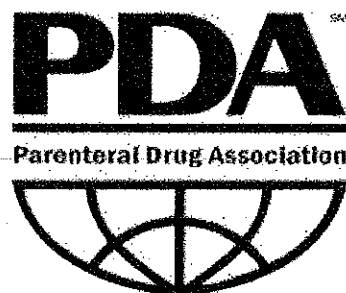


PARENTERAL DRUG ASSOCIATION

2015 Strategic Plan

December, 2010

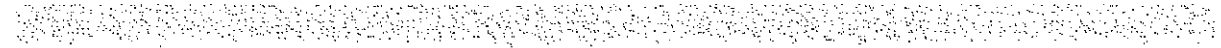


Connecting People, Science and RegulationSM



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INTRODUCTION

This PDA Strategic Plan covers the direction PDA has decided to take during the next 4 years until 2015. The plan covers the areas PEOPLE, SCIENCE, REGULATION and BUSINESS MANAGEMENT. For each of these areas the Strategic Planning Committee and The Board of Directors have defined a clear focus on how PDA can best service it's membership over the next few years.

PDA is a not for profit organization servicing members working in or affiliated with the Pharmaceutical Industry. The organization has promoted science based regulations and the development of pharmaceutical technologies since 1946 and provided an excellent foundation for networking of peers within the industry. The Pharmaceutical Industry is undergoing a lot of change due to consolidations, globalization, increasing importance of biopharmaceuticals, increasing Health Authority enforcement, and other factors. In this environment the importance of a science driven organization providing networking, education and information sharing activities as well as an active dialog with Health Authorities is even more important that it has been in the past.

The PDA strategic plan focuses on these four areas over the next four years:

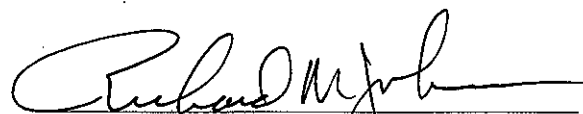
- **PEOPLE:** Enhance the value of the PDA membership
- **SCIENCE:** Be recognized as a leading organization for manufacturing science, quality and innovation
- **REGULATION:** Our regulatory activities are scientifically and technically focused, and current information is communicated to our members
- **BUSINESS MANAGEMENT:** Enhance business processes to provide a solid foundation and organization to sustain PDA's people, science and regulation strategies

For each of these four areas PDA has established annual goals and objectives thus translating the strategic elements into tactical activities. As part of the strategic work PDA has refined it's Governance structure to better align activities and to ensure a continued high level of volunteer involvement in all of PDA's areas of activity.

A number of volunteers and staff members have contributed to the development of this Strategic Plan and we would like to thank each of these volunteers.



Anders Vinther, Chair-Elect



Richard Johnson, PDA President



STRATEGIC PLANNING COMMITTEE

We want to thank the members of the Strategic Planning Committee for their insightful leadership, provision of information, foresight for PDA growth opportunities, and hard work as editors. This execution of this plan would not be possible without the contributions of these dedicated and talented professionals and volunteers.

CONTRIBUTORS TO THE STRATEGIC PLAN

- | | |
|-------------------|--------------------|
| Hal Baseman | Jim Lyda |
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| Rebecca Devine | Wanda Neal |
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| Louise Johnson | Chris Smalley |
| Richard Johnson | Martin Van Trieste |
| Maik Jornitz | Anders Vinther |
| Rich Levy | |

MISSION, VISION AND STRATEGY

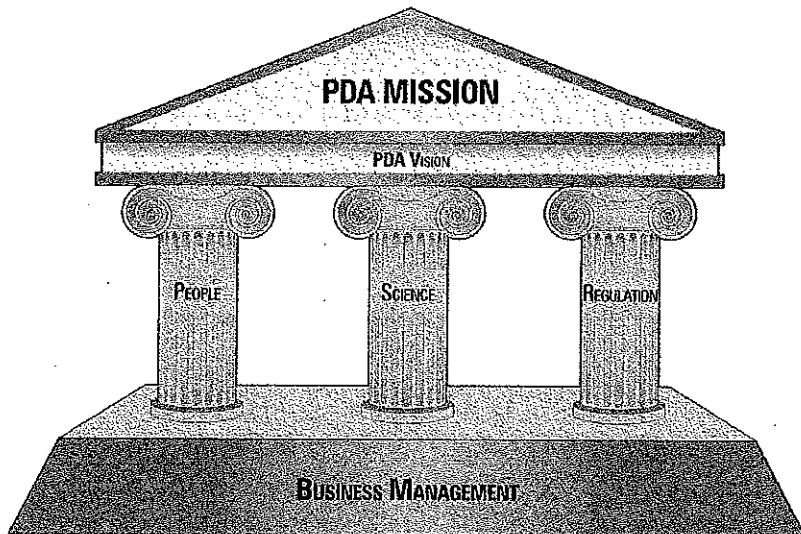
Mission
To develop scientifically sound, practical technical information and resources to advance science and regulation for the pharmaceutical and biopharmaceutical industry through the expertise of our global membership

Vision
To be the foremost global provider of science, technology, and regulatory information and education for the pharmaceutical and biopharmaceutical community

Strategy
Strategies will be aligned to drive the organization to achieve its Mission and Vision. The four strategic focus areas are:

- **People:** Enhance the value of the PDA membership
- **Science:** Be recognized as a leading organization for manufacturing science, quality and innovation
- **Regulation:** Our regulatory activities are scientifically and technically focused, and current information is communicated to our members
- **Business Management:** Enhance business processes to provide a solid foundation and organization to sustain PDA's people, science and regulation strategies

Training/education, publications and conferences will be the key enablers to success.



STRATEGIC AREAS OF FOCUS

Strategy #1 - PEOPLE: *Enhance the value of the PDA membership*

Chairs: Richard Johnson, PDA President
Maik Jornitz, PDA Chair

- 1) Hold Scientific, Quality and Regulatory conferences based on current industry focus, if needed with the support of other organizations or regulators
- 2) Develop a core and standardized curriculum for Education and continually improve training and education programs
- 3) Focus on global membership expansion
- 4) Actively create networking opportunities and use rewards and recognition mechanisms to attract and retain volunteers

Strategy #2 - SCIENCE: *Be recognized as a leading organization for manufacturing science, quality and innovation*

Chairs: Rich Levy, PDA, Sr. V.P., Scientific & Regulatory Affairs
John Shabushnig, PDA Immediate Past Chair

- 1) PDA's technology focus is Pharmaceutical Manufacturing and Quality including:
 - a. Aseptic Processing and Sterile Manufacturing
 - b. API, Non-Sterile and Combination Product Manufacturing
 - c. Quality Management, regulatory compliance and process validation
 - d. Pharmaceutical and biopharmaceutical Supply Chain
- 2) Ensure the most current information about technical topics are published through the PDA Technical Reports, PDA Journal, PDA Letter, PDA Conferences and PDA Website
- 3) PDA will assure that current and upcoming technical and scientific topics within PDA's core competencies will be addressed timely, with high quality and distributed by PDA Task Forces, PDA Interest Groups, PDA TRI and PDA Focus Meetings
- 4) Implement a research strategy and utilize TRI to promote science in PDA's strategic areas



Strategy #3: REGULATION: *Our regulatory activities are scientifically and technically focused, and current information is communicated to our members*

Chairs: Steven Mendivil, PDA Board member
Georg Roessling, Sr. VP PDA Europe

- 1) Provide science and technology based input on regulations and guidelines related to PDA strategic areas, 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
- 3) Engage in activities, for example training and education, in BRIC countries when we can benefit the general membership
- 4) Engage regulatory agencies in the development and adoption of PDA TRs.

Strategy #4: BUSINESS MANAGEMENT: *Enhance business processes to provide a solid foundation and organization to sustain PDA's people, science and regulation strategies*

Chairs: Hal Baseman, PDA Treasurer
Craig Elliott, PDA CFO

- 1) Maintain reserve to a minimum of 12 months of Global Operating Expense
- 2) Establish 5 year rolling financial and marketing plan to sustain and balance major revenue streams
- 3) Leverage staff and volunteer resources by aligning programs, TRs, and other PDA activities
- 4) Maximize the use of the TRI facility and other PDA products as reliable and constant revenue stream, for further investments into the support of PDA's membership