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
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

PDA's Newest Chapter

PDA Chapters
Your Local PDA Connection

Connecting People, Science & Regulation®
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“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
• **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)
• **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)
2017 Conferences

### 3 Workshops on Cell and Gene Therapy/ATMP
- **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

### 4 Meetings on Combination Products
- **MAY 10**: 2017 PDA Pre-Filled Syringe Interest Group Meeting, Bethesda, MD
- **MAY 11**: 2017 PDA Combination Products Interest Group Meeting, Bethesda, MD

### 3 Meetings on Visual Inspection
- **JUNE 27-28**: 2017 PDA Europe Advanced Therapy Medicinal Products, Valencia, Spain
- **SEPTEMBER 27-29**: 2017 PDA Europe Training Week Visual Inspection, Berlin, Germany

### 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…**

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**PDA Schedule of Events**

**DATES**

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

Subject to change www.pda.org/calendar

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<table>
<thead>
<tr>
<th>DATES</th>
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<th>LOCATION</th>
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<tr>
<td>1/17– 1/19</td>
<td>Aseptic Processing Option 3</td>
<td>Bethesda, MD</td>
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<tr>
<td>2/27 – 3/2</td>
<td>Fundamentals of Aseptic Processing</td>
<td>Bethesda, MD</td>
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<tr>
<td>3/27 – 3/31</td>
<td>Sterile Water Systems</td>
<td>Bethesda, MD</td>
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<td>Aseptic Processing Option 2</td>
<td>Bethesda, MD</td>
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<tr>
<td>5/1 – 5/3</td>
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<td>5/21 – 5/23</td>
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<td>5/21 – 5/23</td>
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<tr>
<td>5/29 – 5/31</td>
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<tr>
<td>7/23 – 7/27</td>
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<td>8/28 – 9/1</td>
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<td>9/29 – 10/1</td>
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<tr>
<td>11/27 – 12/1</td>
<td>Aseptic Processing</td>
<td>Bethesda, MD</td>
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<tr>
<td>12/18 – 12/21</td>
<td>Aseptic Processing</td>
<td>Bethesda, MD</td>
</tr>
</tbody>
</table>
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

Sterile Manufacturing

Biotechnology

Quality & Supply Chain Management

Manufacturing Science
PDA The Manufacture of Sterile Pharmaceutical Products Using Blow-Fill-Seal Technology
Technical Report Team

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The Manufacture of Sterile Pharmaceutical Products Using Blow-Fill-Seal Technology
Technical Report No. 77

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This technical report was developed and written in cooperation with the Blow-Fill-Seal International Operators Association (BFS IOA). The content and views expressed in this technical report are the results of a consensus achieved by the PDA authoring task force and are not necessarily views of the organizations they represent.

• All PDA members have access to all PDA TRs via TR Portal
2017 will continue these efforts

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

Just Published!

Technical Report No. 77
The Manufacture of Sterile Pharmaceutical Products Using Blow-Fill-Seal Technology
Strategic Element

REGULATION
• **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 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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