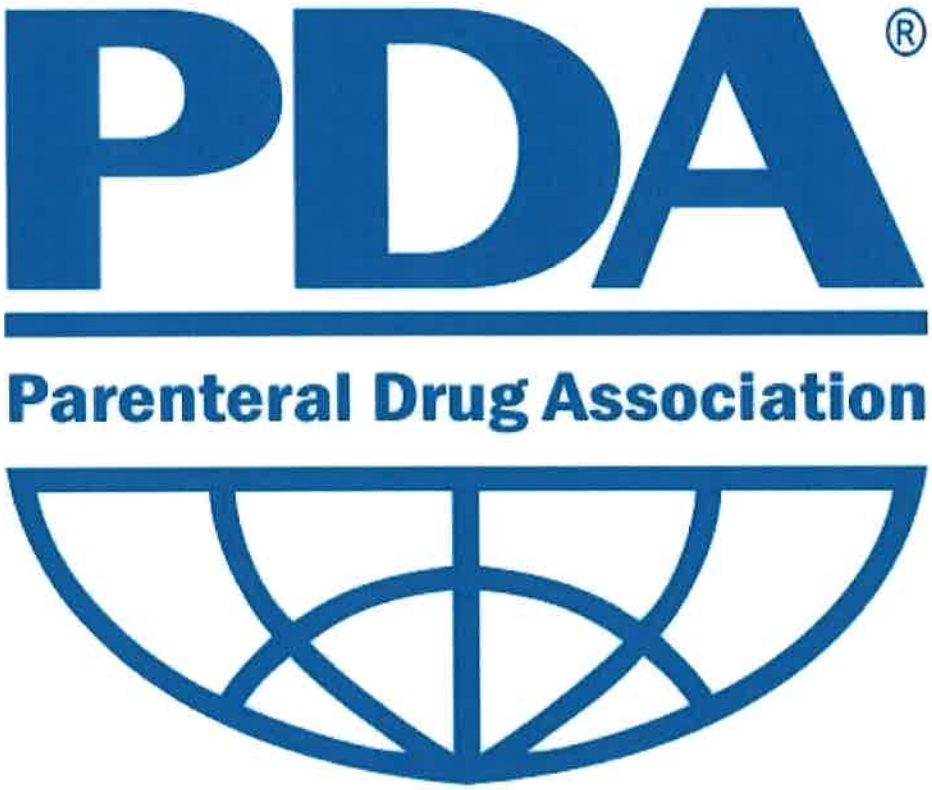
2026 Strategic Plan



Connecting People, Science and Regulation®

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Introduction

Founded in 1946 as a nonprofit organization, the Parenteral Drug Association (PDA) has become a global leader in advancing pharmaceutical and biopharmaceutical manufacturing science, technology and regulations to help members better serve patients.

PDA creates awareness and understanding of important issues facing the pharmaceutical and biopharmaceutical community and delivers education and training to the community. PDA is committed to developing scientifically sound information and expertise to advance science and regulation for the benefit of its members worldwide.

For PDA to serve its members, it must continue efforts to connect people, science and regulation, while also adapting to emerging trends within the pharmaceutical and biopharmaceutical industry. For example:

Globalization of the biopharmaceutical and pharmaceutical industry

- Emerging markets continue to be an important source of raw material, components, APIs, etc.
- Growing complexity of supply chain and increased scrutiny on supply chain security
- Increase in outsourcing operations and use of contract manufacturers
- Increased imbalance between pressure on drug shortages and cGMP expectations

Shift from traditional sterile pharmaceuticals and biologics to other novel therapies and delivery systems

- Biosimilars
- Personalized medicine
- Solid dosage forms
- More and more combination products on the market

Changes in the regulatory landscape globally

- Increased drive for global harmonization
- New strategies required for regulatory filing, approval and post-approval change management

Advances and acceleration in technology innovation

- Movement toward new technologies and analytics, for example:

- Single-use systems
- In-line or on-line monitoring of processes
- Continuous manufacturing
- Gloveless isolators

Evolution of quality systems and performance expectations

- Moving beyond compliance is now key
- Focus on continuous improvements
- Use of Quality Risk Management throughout the lifecycle
- Use of Quality by Design

Changes in key industry and market players

- Contract manufacturers are used more and more
- Generics continuing as a significant proportion of the global drug supply

Changes in workforce, talent pool and competencies

- New generations are entering the industry that might have other competences and skills and might be motivated by other factors than the current workforce. Also, communication methods might change
- As technologies change, new competences and skills are needed
- Training of new employees should be reevaluated

This Strategic Plan has been designed to deliver value to the global biopharmaceutical and pharmaceutical industry, regulatory authorities, vendors for our industry and academia today and for the future. Given the dynamic environment, this Strategic Plan will function as a rolling plan to be reviewed annually by the Board of Directors and adapted as needed based on emerging global trends. The 2026 Strategic Plan is organized into four strategic focus areas:

- **People:** Continue to grow and improve the organization globally to bring and enhance the value to our membership
- **Science:** Be the premier global leader for agile advancement of science, manufacturing, quality and innovation
- **Regulation:** Enable global harmonization of regulatory requirements and industry standards to drive compliance, quality performance and innovation
- **Leadership and Business Management:** Maintain strong organizational leadership to promote teamwork, an environment of sustainable growth and excellence in business management

To effectively deliver value in all four strategic areas requires focus on agility, simplification and innovation. Furthermore, as the four strategic areas are interlinked, many of the objectives will have cross-functional impact. PDA will establish corresponding goals, objectives and programs annually to enable progress toward accomplishing this Strategic Plan to be measured. Our processes will continue to be facilitated by our valued staff and volunteers in Advisory Boards, Interest Groups, Regional Chapters, Task Forces and Committees.

Many members, industry leaders, regulators, staff and the PDA Board of Directors have contributed to the content of the PDA 2026 Strategic Plan, and we would like to thank each of them for their contributions.

Jette Christensen, PDA Chair-Elect and Chair of Strategic Planning Committee

Richard Johnson, PDA President

Rebecca Devine, PDA Chair

Vision, Mission, Values and Motto

PDA's volunteers and staff are guided by our Vision, Mission and Values. Our Motto reflects our way of working to achieve our mission.

Vision

To be the premier global leader in advancing pharmaceutical and biopharmaceutical manufacturing science, technology and regulation, enabling members to better serve patients

Mission

To maximize product quality, availability and value by connecting people, science and regulation within the pharmaceutical and biopharmaceutical community as:

- The preferred choice for professionals who seek to acquire specialized, innovative skills and knowledge enhancing their professional development
- The premier education partner for professionals in academia, industry and government for the advancement of manufacturing, quality and regulatory science
- An organization that aligns its practices and resources to support its core values of science-based approach, integrity and inclusion.

Values

Science Based: Science is the foundation of our organization. We use a scientific approach to meet challenges and continuously improve as this approach is objective, rational and transparent.

Integrity: We are relentless in applying the highest ethical standards to our products, services and actions. We will honor our commitments.

Inclusion: We work together to create a culture of inclusion built on trust, respect and dignity for all. We establish global partnerships with professionals in academia, industry and regulatory bodies.

Motto

CONNECTING PEOPLE, SCIENCE AND REGULATION®

Strategic Focus Areas

PEOPLE: *Continue to enhance the value of PDA membership by growing and improving the organization globally.*

- Our strength lies in *our membership and diversity*. We will grow our membership globally to be able to serve a broader audience.
  - We will define new membership and PDA entry pathways to make PDA's knowledge and network base more widely accessible.
  - We will strengthen the diversity of our members and volunteers with focus on young professionals (including professionals new to the industry) and manufacturing scientists. To do so, we will proactively mentor new members and engage them in a broad range of volunteer opportunities. These opportunities will be available on the PDA chapter level to reach every volunteer in every region.
- We provide *services and products* (conferences, education and training, technical documents) at a global level. We aspire to make our core deliverables accessible and understandable widely.
  - We will strive to increase global engagement by delivering some of our services and products in different languages, through multiple channels, to effectively serve regional needs. In addition, we will increase the visibility of and access to PDA's services through transparency and timely communications.
  - We depend on the contributions of our active volunteers as a source of expertise, deliverables and services. We will continue to strengthen our appreciation and meaningful reward system to recognize our global volunteers and attract new ones.
- We strive to deliver the value that our members and their organizations require for the ultimate benefit of patients.
  - PDA provides a widely respected platform for our members who can use it to enhance their impact and contribute toward creating one industry voice on key topics. As a standards organization, we will encourage more adoption of industry standards for our members.
  - PDA provides access to information, expertise and knowledge that is key to successful performance. PDA will continue to create and broaden access to the latest desired information, expertise, knowledge and new technology transformations to support the global industry and regulatory authorities.

- PDA is a comprehensive scientific, technical and regulatory information source with a vast network of experts. We will continue to strengthen the value PDA volunteers gain when achieving a higher level of expertise and career advancement through mentorship programs and volunteer initiatives.

SCIENCE: *Be the premier global leader for the agile advancement of science, manufacturing, quality and innovation.*

- *Core Expertise:* We will retain and advance our core areas of expertise and leadership in PDA standards, technical documents, training, conferences/workshops and other PDA scientific resources.
  - We will maintain our core competencies in pharmaceutical and biopharmaceutical manufacturing, analytical technologies and quality and regulatory sciences, such as Sterile Manufacturing, Good Manufacturing Practices, Manufacturing, Packaging and Process Science, Quality Management, Microbiology and Biotechnology.
  - We will continue to use techniques such as onsite and classroom training. We will explore and advance new techniques for training such as e-learning, virtual reality and new areas of hands-on laboratory/plant training.
- *Trends and Innovation:* We will proactively identify and respond to emerging science and technology to assure that members are served in these areas.
  - We will enhance processes to respond in a timely manner to emerging issues and future perspectives, including:
    - Ongoing discovery, innovation and intelligence
    - Agile reallocation of resources
    - Speedy delivery of needed information, training, standards, conferences/workshops and science in identified areas
  - We will address current emerging topic areas, such as personalized medicines (including regenerative medicines, cell and gene therapy and combination products) and computer science (including digitalization, automation and artificial intelligence).
- *Applied Research:* We will expand PDA's applied research program to provide useful information and innovation on pharmaceutical and biopharmaceutical science topics.
  - We will establish a clear research strategy with appropriate funding.
  - We will explore ways to leverage the PDA Foundation to support research projects.
  - We will develop partnerships to facilitate research projects (e.g., with academia and suppliers).

- We will provide a research support program for students and young professionals in pharmaceutical and biopharmaceutical science projects of interest to PDA members.

- *Partnerships:* We will explore and advance partnerships with regulatory authorities, intergovernmental organizations, suppliers, academic institutions and other associations and groups to advance science, education, emerging topics and research.

REGULATION: *Enable global harmonization of regulatory requirements and industry standards to drive compliance, quality performance and innovation.*

- *Monitoring and Training:* We will continue to monitor, promote and provide training in the latest global regulatory requirements and evolving expectations.
  - We will set up a robust, sustainable system for monitoring the regulatory landscape.
  - We will provide training on basic and advanced GMP/GDP and related topics that consider evolving technologies and regulatory expectations (e.g., supply chain management, delivery systems/combination products) and bridge education to industry needs for young professionals.
- *Advocacy and Engagement:* We will maintain our commenting, advocacy and engagement in regulatory matters.
  - We will advocate for global harmonization, simplification, efficiency and practical implementation based on science, technology and risk.
  - We will enable regulatory acceptance of efficient new technologies and innovation.
  - We will increase our advocacy by leveraging collaboration and partnerships with other organizations, where applicable (e.g., regulators (MARS^{SM}), PIC/S and other associations).
  - We will advance our engagement in countries with growing manufacturing capabilities to educate on standards and best practices.
- *Establish Industry Standards:* We will continue to develop and advance industry standards on key topics through position papers, technical reports and standards. Additionally,
  - We will expand the portfolio of topics covered by ANSI/ISO standards.

LEADERSHIP AND BUSINESS MANAGEMENT: *PDA will maintain strong organizational leadership to promote teamwork, an environment of sustainable growth and excellence in business management.*

- *Governance:* We will continuously review, update and simplify our governance and business processes to balance agility with control in all our activities—at the committee level, volunteer level and staff level.
  - We will focus on improving diversity and inclusion in our volunteer activities, so the organization is representative of our membership and gives all parties a voice.
  - We will expand the activities of the PDA Foundation to better support our mission and serve the pharmaceutical and biopharmaceutical community.
  - We will optimize our online presence and leverage technology to enhance interaction.
- *Fiscal Stewardship:* We will be good stewards of the Association's assets to ensure that we have sustainable capabilities to deliver value to our members.
  - We will respond to changing conditions and make strategic investments in new capabilities to maintain our leadership.
  - We will evaluate alternate models for some activities to further our ability to fulfill our mission.
- *Resource Management and Partnerships:* We will continue to optimize management of our resources to advance the value of our services and engage in partnerships.
  - We will use effective portfolio prioritization and project management to maximize the value of their efforts.
  - We will explore alternate models to further enable and sustain PDA's growth, e.g., membership models, engagement models (for volunteers, members and young professionals).
  - We will seek and leverage strategic partnerships, alliances and senior leader engagement to best achieve our goals. We will strive for complementary deliverables with other organizations' activities and focus on our unique contributions.
  - We will use active succession planning for volunteers and staff to assure a sustainable, vibrant association.

Strategic Planning Committee

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