriately tailored standards to promote timely access to new ophthalmic products. Engagement and collaboration are key components of capacity building. By ensuring that different areas of medicine, including ophthalmology, are able to weigh in on existing standards that may be having a detrimental impact on their field, USP's 2025 strategy will be much more successful.