Parenteral Drug Association
2020 Strategic Plan

November 2015

Connecting People, Science and Regulation®

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Introduction

The Parenteral Drug Association (PDA) is the leading global facilitator of science, technology and regulatory information. The PDA creates awareness and understanding of important issues facing the pharmaceutical and biopharmaceutical community and delivers education for the community. Founded in 1946 as a nonprofit organization, PDA is committed to developing scientifically sound, practical technical information and expertise to advance science and regulation through its members worldwide.

For PDA to continue to serve its members, it must continue its leadership in connecting people, science and regulation, but it must also adapt to emerging trends within the pharmaceutical/biopharmaceutical industry. For example:

- Globalization of the pharmaceutical industry
    - Emerging markets have become a more important source of raw materials, components, APIs, and pharmaceuticals/biopharmaceuticals
    - More countries are developing their own regulatory requirements and enforcement systems and therefore there are more inspections from more regulatory bodies
    - Increase in outsourcing operations and use of contract manufacturing
    - Growing complexity of supply chain and increased scrutiny on supply chain security
    - Increasing imbalance between pressure on drug shortages and cGMP expectations
    - Increased drive for global regulatory harmonization (e.g., through ICH, WHO, industry and trade associations)
- Evolution of the Quality System
    - Modern Quality Systems that have been used in other industries are being adopted in the pharmaceutical industry
    - Regulators and industry are moving beyond compliance to quality by design by focusing more on continuous improvement and product quality. Adopting modern quality systems that gain product and process understanding, measure and improve process capabilities and achieving six sigma performance
- Global shift in product and regulatory landscape from traditional pharmaceuticals to biologics and other novel therapies
    - Biosimilars will have significant utilization around the world
    - New therapies will require new unique manufacturing processes, analytics
    - Personalized healthcare is raising the need to integrate companion diagnostics
    - Accelerated development and regulatory approval programs are requiring innovative strategies not only for product development and commercial manufacturing, but also in regulatory filing, approval and post approval change management.

- Advances and acceleration in technology innovation (manufacturing and analytics)
    - There is a movement towards new manufacturing and analytical technologies, processes and equipment
    - Embracing continuous manufacturing, disposable technologies, process analytical technologies, resulting in smaller plants
    - Technology is advancing and changing at an accelerating rate
- Shift in key industry players
    - Industry consolidation in parallel with new start-up companies and at the same time new start-up companies appear weekly
    - Expanding presence of and competitive pressures in emerging markets
    - Generics continuing as a significant proportion of the global drug supply
- Shift in workforce and talent pool
    - Many organizations are dependent on external groups for provision of fundamental education and training for core disciplines
    - Millennials and Generation Z are entering the industry at the same time that the most long-term and knowledgeable personnel are leaving the workforce, leading to challenges in knowledge management
    - These employees learn, network, communicate, network, and manage their career/development differently from the majority of those currently in the workforce
    - Social media has become a common communication method

These dynamic forces require the PDA to adapt how we advance our core mission of connecting people, science and regulation and to focus on the opportunity these changes offer if the organization is going to remain a vibrant and viable organization that is seen as the forefront of new innovations in science, technologies, and quality.

This strategic plan is designed to prepare PDA for the future and to focus PDA's activities on several key strategic priorities over the next 5 years ending in 2020. In order to create a visionary plan, the team considered the evolution and anticipated state of the industry, which PDA serves over the next 10 years. As with the previous plan, the 2020 plan will be organized into the three PDA Pillars: People, Science and Regulation, and will include the enablers of Organizational Leadership and Management.

The PDA strategic plan focuses on the following four areas:

- **People:** Continue to enhance the value of PDA membership, grow and enhance the organization globally.
- **Science:** Be recognized by professionals in academia, industry and regulatory bodies as the premier global leader for the advancement of science, manufacturing, quality and innovation.

- **Regulation:** Regulatory activities are scientifically, risk-based and technically focused. Assist the regulators and industry by providing the knowledge and tools to drive ideological movement that goes beyond compliance towards continuous improvement, quality performance and true quality innovation.
- **Leadership and Management:** Foster an environment of sustainable growth, strong organizational leadership, a mindset of continuous improvement, and discipline in business process management; so that PDA can flourish and achieve its mission and vision while living the values.

For each of these four strategic areas, PDA will establish goals, objectives and programs annually that will measure progress towards accomplishing the strategic plan of the organization.

Training/education, publications, conferences and networking opportunities will be the key enablers to success although we must continue to adapt as the communication means of our industry evolve. Our basic tools will continue to be facilitated by our valued staff, volunteers, Advisory Boards, Interest Groups, Regional Chapters, Task Forces and Committees.

Once a year, the PDA will provide a verbal or written update on progress against the 2020 Strategic Plan to the Board of Directors.

A number of volunteers and staff members have contributed to the content of PDA 2020 Strategy and we would like to thank all of these contributors.

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Mission, Vision, Values and Motto

PDA's staff and volunteers are guided by our Mission, Vision, Values, and our Motto reflects what we strive to achieve as an organization.

Mission

To advance pharmaceutical / biopharmaceutical manufacturing science and regulation so members can better serve patients.

Vision

To maximize product quality, availability, and value by connecting people, science, and regulation within the pharmaceutical and biopharmaceutical community so that PDA is:

- The preferred choice for professionals who seek specialized, innovative skills and knowledge enhancing their professional development
- The premier educational 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 in support of its core values of science based, integrity, and inclusion

Values

Science Based: Science is the foundation of our organization. We utilize a scientific approach to meet challenges and continuously improve. It is not subjective or emotional, but rather a logical, open, rational and transparent process.

Integrity: We are relentless in applying the highest ethical standards to our products, services and actions. We will never compromise ethics. We will be known for living to the highest forms and standards of ethical behavior. We will honor our commitments.

Inclusion: We work together to create a culture of inclusion built on trust, respect and dignity for all. We contribute to the advancement of pharmaceutical / biopharmaceutical operations by building partnerships with professionals in academia, industry and regulatory bodies to better serve patients.

Motto

CONNECTING PEOPLE, SCIENCE AND REGULATION®

Strategy

Our strategy is aligned to drive the organization to achieve its Mission and Vision while living our values. There are four strategic areas of focus:

- **People:** Continue to enhance the value of PDA membership, grow and enhance the organization globally.
- **Science:** Be recognized by professionals in academia, industry and regulatory bodies as the premier global leader for the advancement of science, manufacturing, quality and innovation.
- **Regulation:** Regulatory activities are scientifically, risk-based and technically focused. Assist the regulators and industry by providing the knowledge and tools to drive ideological movement that goes beyond compliance towards continuous improvement, quality performance and true quality innovation.
- **Leadership and Management:** Foster an environment of sustainable growth, strong organizational leadership, a mindset of continuous improvement, and discipline in business process management; so that PDA can flourish and achieve its mission and vision while living the values.

For each of these four strategic areas, PDA will establish programs that advance these strategies. PDA will measure progress toward achieving the 2020 Strategic Plan.

Training/education, publications, conferences and networking opportunities will be the key enablers to success. Our basic tools will continue to be facilitated by our volunteers, Board of Directors, Advisory Boards, Interest Groups, Regional Chapters, Task Forces and Committees and professional staff.

Strategic Areas of Focus

Strategy #1 — PEOPLE: *Continue to enhance the value of PDA membership, grow and enhance the organization globally.*

1) Grow Membership Internationally.

   a) The majority of our members come from North America, Europe and Japan; however, our industry is rapidly globalizing. PDA should actively focus on further expanding our global membership.

   b) Engage in activities in emerging markets such as the BRIC countries to benefit the general membership and attract new members.

2) Member/Volunteer Diversity

   - Increase diversity of the membership, by increasing the number of manufacturing professionals, recent graduates/those new to the industry and senior executives who become PDA members.

   - Increase member / volunteer participation. PDA is at its heart a member based organization, and member volunteers are key to the success of the organization and mission.

   - Actively create networking opportunities and use rewards and recognition mechanisms to attract and retain volunteers.

3) Hold conferences globally based on current and emerging topics, possibly with the support of other organizations or regulators, to promote increased understanding and exchange of information.

4) Develop a core and standardized education curricula that supports the needs of our constituencies and supports PDA's key technical areas in alignment with the membership.

Strategy #2 — SCIENCE: *Be recognized by professionals in academia, industry and regulatory bodies as the premier global leader for the advancement of science, manufacturing, quality and innovation.*

1) Areas of Interest
    a) Anticipate manufacturing and technology trends, regulatory focus and industry hot topics to proactively develop science and risk-based initiatives.
    b) Maintain focus on core competencies of pharmaceutical/ biopharmaceutical manufacturing, analytical technologies, quality and regulatory science, including:
        i. Aseptic Processing and Sterile Manufacturing
        ii. Manufacturing techniques and technologies
        iii. Analytical techniques and technologies
        iv. Quality Management and Quality Systems
        v. Regulatory Science and GMP and GDP Compliance
    c) Increase PDA's focus on developing areas:
        i. Manufacturing systems (continuous manufacturing, single use systems, automation and robotics, use and integration of electronic data hardware and software to control and document processes).
        ii. Product Categories (combination products (drug/device delivery systems), biologics, biosimilars, gene and cell therapy and precision/personalized medicine)
        iii. Supply Chain integrity (cold chain, track and trace/serialization, pedigree)
2) Promote proactive behavior and advocate for solutions that will benefit the pharmaceutical/ biopharmaceutical community and patients.
3) PDA will ensure that current and upcoming technical and scientific topics within PDA's core competencies will be addressed in a timely and high-quality manner, through the activities of PDA volunteer groups, Interest Groups, Education, Conferences, and Publications.
4) Develop and provide training that will further strengthen PDA's position and leadership as the provider of choice for the community for practical, science-based solutions for key topics that are in alignment with professional needs of the membership.
5) Develop and execute research projects that leverage PDA's resources and facilities to address key needs of our industry.

Strategy #3 — REGULATION: *Regulatory activities are scientifically, risk-based and technically focused. Assist the regulators and industry by providing the knowledge and tools to drive beyond compliance towards continuous improvement, quality performance and true quality innovation.*

1) Provide science and technology based input on regulations and guidelines related to PDA's strategic focus, utilizing PDA's volunteer and membership base.

2) Bring sound scientific and technical information to the regulatory process, maintain valuable and effective relationships with global regulators, and educate members on current expectations. Lead the dialogue for new topics and improvements with regulators worldwide.

3) Advocate moving from compliance to quality performance and adopting modern quality systems that foster continuous improvement, gain process understanding, and measure and improve process capabilities.

4) Promote the development of international regulatory harmonization and convergence.

5) Expand interaction with global health authorities to develop more clear understanding of problems/potential solutions and promote their participation in conferences, training and development of technical documents.

Strategy #4 — LEADERSHIP AND MANAGEMENT: *Foster an environment of sustainable growth, strong organizational leadership, a mindset of continuous improvement, and discipline in business process management; so that PDA can flourish and achieve its mission and vision while living the values.*

1) Governance

   Map, deploy and continuously improve a clear and effective governance structure for Advisory Boards, Interest Groups, Chapters, Programs, Committees and Task Forces to assure that PDA volunteers are engaged.

2) Fiscal Stewardship

   - Maintain strong fiscal discipline to ensure that spending is in line with revenue to achieve long-term sustainability.
   - Continuously review and improve the application of the PDA capabilities and products to achieve a reliable and constant revenue stream, to maintain reserves at a minimum of 12 months of Global Fixed Operating Expense. Invest PDA financial resources to promote the Strategic Plan.

3) Human Resource

   - Leverage staff and volunteer resources by aligning programs, TRs, technical reports, regulatory responses and other PDA activities.
   - Continuously update volunteer and staff talent management processes, personal development and succession planning.

4) Communication

   Continuously review and improve PDA's communication [brand, image, etc.] to ensure it is globally consistent with PDA's mission, supports the strategic initiatives, and is effective.