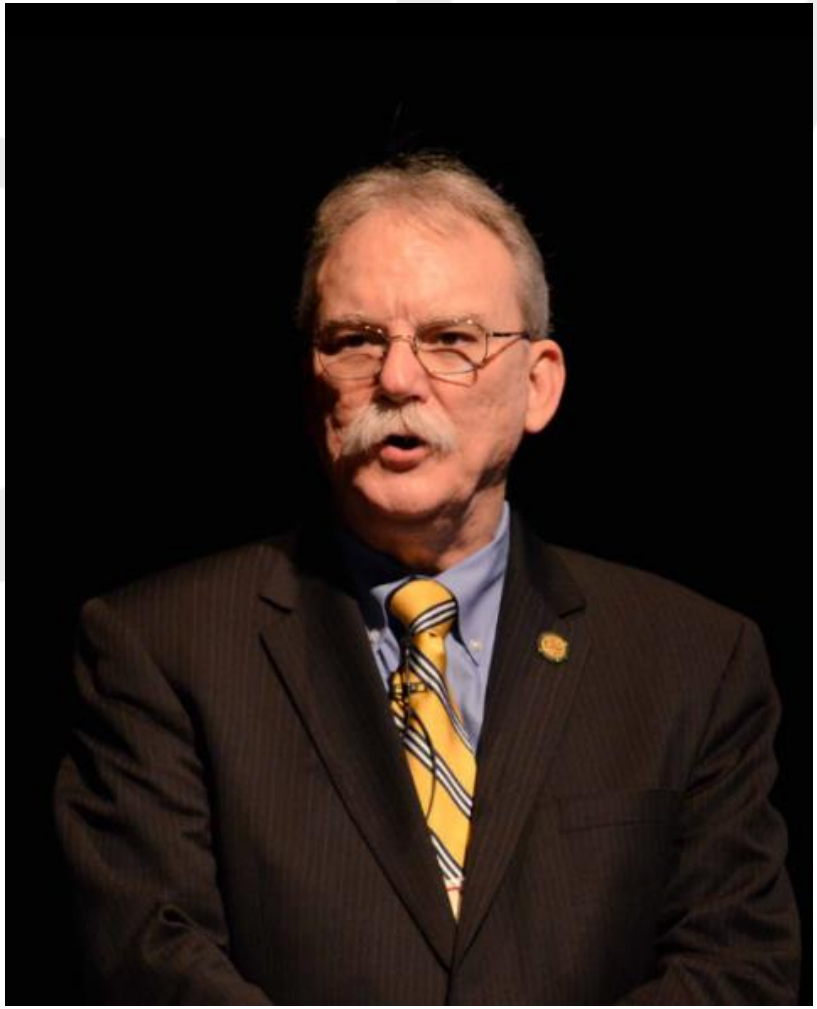
PDA
71 Years of
Connecting People, Science and Regulation®

I'm happy to be here.

Bom Dia. Estou feliz por estar aqui.

Richard M. Johnson

- PDA President & CEO since 2009
- 38 years experience in US and International pharma and medical device operations



Parenteral Drug Association

Since 1946

Leading global provider of science, technology and regulatory information and education for the pharmaceutical and biopharmaceutical community.

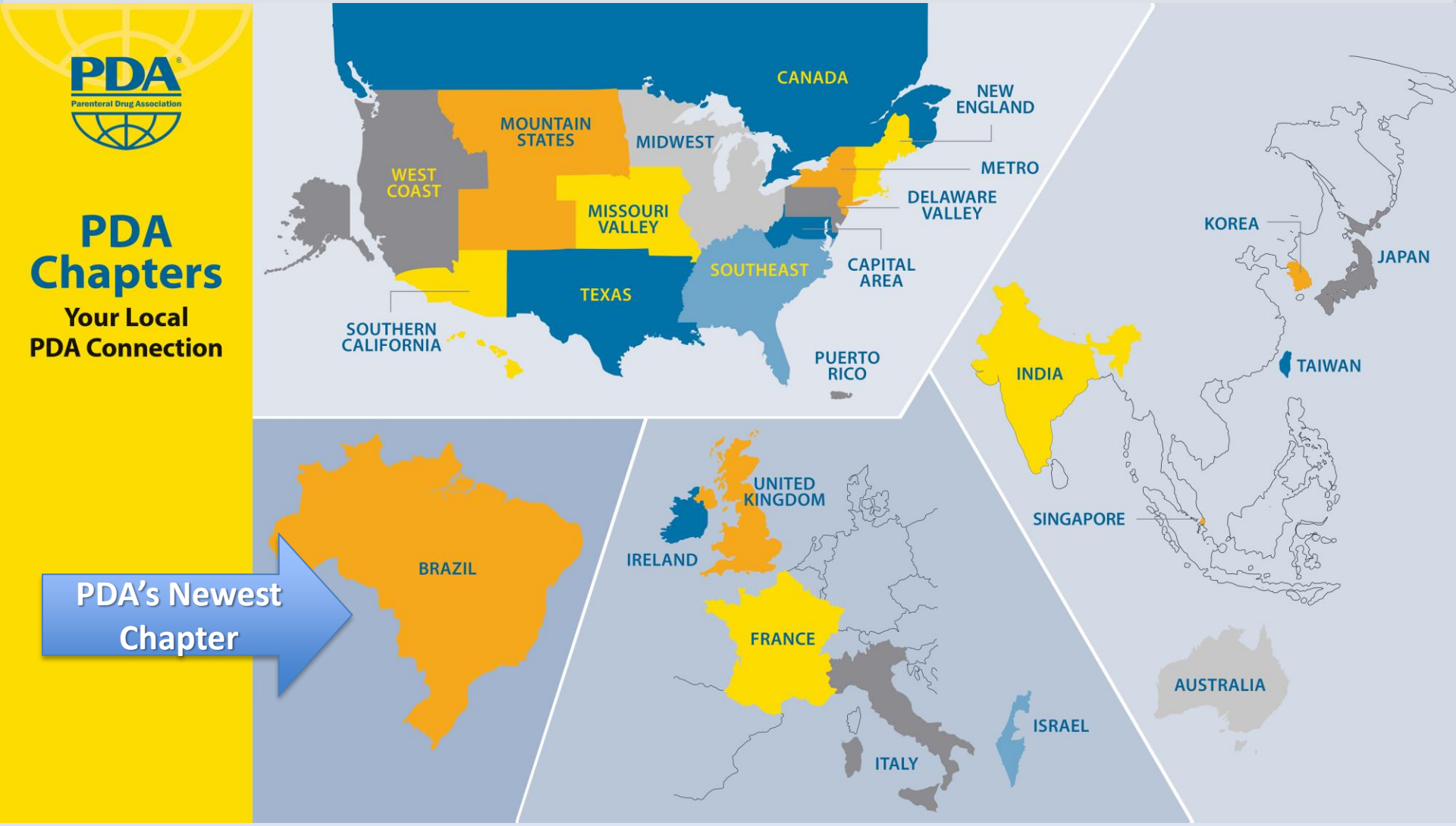
Global Offices & International Membership

25 Chapters Around the Globe

&

More than 10,000 Members

PDA Chapters around the World



WHY WE HAVE CHAPTERS

From the PDA By Laws:

"Article IX: Chapters

Section 1. Establishment. *The association shall have such chapters, domestic or foreign, as may be granted a charter by the Board of Directors upon petition of at least ten (10) Association members residing in a common geographic area. Appropriate common geographic areas shall be determined by the President with approval of the Board of Directors.*

Section 2. Activities. *Chapters may engage in program activities consistent with the purpose of the Association and deemed to serve the needs and interests of Chapter members*

WHY WE HAVE CHAPTERS

From the Chapter By Laws:

"ARTICLE II

Corporate Purpose

The Purpose of the Chapter is to provide a local forum for discussion, meetings and information exchange and to promote PDA membership, and to further PDA's mission as determined by PDA's Board of Directors from time to time. As such, the Chapter shall:

1. *Promote and enhance knowledge within the sciences and technologies addressed by PDA for the benefit of members and potential members within the Chapter's geographic territory which shall be provided for in the Charter of the Chapter.*
2. *Develop programs and other activities that are designed to meet local and/or global needs consistent with the mission and objectives of PDA.*
3. *Encourage membership in PDA and promote attendance at functions sponsored by the Chapter and PDA.*
4. *Submit all scientific papers presented at Chapter meetings and intended for publication to PDA for consideration/inclusion in PDA proceedings and/or the PDA Journal of Pharmaceutical Science and Technology."*

PDA 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

PDA Mission

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

PDA 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.

PDA Strategic Activities

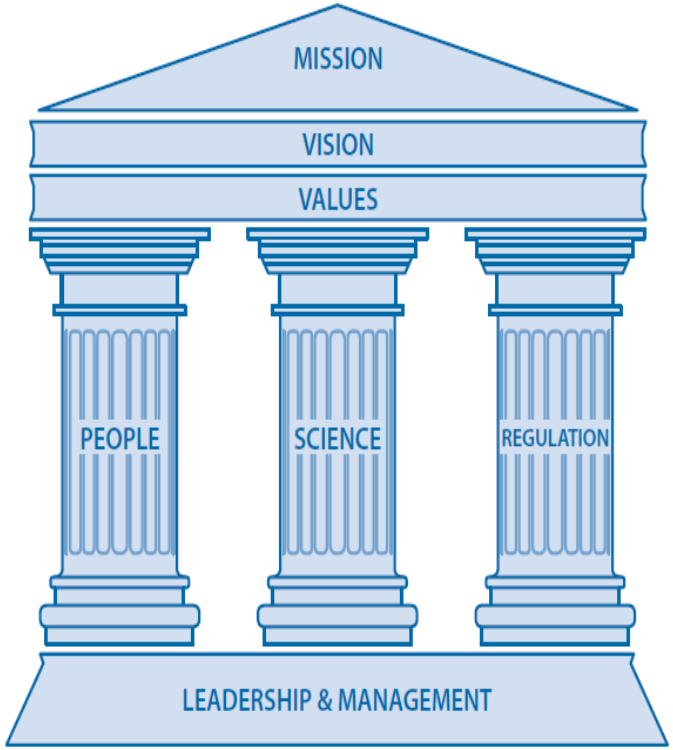
- **People:** Continue to enhance the value of PDA membership, grow and enhance the organization globally.
- **Science:** Be recognized by professionals in academia, industry and regulatory bodies as the premier global leader for the advancement of science, manufacturing, quality and innovation.
- **Regulation:**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

Strategic Initiatives

- **Aseptic Processing /Revision of EMA-PIC/S Annex 1**
  - PDA continues a long tradition of leadership in Sterile manufacturing focusing on driving aseptic processing to continued improvement and better alignment of regulatory guidance
- **Manufacturing Science and Operations Program**
  - Highlight the ongoing focus PDA has on pharmaceutical and biopharmaceutical manufacturing.
  - Strengthen and build practical solutions by filling known gaps in current manufacturing science as well as gaps that will become apparent based on ongoing developments and analyses.
  - Identify and encourage use of new manufacturing technology and methods.
  - Provide Portfolio Analysis and Management of these activities across PDA.
- **Post Approval Changes / Innovation for Access to Medicines**
  - The Parenteral Drug Association (PDA) has announced its program to reduce hurdles to pharmaceutical manufacturing innovation caused by disparate national regulations that discourage changes.

Strategic Element

PEOPLE



PDA Strategic Activities - PEOPLE

- **GROWTH**
  - Membership is growing – Over 10,000
  - PDA Brazil is PDA's newest chapter
- **INTERNATIONAL OUTREACH**
  - 41% of membership is outside US
- **SERVICE**
  - More members attending events (conference & training)

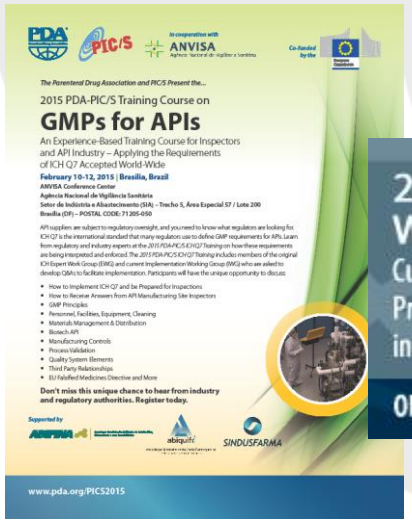
Volunteer Driven..

- ***More than 2,500 active volunteers***
- **Board of Directors**
  - PDA President reports to Chair of Board
  - PDA Staff reports to President
- **Advisory Boards**
  - Science Advisory (SAB) – Pharmaceutical focus
  - Bio Advisory (BioAB) – Biotech focus
  - Regulatory Affairs and Quality (RAQAB)
  - Education Advisory Board (EAB)

- **Committees**
  - Awards, Audit, Chapters, Executive, Exhibits, Interest Groups, Membership, Nominating, Strategic Planning, Conference Planning Committees
- **Task Forces**
  - For every Technical Report & Regulatory Comment (more than 70)

Global Workshops and Conferences

Educate • Inform • Connect



2017 Conferences

2017 PDA Schedule of Events

CURRENT AS OF 12/12/2016

DATES	EVENT	LOCATION
FEBRUARY 14-15	2017 PDA Europe Pharmaceutical Microbiology	Porto, Portugal
FEBRUARY 21-22	2017 PDA Pharmaceutical Quality Metrics and Quality Culture Conference	Bethesda, MD
MARCH 13	2017 PDA Europe Interest Group Meeting Pre-Filled Syringes	Barcelona, Spain
MARCH 14-15	2017 PDA Europe Parenteral Packaging	Barcelona, Spain
MARCH 21-23	INTERPHEX	New York, NY
MARCH 21 MARCH 22-23	2017 PDA Europe IG Mtg Visual Inspect. & Freeze Drying 2017 PDA Europe An Introduction to Visual Inspection	Berlin, Germany
APRIL 3-5	2017 PDA Annual Meeting	Anaheim, CA
APRIL 5-6	2017 PDA Cell and Gene Therapy Workshop	Anaheim, CA
APRIL 26-27	2017 PDA Europe Fill & Finish for Prefilled Syringes	Lindau, Germany
MAY 8-9	2017 PDA Extractables & Leachables Workshop	Washington, DC
MAY 10-11	2017 PDA Annex 1 Workshop	Washington, DC
MAY 10	2017 PDA Pre-Filled Syringe Interest Group Meeting	Bethesda, MD
MAY 11	2017 PDA Combination Products Interest Group Meeting	Bethesda, MD
MAY 30-JUNE 1	2017 PDA Europe Virus & TSE Safety Forum	Dubrovnik, Croatia
JUNE 13-14	2017 2nd PDA Europe Annual Meeting	Berlin, Germany
JUNE 19-20	2017 PDA Quality Risk Management for Manufacturing Systems Conference	Chicago, IL
JUNE 26-27	2017 PDA Biosimilars Conference	Bethesda, MD
JUNE 27-28	2017 PDA Europe Advanced Therapy Medicinal Products	Valencia, Spain
SEPTEMBER 11-13	2017 PDA/FDA Joint Regulatory Conference	Washington, DC
SEPTEMBER 13-14	2017 PDA PAC iAM Workshop	Washington, DC
SEPTEMBER 19-20	2017 PDA Europe Pharmaceutical Freeze Drying Technology	Cologne, Germany
SEPTEMBER 26-27	2017 PDA Europe 10th Workshop Monoclonal Antibodies	Berlin, Germany
SEPTEMBER 27-29	2017 PDA Europe Training Week Visual Inspection	Berlin, Germany
OCTOBER 10-11	2017 PDA Europe Pharmaceutical Cold & Supply Chain Logistics	Rotterdam, Netherlands
OCTOBER 16-18	12th Annual PDA Conference on Pharmaceutical Microbiology	Bethesda, MD
OCTOBER 18-19	2017 PDA Endotoxins Workshop	Bethesda, MD
OCTOBER 23-24	2017 PDA Visual Inspection Forum	Bethesda, MD
NOVEMBER 7-8	2017 PDA Europe The Universe of Pre-filled Syringes & Injection Devices	Vienna, Austria
NOVEMBER 21-22	2017 PDA Europe Outsourcing & Contract Manufacturing	Munich, Germany
DECEMBER 5-6	2017 PDA Cell and Gene Therapy Conference	San Diego, CA

Subject to change www.pda.org/calendar CONFERENCE WORKSHOP/FORUM

3 Workshops on Cell and Gene Therapy/ATMP

4 Meetings on Combination Products

3 Meetings on Visual Inspection

Continuing focus:

- Annual Meetings in US and Europe
- 2 Microbiology Meetings + 1 Endotoxin Meeting
- Quality & Regulatory Meetings: (PDA/FDA, Quality Metrics, Annex 1, QRM, PAC iAM, Cold Chain)
- Biotech meetings: (Biosimilars, Virus/TSE, MAb)
- And others…

PDA Connect℠

Where Excellence Begins…

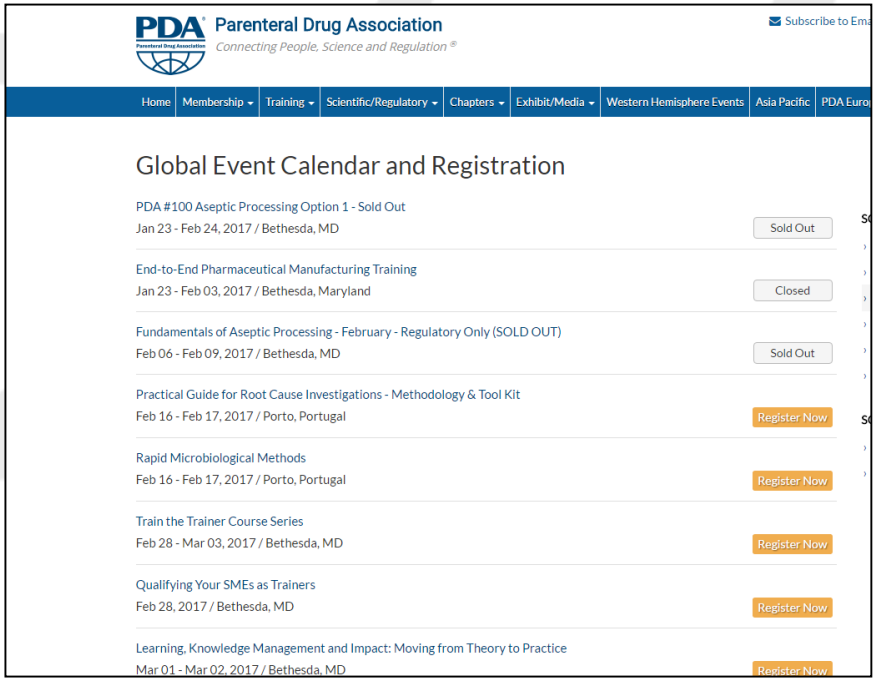
2017 PDA U.S. Education Courses

JANUARY – OCTOBER

Check ***PDAtraining.org*** for an updated list of courses

Denotes Laboratory Courses Denotes Lecture Courses

DATES	COURSE NAME	LOCATION
1/23 – 1/27 2/20 – 2/24	**Aseptic Processing Option 1** | pda.org/2017aseptic1 SOLD OUT	Bethesda, MD
2/6 – 2/9	**Fundamentals of Aseptic Processing (Feb)** | pda.org/2017FundAPGOV REGULATORY ONLY SOLD OUT	Bethesda, MD
2/28 – 3/3 2/28 3/1 – 3/2 3/3	**Train the Trainer Course Series** | pda.org/2017Trainer Qualifying Your SMEs as Trainers Learning, Knowledge Management and Impact: Moving from Theory to Practice Designing/Presenting GXP Training Programs to Meet FDA Requirements	Bethesda, MD
3/6 – 3/10 3/6 3/7 – 3/8 3/9 – 3/10	**Visual Inspection Course Series** | pda.org/2017VI Identification and Classification of Nonconformities in Molded and Tubular Glass Containers for Pharmaceutical Manufacturing An Introduction to Visual Inspection (Mar) Foreign Particulate Examination, Isolation and Analysis	Bethesda, MD
3/13 – 3/17 3/13 – 3/14 3/15 3/16 – 3/17	**Validation Course Series** | pda.org/2017VCS Development and Implementation of Qualification and Validation Protocols – A Risk and Science Based Approach Applying Six Sigma Techniques to the Process Validation Lifecycle Analytical Method Qualification, Validation, Verification and Transfer for Biotechnological Products	Bethesda, MD
3/21 – 3/23	**Design, Operation and Qualification of Pharmaceutical Water Systems** | pda.org/2017PWS	Bethesda, MD
3/27 – 3/31 4/24 – 4/28	**Aseptic Processing Option 2** | pda.org/2017aseptic2	Bethesda, MD
4/6 – 4/7 4/6 – 4/7 4/6 – 4/7 4/6 – 4/7 4/6 – 4/7 4/6 – 4/7	**2017 PDA Annual Meeting Course Series** | pda.org/2017AnnualCourses *Immediately following the PDA Annual Meeting* Quality Metrics and Quality Culture Cleanroom Management Quality Strategy for Biopharmaceuticals Knowledge Management Applied in Facilities & Engineering to Improve Manufacturing Reliability Container Closure Systems and Integrity Testing	Anaheim, CA
4/11 – 4/13	**Validation of Biotechnology-Related Cleaning Processes (Apr)** | pda.org/2017AprBio	Bethesda, MD
4/18 – 4/20	**Airflow Visualization Techniques and Practices (Apr)** | pda.org/2017AprAir	Bethesda, MD
4/18 – 4/21 4/18 4/19 4/20 4/21	**Regulatory and Compliance Course Series** | pda.org/2017RCS Regulatory Aspects of Microbiology in a Non-Sterile Environment Environmental Control and Monitoring for Regulatory Compliance Establishing and Implementing an Effective GMP Audit Program Preparing and Managing Documents and Documentation for Compliance	Bethesda, MD
5/1 – 5/4	**Fundamentals of Aseptic Processing (May)** | pda.org/2017FundAPT	Bethesda, MD
5/12	**Technical and Regulatory Challenges of Combination Products, Drug Delivery Products – Prefilled Syringes, Autoinjectors and Injection Pens** | pda.org/2017TRC *Immediately following the PDA Pre-Filled Syringes Interest Group Meeting and PDA Combination Products Interest Group Meeting*	Bethesda, MD
5/15 – 5/19 6/12 – 6/16	**Aseptic Processing Option 3** | pda.org/2017aseptic3	Bethesda, MD
5/22 – 5/25 5/22 – 5/23 5/24 – 5/25	**Lyophilization Course Series** | pda.org/2017Lyo Fundamentals of Lyophilization Validation of Lyophilization	Bethesda, MD
5/23 – 5/24	**Single Use Systems for the Manufacturing of Parenteral Products** | pda.org/2017SUS	Bethesda, MD
5/31 – 6/2	**Validation of Moist Heat Sterilization Processes (May)** | pda.org/2017MayMH	Bethesda, MD



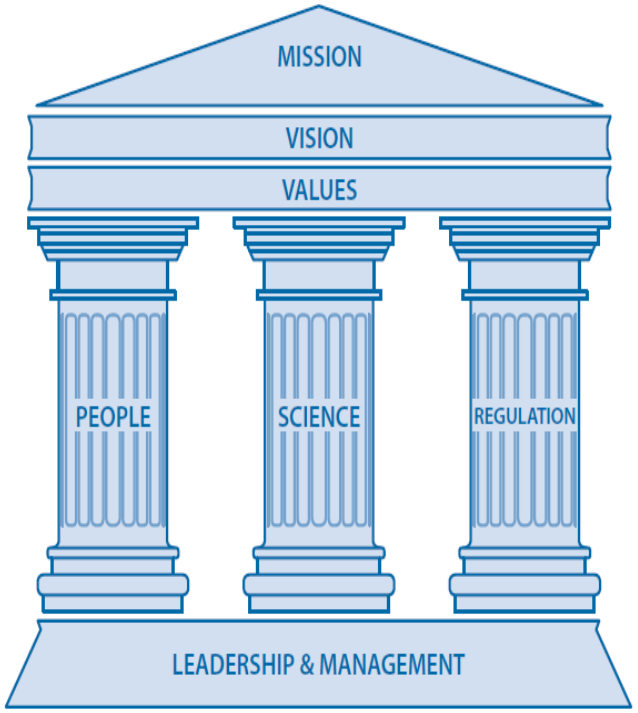
Some of Our Training Experiences

- US FDA
- EMA
- Irish Medicines Board (now HPRA)
- MHRA
- Italian Inspectorate
- Kazakhstan Ministry of Health
- Health Canada

- Russian Ministry of Health
- CFDA
- ANVISA
- PIC/S
- Individual pharmaceutical companies
- Company executive management

Strategic Element

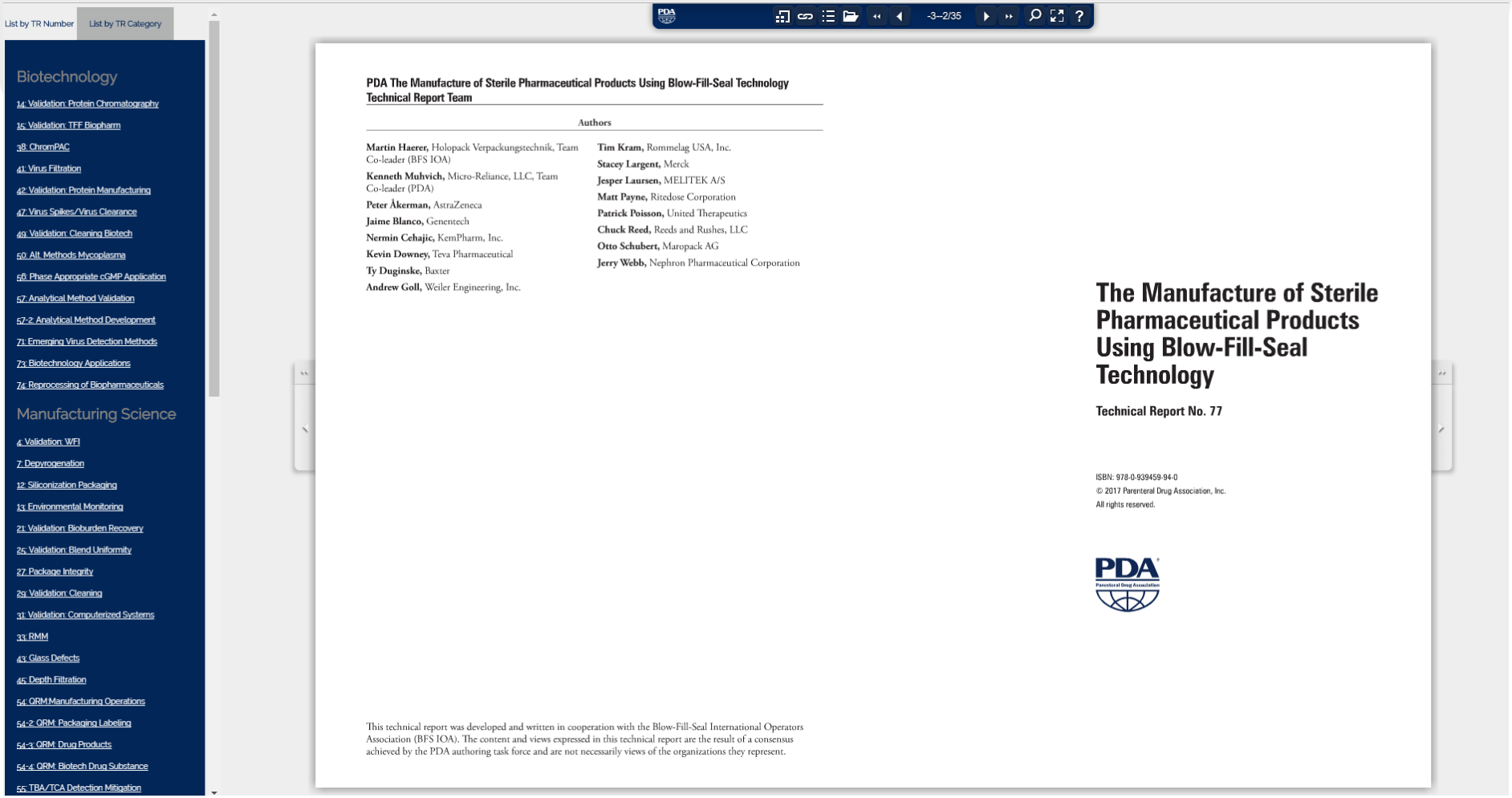
SCIENCE



PDA's Science-Based Activities

Publications

Technical Report Portal



- **All PDA members have access to all PDA TRs via TR Portal**

PDA Strategic Activities - SCIENCE

Published in 2016!

2017 will continue these efforts

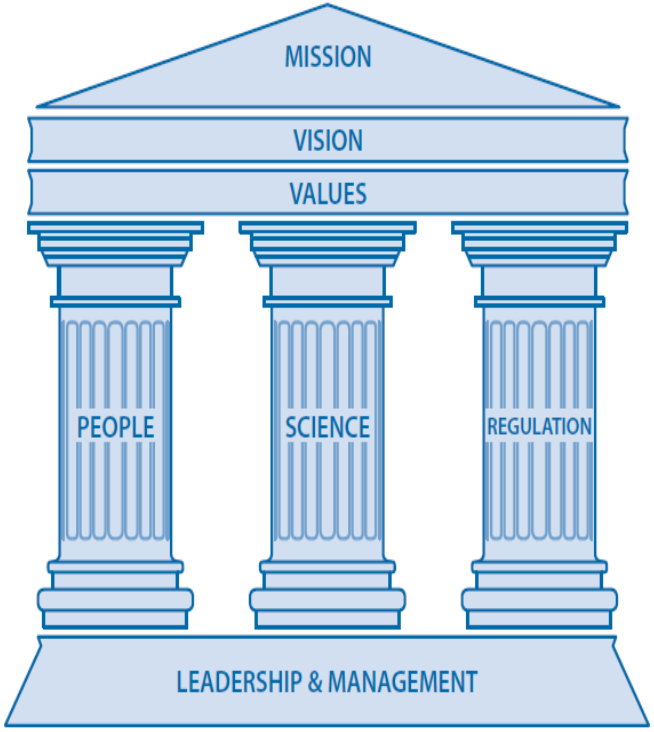
Just Published!

Coming soon…

- **TR 60-2: Process Validation: A Lifecycle Approach - Solid and Semi-Solid Dosage Case Studies**
- **Aging Facilities - White Paper**
- **QRM For Equipment, Facilities, And Critical Utilities: A Life Cycle Approach To Managing Risk Throughout The Design, Qualification, And Operation Of Manufacturing Systems (R08)**
- **Data Integrity Technical Report -- Laboratory Systems**

Strategic Element

REGULATION



Regulatory Policy and Quality Activities

- **Monitor Global Regulatory Activity**
  - Primary Focus: U.S. and European Regulatory Agencies
    - Includes International Conference on Harmonization (ICH), PIC/S, USP, EP and World Health Organization (WHO)
  - Developing interest in Asia, Brazil and India
- **Influence Global Regulatory Policy**
  - Interactions with global regulatory authorities
  - Co-sponsor meetings with Regulators (FDA,EMA,PIC/S,ICH, ANVISA)
  - Comments on proposed regulations and guidance
  - Promote science-based regulations

16 PDA Comments on Regulatory Documents submitted in 2016 …

PDA Comments to EMA - Guideline on Manufacture of the Finished Dosage Form

PDA Comments to eCTD Conformance Guide - Combination Product Considerations

PDA Response to USP General Chapters Prospectus

PDA Comments FDA Draft Guidance on Human Factors Studies in Combination Products

PDA Response to FDA Draft Guidance NDA to BLA Conversion

PDA Response to FDA Draft Guidance Data Integrity and Compliance with cGMP

PDA Response to FDA Draft Guidance Comparability Protocols

PDA Response to FDA Draft Guidance Analytical Method Development and Validation for Immunogenicity Testing of TPPs

PDA Response to WHO Draft QAS/16.666: Guidelines on Validation

PDA Comments to WHO Working Document QAS/16.673: Guidelines on Validation - Appendix 6: Validation on Qualification of Systems, Utilities and Equipment

PDA Comments to WHO Draft Guideline QAS 16.671 Appendix 4 Analytical Method Validation

PDA Comments to FDA Metrics Technical Conformance Guide

PDA Comments to FDA Draft Guidance Insanitary Conditions at Compounding Facilities

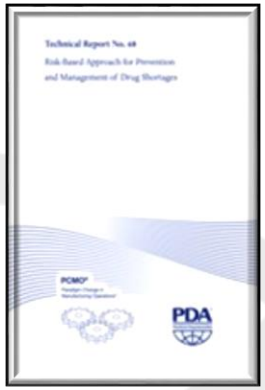
PDA Comments to EMA Guideline on Sterilisation of Medicinal Product, Active Substance, Excipient and Primary Container

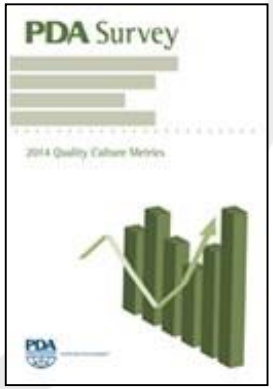
PDA Response to EMA WFI Non-Distillation

PDA Response to MHRA Data Integrity GxP Draft

Key Regulatory Initiatives

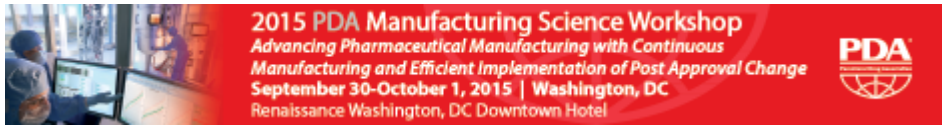
- Drug Shortages



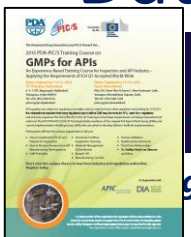


- Quality Metrics/Culture

- Post-Approval Changes



- Data Integrity



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