

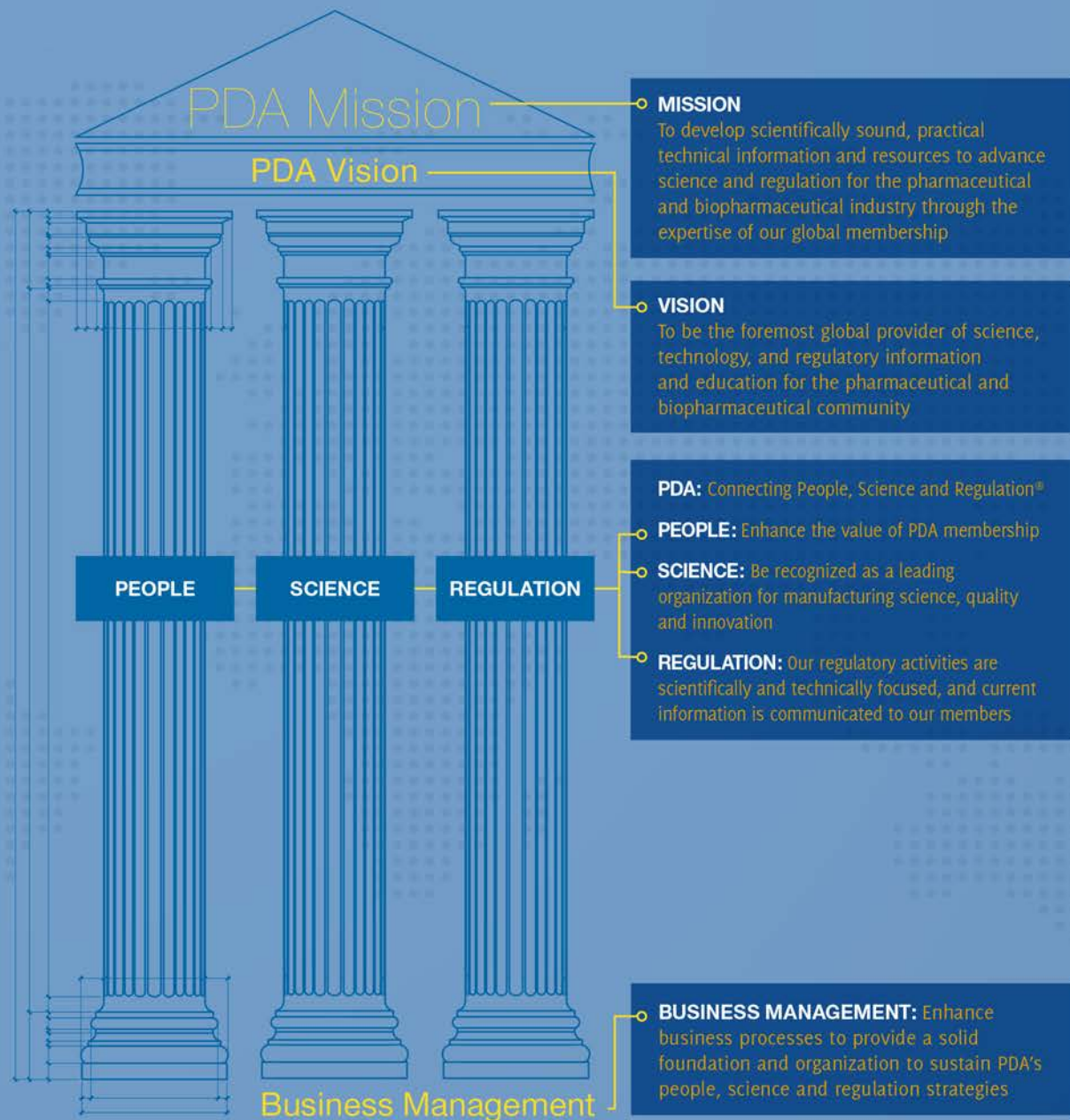
Showcase Event - Cold Chain Distribution Practices

Principal Sponsor: Envirotainer
Sponsor: Coolpac

Tuesday February 16th, 2016
Venue: L'Unica on Parkville

What is PDA?

The Parenteral Drug Association (PDA) is the leading global provider of science, technology and regulatory information and education for the pharmaceutical and biopharmaceutical community. Founded in 1946 as a nonprofit organization, PDA is committed to developing scientifically sound, practical technical information and resources to advance science and regulation through the expertise of its more than 9,500 members worldwide.



Volunteer Opportunities at PDA

volunteer@pda.org

Leadership

- ◉ PDA Executive Officers

- ◉ Director

- ◉ Scientific Advisory Board
- ◉ Biotechnology Advisory Board

- ◉ Regulatory Affairs and Quality Advisory Board

- ◉ PDA Committee Chair/Co-Chair
- ◉ Task Force Co-Chair

- ◉ Author/Contributor to the *PDA Letter*
- ◉ Author/Contributor to the *PDA Journal*
- ◉ Poster Presenter
- ◉ Attend Chapter Committee/Planning Meetings
- ◉ Technical Report Peer Reviewer

- ◉ Speaker
- ◉ Chapter Leader
- ◉ Task Force Member
- ◉ TRI Instructor
- ◉ Interest Group Leader

PDA Committees:

- ◉ Program Planning Committee
- ◉ PDA Letter Committee
- ◉ Membership Committee
- ◉ Education Committee
- ◉ Audit Committee

- ◉ PDA Membership
- ◉ Attend Global PDA Meetings

- ◉ Attend Chapter Events
- ◉ Survey Reviewer

- ◉ Interest Group Member
- ◉ Attend TRI Courses

1,000

Over 1,000
volunteers
worldwide
actively carry out
PDA's Mission

Getting Involved

Join the Conversation @ PDA CONNECTSM



The interactive, members-only
online community exclusively *for you!*

With PDA ConnectSM, you can:

- Connect and engage with your local chapter
- Participate in discussions about niche topics in your Interest Groups
- Network and build collaboration with fellow PDA members around the world
- Gain access to members-only digital resources

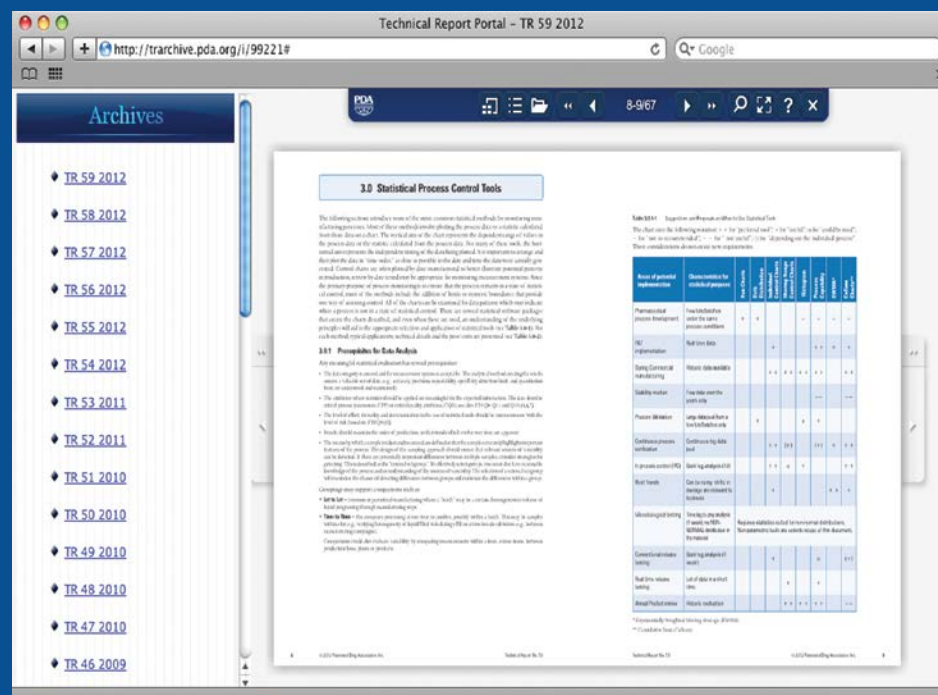
Community.pda.org

Continue the Conversation @PDA CONNECTSM !

Not a PDA Member? *Join today to gain full access to PDA ConnectSM and more!*

PDA Technical Report Portal

PDA Members have 24/7 access to more than 40 active Technical Reports in the PDA Technical Report Portal.



Technical Report Portal – TR 59 2012

Archives

- TR 59 2012
- TR 58 2012
- TR 57 2012
- TR 56 2012
- TR 55 2012
- TR 54 2012
- TR 53 2011
- TR 52 2011
- TR 51 2010
- TR 50 2010
- TR 49 2010
- TR 48 2010
- TR 47 2010
- TR 46 2009

3.0 Statistical Process Control Tools

The following technical report provides a review of the most common statistical methods for monitoring and controlling processes, their uses and limitations, and the process data to which they are applied. The report also provides a review of the statistical methods used in the process data to which they are applied. The report also provides a review of the statistical methods used in the process data to which they are applied.

3.01 Principles for Data Analysis

Any statistical analysis of process data must be preceded by a careful examination of the data to ensure that the data are suitable for analysis. The data should be examined for the following factors:

- The data should be representative of the process under study.
- The data should be free from any systematic bias.
- The data should be free from any random variation.
- The data should be free from any outliers.
- The data should be free from any missing values.
- The data should be free from any other factors that may affect the results of the analysis.

3.02 Statistical Process Control Tools

The following table provides a summary of the most common statistical methods used in process control. The table lists the method, its purpose, its advantages, and its limitations.

Method	Purpose	Advantages	Limitations
Mean and Standard Deviation	Monitoring process performance	Simple to use	Only measures central tendency and spread
Range	Monitoring process variability	Simple to use	Only measures spread
Process Capability	Assessing process performance	Provides a measure of process performance	Requires knowledge of process specification
Control Charts	Monitoring process performance over time	Provides a visual indication of process performance	Requires knowledge of process specification
Regression Analysis	Identifying relationships between variables	Provides a mathematical model of the process	Requires knowledge of process specification
Design of Experiments	Identifying the factors that affect process performance	Provides a systematic approach to process improvement	Requires knowledge of process specification

PDA Member Types and Benefits



		Standard/Individual	Young Professional	Emerging Economy/Academic	Student	Retired/Unemployed	Regulator/Health Authority
		\$259 per year	\$100 per year	\$100 per year	\$30 per year	\$25 per year	\$0-12 per year
Membership Benefits	PDA Letter (hard copy)	✓	NA	NA	NA	NA	NA
	PDA Technical Report Portal (electronic)	✓	✓	NA	NA	NA	✓
	PDA Journal (electronic)	✓	✓	✓	✓	✓	✓
	PDA Letter (electronic)	✓	✓	✓	✓	✓	✓
	PDA Member Directory	✓	✓	✓	✓	✓	✓
	PDA Member Discounts	✓	✓	✓	✓	✓	✓
		Join PDA	Join PDA	Join PDA	Join PDA	Join PDA	Join PDA

PDA Membership is individual-based in all cases. PDA does not offer corporate membership at this time.

The Parenteral Drug Association presents the...

2016 PDA Annual Meeting

***Achieving Manufacturing Excellence:
Current Trends and Future Technologies in Bioprocessing***

March 14-16, 2016 | San Antonio, TX

JW Marriott San Antonio Hill Country

Exhibition: March 14-15 | Post-Workshop: March 16-17 | Courses: March 17-18



*New Technology, New Facilities to Support Current
and New Therapies and Drug Products*

**pdaannualmeeting.org
#2016annual**

Name	Company	Position
David Spaulding	SeerPharma	President
Eoin Hanley	PharmOut	President Elect
Ken Dibble	Professional	Secretary
Paul Kerr	SeerPharma	Treasurer
Eoin Hanley	PharmOut	Membership Liaison
Kim Waters	GSK	Past President
Ano Xidias	CSL Behring	Committee Member
John Montalto	CSL Behring	Committee Member
Robert Caunce	Hospira	Committee Member
Usha Gullapalli	Hospira	Committee Member
Mark Dickson	Novartis	Committee Member
Rob Sullivan	Professional	Committee Member
Paul Doughty	Morilla Technology	Committee Member
Trevor Schoerie	PharmOut	Committee Member
Tina Khamu	Pall	Committee Member

1. Introduction
 - What & Why
 - Considerations
2. Glossary of terms
3. Overview
 - Principles
 - Understanding types of systems
 - Characteristics
4. Qualification Guidance
5. Operational Considerations
6. Conclusions
7. Appendix & Reference

What is TPS?

- Passive Thermal Protection System
 - Non-powered
 - Insulation or barrier to heat exchange
 - Protection of temperature sensitive freight
- System components
 - Covering
 - Insulation



Why Choose Passive Protection?

- Energy Savings
- Simplicity
- Availability of Active Systems
- No Mechanical parts to break down
- Continuous Product Protection
- Carbon Emission Reductions
- Less Expensive

Cold Chain Distribution Practices

Speakers

Stephen Winyard – Envirotainer

Stephen Maietta – Envirotainer

10 min break

Nigel Bleakley – Pfizer

Andrew Gibson – CoolPac

Dinner

Question cards available on the tables

Tuesday February 16th 2016

Venue: L'Unica on Parkville